Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2002/0128(COD)
Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution Subject 4.20.01 Medicine, diseases 4.20.02 Medical research 4.20.02.06 Clinical practice and experiments 4.20.05 Health legislation and policy	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health, Consumer Policy		02/10/2002
	PPE-DE LIESE Peter	
Former committee responsible		
ENVI Environment, Public Health, Consumer Policy		02/10/2002
	PPE-DE LIESE Peter	
Former committee for opinion		
CONT Budgetary Control	The committee decided not to give an opinion.	
JURI Legal Affairs and Internal Market		11/07/2002
	PPE-DE BARTOLOZZI Paolo	
BUDG Budgets		18/07/2002
	ELDR VIRRANKOSKI Kyösti	

Council of the European Union

Council configuration	Meeting	Date
Environment	2566	02/03/2004
Agriculture and Fisheries	2524	22/07/2003
Employment, Social Policy, Health and Consumer Affairs	2512	02/06/2003
Employment, Social Policy, Health and Consumer Affairs	2470	02/12/2002
Health	2440	26/06/2002

European Commission

Commission DG	Commissioner
Health and Food Safety	

Key events

18/06/2002	Legislative proposal published	COM(2002)0319	Summary
26/06/2002	Debate in Council	2440	
01/07/2002	Committee referral announced in Parliament, 1st reading		
02/12/2002	Debate in Council	2470	

25/03/2003	Vote in committee, 1st reading		Summary
24/03/2003	Committee report tabled for plenary, 1st reading	A5-0103/2003	
09/04/2003	Debate in Parliament		
10/04/2003	Decision by Parliament, 1st reading	T5-0182/2003	Summary
27/05/2003	Modified legislative proposal published	COM(2003)0340	Summary
21/07/2003	Council position published	10133/3/2003	Summary
04/09/2003	Committee referral announced in Parliament, 2nd reading		
04/11/2003	Vote in committee, 2nd reading		Summary
03/11/2003	Committee recommendation tabled for plenary, 2nd reading	A5-0387/2003	
15/12/2003	Debate in Parliament		
16/12/2003	Decision by Parliament, 2nd reading	T5-0570/2003	Summary
02/03/2004	Act approved by Council, 2nd reading		
31/03/2004	Final act signed		
31/03/2004	End of procedure in Parliament		
07/04/2004	Final act published in Official Journal		

Technical information

Procedure reference	2002/0128(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Legal basis	EC Treaty (after Amsterdam) EC 152-p4
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/19456

Documentation gateway

Legislative proposal		COM(2002)0319 OJ C 227 24.09.2002, p. 0505 E	19/06/2002	EC	Summary
Economic and Social Committee: opinion, report		CES1361/2002 OJ C 085 08.04.2003, p. 0044-0050	11/12/2002	ESC	
Committee report tabled for plenary, 1st reading/single reading		A5-0103/2003	25/03/2003	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0182/2003 OJ C 064 12.03.2004, p. 0391-0505 E	10/04/2003	EP	Summary
Modified legislative proposal		COM(2003)0340	28/05/2003	EC	Summary
Council statement on its position		11379/2003	11/07/2003	CSL	

Council position		10133/3/2003 OJ C 240 07.10.2003, p. 0012-0024 E	22/07/2003	CSL	Summary
Commission communication on Council's position		SEC(2003)0906	11/08/2003	EC	Summary
Committee recommendation tabled for plenary, 2nd reading		A5-0387/2003	04/11/2003	EP	
Text adopted by Parliament, 2nd reading		T5-0570/2003 OJ C 091 15.04.2004, p. 0029-0090 E	16/12/2003	EP	Summary
Commission opinion on Parliament's position at 2nd reading		COM(2004)0080	05/02/2004	EC	Summary
Implementing legislative act		32006L0017 OJ L 038 09.02.2006, p. 0040-0052	08/02/2006	EU	Summary
Follow-up document		COM(2006)0593	16/10/2006	EC	Summary
Implementing legislative act		32006L0086 OJ L 294 25.10.2006, p. 0032-0050	24/10/2006	EU	Summary
Follow-up document		COM(2009)0708	07/01/2010	EC	Summary
Follow-up document		COM(2011)0352	17/06/2011	EC	Summary
Follow-up document		COM(2016)0223	21/04/2016	EC	Summary
Follow-up document		SWD(2016)0127	21/04/2016	EC	
Follow-up document		SWD(2016)0128	21/04/2016	EC	

Additional information

European Commission	EUR-Lex

Final act

Directive 2004/23
OJ L 102 07.04.2004, p. 0048-0058 Summary

Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

PURPOSE : Proposal on setting quality and safety standards in relation to human tissue and cells. CONTENT : This proposal for a directive aims to cover all human cells and tissues which are used for application to the human body, in order to ensure their quality and safety. It excludes blood and blood products (other than blood precursors), human organs as well as organs, tissues or cells of animal origin. Autologous cells used or medicinal products require a completely different regulatory approach and are therefore excluded from this directive. The aims of the 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; -strengthen requirements related to the suitability of donors of tissues and cells and the screening of donated substances of human origin in the EU; -establish at Member State level requirements for establishments involved in the procurement, testing, processing, storage and distribution of tissues and cells of human origin, as well as national accreditation and monitoring structures; -lay down provisions at Community level for the formulation of a register of accredited establishments; -lay down provisions at Community level for the formulation of a quality system for tissues and cells related establishments; -lay down common provisions at Community level for the training of staff directly involved in the procurement, testing, processing, storage and distribution of tissues and cells of human origin, without prejudice to existing legislation; -establish rules for ensuring the traceability of tissues and cells of human origin from donor to patient and vice versa, which are valid throughout the EU; -establish a system for the regulation of imports of human tissues and cells from third countries that ensure equivalent standards of quality and safety.?

Human tissues and cells: quality and safety for the donation, procurement, testing, processing,

preservation, storage and distribution

The committee adopted the report by Peter LIESE (EPP-ED, D) amending the proposal under the 1st reading of the codecision procedure. The key amendments focused on the scope of the directive, compensation for tissue and cell donation, donor consent, donor anonymity and ethical issues: - Member States should encourage strong public and non-profit sector involvement in the provision of tissue and cell transplant services and related research; - donations should be made with the donor's free will and without any payment except compensation, for example travel expenses. However, rules on compensation should be left to the Member States; - EU-wide rules should be laid down to ensure the traceability of tissues and cells of human origin. Although anonymity of donors was strongly supported, the committee said that in the case of gametes (sperm and eggs) in particular, Member States may waive anonymity in order to respect the right of children to know their genetic parents; - on the procurement of human tissues or cells, the committee wanted to go even further than the Commission with regard to mandatory consent requirements. It said that the EU Member States should take account of at least the following: before any procurement of tissues or cells, living donors must have given their prior, informed and express consent in writing or, in exceptional cases, orally in the presence of witnesses. Until the moment the donated or cells are actually used, donors shall have the right to withdraw their consent without having to face any negative consequences; in the case of procurement of tissues and cells from deceased persons, donors must not have expressly refused their consent during their lifetime. In the absence of any declaration by donors during their lifetime, tissues or cells may only be procured if the relatives of the deceased have given prior and express consent; cells and tissues may not be retrieved for the purpose of allogeneic donation from individuals who are not in a position to give informed legal consent; exceptionally regenerative tissue and regenerative cells may be retrieved under strict conditions, e.g. if the recipient is a brother or sister of a donor, the donation is potentially lifesaving for the recipient and the potential donor does not refuse; - Member States should at least prohibit research on human cloning for reproductive purposes and research designed to create human embryos solely for research purposes or to supply stem cells, including by means of the transfer of somatic cell nuclei. No tissues or cells derived from human embryos should be used for transplantation. Cloned human embryos, and human/animal hybrid embryos produced by cloning, aggregation or any other procedure, and cells and tissues derived from them, should be excluded as sources of material for transplant; - the committee clarified the directive's scope even further by including the research use of tissues, haematopoietic peripheral blood, placenta and bone marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells, adult and embryonic stem cells. However, it said that hair, nails and body waste products should be excluded from the directive; - lastly, the Commission was urged to bring forward before July 2003 a separate legislative proposal on human organ transplants, on the grounds that there was a need to take into account the severe shortages that were currently resulting in many patients going untreated. ?

Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

The European Parliament adopted a resolution drafted by Peter LIESE (EPP-ED, Germany) and made several amendments to the Commission's proposal. (Please refer to the summary of 25/03/03.) The following amendments were also made: - "tissue" is redefined more precisely and explicitly excludes organs, blood and blood products; - the Directive expressly recognises the right of Member States to prohibit donation, procurement, testing, processing and distribution of tissues and cells of a particular origin, as well as imports of cells; - the Commission will assist Member States in cooperating in the preparation of guidance concerning the training and qualification of officials involved in inspection and control measures; - tissue banks have prescribed obligations in relation to human tissues and cells imported from third countries; - the data required to ensure full traceability must be kept for at least thirty years; - there must be no trading in unmodified tissues and cells. Where they are used as source material for manufacturing products for therapeutic use, such activities may be permitted for bodies and organisations operating on a profit basis; - in relation to commercial establishments, Member States must ensure tissues and cells are properly transferred in the event of termination of business or bankruptcy; - the procurement of tissues after an abortion requires special rules, and the directive introduces some details on this; - Parliament lays down detailed provisions for the protection of persons who are not in a position to give voluntary informed legal consent. Tissue and cell retrieval must be endorsed by an ethics committee. The interests of the donor who is unable to give consent must always take precedence over those of science and society; - Member States may exempt tissue banks which provide only tissues and cells for which there is no urgency from the requirement to operate on a 24-hour basis; - there are special requirements for umbilical cord and placenta, and the provision of information to parents; - there are special requirements for laboratory tests in relation to the collection of umbilical cord blood; - maximum storage time may be extended under certain conditions.?

Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

The Commission accepted 35 of the 76 amendments made by Parliament, 16 in full and 19 in part, conditionally, or after reformulation. In the light of this, the Commission has drafted an amended proposal. The Commission has made a number of amendments to its original proposal, reflecting those modifications introduced by the European Parliament and accepted by the Commission. In addition, the Commission has made some revisions as a direct consequence of the Parliament's amendments, and in order to clarify the text. In the amended proposal, the Commission has also taken into account the current status of the dossier in the Council. Reflecting the key concerns of the European Parliament, the main amendments to the original proposal can be grouped as follows: - ethical provisions: the Commission can accept provisions related to the anonymity of donors and/or non-profit procurement. Other provisions, however, cannot be accepted as they fall outside the scope of Article 152 of the Treaty, which provides for public health protection and not for the implementation of ethical objectives. - scope of the Directive: this has been extended to include the donation, procurement and testing of autologous cells to be used for the manufacturing of medicinal products. The Commission states that this will facilitate a consistent approach to quality and safety measures for all substances of human origin, and is consistent with the approach already adopted in the Directive 2002/98/EC. The scope has been also widened to cover further steps in the process. The term 'transplantation' has been changed to 'human application', in order to clarify that other therapies, such as reproductive medicine (reproductive cells), are also covered for the processing, preservation, storage and distribution steps. This modification of the scope has implications for the definition of transplantation, and consequently for other provisions of the text. The range of establishments covered by the directive includes not only traditional tissue banks but also all establishments where activities related to the human application of human tissues and cells are undertaken. The Commission did not accept certain other amendments, notably those which introduce 'in vitro' research on tissues and cells into the scope of the Directive, an area outside the scope of Article 152. Use of any specific type of tissues and cells: the Commission accepts those amendments that strengthen the principle that the Directive should not interfere with

Member States' decisions with respect to prohibition on the use of any specific tissue or cell. Accreditation: the accreditation of tissue establishments has been modified as a result of the extension of the scope of the Directive and the new concept of tissue establishments. These establishments can also procure tissues and cells. A direct consequence of this, in keeping with the orientations of the Council, is the importance of the authorisation of the procurement conditions and the staff involved - both key elements of the process. Import and export: the Commission accepts these amendments; it is equally important to ensure that no 'sub-standard' tissues and cells are exported to third countries. Anonymity and traceability: the amendments strengthen the provisions on traceability, extending it to materials in close contact with the tissues and cells, ensuring a minimum period of thirty years for keeping the data and including the final destination in the quality system. The Commission has amended its proposal as a consequence. The principle that tissue and cell donation should respect the anonymity of the donors and recipients is also respected in these amendments. However, the Parliament would like an exemption in the case of specific types of cells. The Commission proposal already introduces the possibility for Member States to keep or adopt different legislation in case of donors closely related to the recipient, but a modification has been introduced. The Commission did not accept Parliament's amendment with regard to the establishment of technical implementing provisions.?

Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

The common position has been adopted by unanimity. The Council states that it 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. 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 proposal. These amendments are useful clarifications to the proposal that strengthens the quality and safety requirements. The scope of the directive is widened to include autologous cells to be used for medicinal products. Those amendments accepted by the Commission but not by the Council include: -one which aims to strengthen the provisions on traceability; -the requirement that the person responsible must have three years experience. These are therefore not part of the common position. Amongst the amendments accepted by the Council but not part of the amended proposal is the inclusion of a recital on the need to promote information and awareness campaigns with the specific theme "we are all potential donors." The following amendments were amongst those which were not integrated into the proposal by the Council or the Commission, and mainly deal with the following: -widen the scope of the Directive to include research with tissues/cells not intended to be applied in humans; -the use or non/use of certain types of tissues/ cells not intended to be applied in humans; -the use or non-use of certain types of tissues/ cells or some processes (i.e. embryos, cloning. See below on the declarations by the German and Italian delegations.) -ethical issues such as voluntary or unpaid donation, non-profit procurement, consent or ethics in general. Issues where the Council differs from the amended proposal deal mainly with the following: -the accreditation requirement not only for the establishments dealing with tissues and cells, but also for the procedures that they perform has been strengthened; -The Council has reaffirmed Member States' competence in matters of publicity in implementing the Directive; -the Council has also decided to refer the matters listed in the annex to the regulatory committee procedure. The following statement was made by the Italian delegation and entered in the minutes: "The Italian delegation considers that the principles set out in European Parliament amendment relating to the prohibition of the use of cloned embryos or human/animal hybrid embryos obtained through cloning as sources of material for transplants, should be retained. The risks inherent in the transplanting of cells or the use oftissues derived from cloned cells are considerable and evident, and are not in our view consistent with the provisions of a legislative proposal which has the ultimate aim of protecting human health by setting standards of quality and safety for cells and tissues used for human applications." The following statement was made by the German delegation and entered in the minutes: "The German delegation supports efforts to achieve a high level of health protection for EU citizens, in the framework of the above proposal for an EU Directive, in regard to the quality and safety of tissues and cells used in human beings. In this, the German delegation is guided by the strict requirements which already exist in Germany under current national legislation and by the legal framework set out in Article 152(4)(a) of the EC Treaty. The German delegation welcomes the intentions pursued by the European Parliament with its amendments to the proposed Directive, in particular the proposal contained in the amendment relating to the prohibition of the use of cloned embryos or human/animal hybrid embryos obtained through cloning as sources of material for transplants. Germany reserves the right to lay down more stringent protection measures when the Directive is transposed into national law, using the option provided for in the second clause of Article 152(4)(a) of the EC Treaty.?

Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

The Commission notes with satisfaction that the Council has endorsed the general approach taken in its amended proposal. The common position has followed the same direction on the Parliament's amendments as that of the Commission - accepting the majority of those related to technical aspects and, given the absence of a legal basis, rejecting those dealing with ethics. Although the common position differs on some particular issues from the Commission's amended proposal, it does cover 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 common position represents a carefully balanced compromise. In particular it maintains the Community's obligation to establish and regularly update specific technical requirements in all relevant fields. With regard to one of the key amendments rejected by both Commission and Council, the Commission stated that it aimed to prohibit the use of 'cells derived from cloned embryos' for 'transplant' - so-called 'therapeutic cloning' - using cells with genetic features identical to an existing cell or organism. Such applications are controversial ethical issues, with no consistent opinion in Member States and no likelihood of one being reached in the near future. In the opinion of the Commission, the Directive should not interfere with decisions to be made by each Member State concerning the use or non-use of any specific type of human cells or tissues, as was foreseen in the Commission's amended proposal. A solution that sets safety and quality requirements in cases where the use of such cells is permitted in a Member State is the preferred option. In conclusion, the Commission considers the common position to be a good compromise, which takes on board key European Parliament amendments, while still being in line with the Commission's amended proposal on all essential questions.?

Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

The committee adopted the report by Peter LIESE (EPP-ED, D) amending the Council's common position under the 2nd reading of the codecision procedure. The key amendments were as follows: - Member States should ensure, rather than merely "encourage", voluntary and unpaid donations of tissues and cells. Donation "must be done out of the donor's free will without payment except compensation". However, detailed rules should be left to each Member State. Member States should report to the Commission every two years (rather than every three years) on the way in which they implement this requirement; - the traceability requirements laid down in the directive for tissues and cells should also apply to all relevant data relating to products and materials coming into contact with those tissues and cells. Moreover, the data required to ensure full traceability in accordance with the directive should be kept for at least 30 years; - Member States should ensure that tissues and cells imported from third countries have been donated, procured and exported in accordance with the laws of those countries and that they can be traced from the donor to the recipient and vice versa; - in order to guarantee full and effective traceability of human tissues and cells, Member States may authorise, although only in exceptional circumstances, the lifting of donor anonymity in the case of gamete donations; - Member States should ensure that there is no trading in unmodified tissues and cells. However, where human tissues or cells are used as source material for manufacturing products for therapeutic use, such activities may be permitted by bodies and organisations operating on a profit basis; - special rules should be required for the procurement of tissues after an abortion, and no abortion should be performed to obtain foetal tissue. Measures should be put in place to ensure that no pregnant woman is put under any kind of pressure to undergo an abortion in order to obtain tissue. The timing of an abortion and the way it is carried out should not be influenced by the wish to obtain foetal tissue; - Member States should encourage the donation of umbilical cord blood for the public; - cloned human embryos should be excluded as sources of material for transplantation; - a separate directive on organ transplants should be published by the end of 2003. The committee added that, once tissues have been retrieved, the deceased donor body should be reconstructed so that it is as similar as possible to its original anatomical shape. Finally, MEPs were opposed to the commitology procedure being used to decide on the conditions for donor selection, evaluation and procurement in the case of cells used for reproduction purposes. They argued that Parliament should be able to scrutinise any rules proposed in this very sensitive area. ?

Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

The European Parliament adopted a resolution drafted by Peter LIESE (EPP-ED, Germany) and reached agreement on a package of compromise amendments regarding the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. With the support of other political groups, the rapporteur reached an agreement in negotiations with the Council that tissues and cells should be donated on a voluntary basis without direct payment. Detailed rules will be left to the Member States. The Council agreed to accept Parliament's opinion on this key issue. It was also agreed that Member States should endeavour to ensure voluntary and unpaid donations of tissues and cells. Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. Member States will define the conditions under which compensation may be paid. The procurement of tissues and cells as such is carried out on a non-profit basis. On the question of traceability of human tissues and cells, it was agreed that tissue establishments should keep the data necessary to ensure traceability at all stages. Data required for full traceability shall be kept for a minimum of 30 years after clinical use. Data storage may also be in electronic form. Regarding cloned human embryos, it was agreed that existing legislation in the Member States should remain into force. This directive does not interfere with Member States' decisions concerning the use or non-use of any specific type of human cells, including germ cells and embryonic stem cells. However, for any particular use of such cells in a Member State, this directive will require the application of all provisions necessary to protect public health, given the specific risks of these cells based on the scientific knowledge and their particular nature, and guarantee respect for fundamental rights. This compromise amendment replaces the original amendment, in which Parliament had demanded that cloned human embryos, and human-animal hybrid embryos produced by cloning, aggregation or any other procedure, and tissues and cells derived from that, should be excluded as sources of material for transplantation. Since the Council could not accept this amendment, the rapporteur recommended that the House accept the less far-reaching compromise amendment, indicating that in doing so a conciliation procedure could be avoided. Parliament adopted this amendment with 503 votes in favour, 42 against and 12 abstentions.?

Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

A compromise package concerning the proposed amendments of the European Parliament and which includes three draft declarations involving the Commission, 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, 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 amendments accepted concern the following issues: - promotion of worldwide standards; - clarification of the scope; - clarification on accreditation of establishments; - traceability; - labelling; - clarification on comitology; - clarification on the roles of third parties; - promotion of donation, - clarification on specific risks of cells, - equal access and transparency; - reconstruction of the donor's body; - voluntary and unpaid donations; - access to tissues and cells for establishments; - the mention of the chapter of human rights and the Convention; - anonymity; - comitology; - guidelines for inspection and training; - import; - non profit procurement; - editorial clarification; - provisions in case of termination of activities in the tissue establishments and - new annex on information to the donor. The Commission has included 3 declarations 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 onthe 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.?

Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

PURPOSE : to lay down standards of quality and safety for human tissues and cells intended for human applications. LEGISLATIVE ACT : Directive 2004/23/EC 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. CONTENT : 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. This Directive aims 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; the directive provides for principles, minimum standards and obligatory procedures for the whole chain (donation, procurement, testing, processing, storage and distribution); - strengthen requirements related to the suitability of donors of tissues and cells and the screening of these donated substances of human origin in the European Union; - elaborate at Member State level requirements for establishments involved in the procurement, testing, processing, storage, and distribution of tissues and cells of human origin, as well as national accreditation and monitoring and inspection structures; - lay down provisions at Community level for the formulation of a register of accredited establishments; - lay down provisions at Community level for the formulation of a quality system for establishments involved in activities related to tissues and cells; - lay down common provisions at Community level for the training of staff directly involved in the procurement, testing, processing, storage, and distribution of tissues and cells of human origin, without prejudice to existing legislation; - establish rules for ensuring the traceability of tissues and cells of human origin from donor to patient and vice versa, which are valid throughout the European Union; - establish a system for the regulation of imports of human tissues and cells from third countries that ensure equivalent standards of quality and safety. The following points should be noted: - The Directive applies to tissues and cells including haematopoietic peripheral blood, umbilical-cord (blood) and bone marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells. It excludes blood and blood products. - The Directive does 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, the Directive requires the application of all provisions necessary to protect public health, given the specific risks of these cells based on the scientific knowledge and their particular nature, and guarantee respect for fundamental rights. Moreover, the Directive does not interfere with provisions of Member States defining the legal term 'person' or 'individual'. - Tissues and cells used for allogeneic therapeutic purposes canbe 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 is required. The dignity of the deceased donor must be respected, notably through the reconstruction of the donor's body. - Member States are urged to take steps to encourage a strong public and nonprofit sector involvement in the provision of tissue and cell application services and the related research and development. - As a general principle, the identity of the recipient(s) must not be disclosed to the donor or his/her family and vice versa, without prejudice to legislation in force in Member States on the conditions of disclosure, which could authorise in exceptional cases, notably in the case of gametes donation, the lifting of donor anonymity. ENTRY INTO FORCE : 7 April 2004. DATE OF TRANSPOSITION : 7 April 2006.?

Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

ACT: Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.

CONTENT: this Commission Directive relates to the establishment of specific technical requirements for each step in human tissue and cell application processes and implements Directive 2004/23. This is being done in order to avoid and minimise any adverse risks to human health. Risks can be reduced by careful donor selection, testing of each donation and the application of procedures to procure tissue and cells in accordance with rules and processes established and update according to best available scientific advice. Under the terms of the Directive, all tissues and cells, including those used as starting material for the manufacture of medicinal products to be used in the Community, must meet the safety requirements set out in this Directive.

There are special procedures governing reproductive cells, which due to their specific nature require certain unique requirements. For example, for the donation of reproductive cells between partners that have an intimate physical relationship, it is justified to require less stringent biological testing ? given that in such a case the risk for the recipients is less than for donation from a third party. In order to minimise the risk of cross-contamination, biological testing of the donor will only become necessary in cases where the donated cells are processed, cultured or stored.

The Directive defines a number of related terms including, inter alia, reproductive cells, partner donation, direct use, quality system, standard operating procedures, validation or qualification, traceability and procurement organisation. The Directive states that, with the exception of partner donation of reproductive cells for direct use, Member States are obliged to ensure that the procurement of human tissues and cells is accredited, designated, authorised and licensed under certain strict criteria, the conditions of which are set out in the Directive. The provisions governing laboratory tests required of donors as well as the selection criteria of donor?s tissues and cells are set out in Annexes attached to the Directive. In additions Member State authorities are obliged to follow procurement procedures relating to tissue and/or cell donation that are compatible with requirements set out in Annex to the Directive. The authorities may authorise the direct distribution of specific tissues and cells, from where the procurement is carried out, to a health care establishment for immediate transplantation.

TRANSPOSITION: 1 November 2006.

ENTRY INTO FORCE: 1 March 2006.

Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

This Report has been prepared in accordance with Article 12 of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. It analyses measures taken by the Member States to ensure voluntary and unpaid donations. It covers the donation of tissues and cells from a general point of view and has been complemented, where appropriate, with the results of the report on reproductive cells.

The Report finds that although the principle of voluntary unpaid donation is recognised by the Member States, the concrete interpretation of this principle differs from one Member State to another. Most, namely 62.5% of all the EU Member States, allow some form of compensation to be offered to donors of tissues and cells. In cases where compensation is permitted compensation comes in the form of expenses only. Although the Directive permits compensation for ?inconvenience? only one Member State does so. Largely because ?inconvenience? can easily be misinterpreted as an incentive. It is more difficult to objectively quantify compensation for inconvenience than it is for expenses incurred.

As far as the actual amounts reimbursed are concerned the Commission confirms that it has received scant information from the Member States. The amount of compensation paid depends on individual circumstances, the number of times a donor has visited the hospital, the type of treatment needed, the effect of voluntary donation on an individual?s ability to work etc.

Different initiatives exist to promote the principle of voluntary unpaid donations. Techniques are diverse and include advertising, student information programmes and donor days. The promotional measures do not always cover the unpaid character of the donation focusing instead on the need to increase donation. Not all Member States have provisions in place that restrict or prohibit the advertising of tissues and cells for financial gain. Those restrictions that do exist vary.

Based on the above, the Commission proposes the following lines of action:

- The collection of more detailed information on the day-to-day practice of compensation at different hospitals or procurement organisation.
- Investigating the possibility of issuing guidelines on the principle of unpaid donation based on the information received. The guidelines would promote, for example, greater transparency regarding compensation for donation ? specific mention of the amount paid or expenses reimbursed.
- Investigating the possibility of issuing guidelines on Article 12 (2) of the Directive and the need for appropriate restrictions/prohibitions on advertising for the financial gain of donating tissues or cells.

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LEGISLATIVE ACT: Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

CONTENT: this Directive implements Directive 2004/23/EC, which calls for the establishment of specific technical requirements for each one of the steps in the human tissues and cells application process, including standards and specifications with regard to a quality system for tissue establishments. It establishes technical requirements for an accreditation, designation, authorisation or licensing system for tissue establishments and for the preparation processes at the tissue establishments in Member States.

The Directive applies to the coding, processing, preservation, storage and distribution of:

- human tissues and cells intended for human applications; and

- manufactured products derived from human tissues and cells intended for human applications, where those products are not covered by other directives. However, it does not extend to the human application of these tissues and cells (such as implantation surgery, perfusion, insemination or transfer of embryos).

The main points are as follows:

- requirements for the accreditation, designation, authorisation or licensing of tissue establishments are set out in Annex I. They coverthe organisation and management, personnel, equipment and materials, facilities/premises, documentation and records and quality review;

- requirements for the accreditation, designation, authorisation, licensing of tissue and cell preparation processes are set out in Annex II, and include the air quality standard during the processing of tissues and cells;

- since the use of tissues and cells for human application carries a risk of disease transmission and other potential adverse effects in recipients, specific requirements for traceability and a Community procedure for notifying serious adverse reactions and events are set out;

- to facilitate traceability and information on the main characteristics and properties of tissues and cells, the Directive lays down the basic data to be included in a single European code.

Lastly, provisions of the Directive concerning traceability and the reporting of serious adverse reactions and events also apply to the donation, procurement and testing of human tissues and cells.

ENTRY INTO FORCE: 14/11/2006.

TRANSPOSITION: 01/09/2007. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 10 of the Directive (European coding system) by 1 September 2008.

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The Commission presents its report on the application of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Overall, the report states that the implementation of the Directives by the Member States is satisfactory. This concerns in particular the following:

- the requirement to designate a competent authority or authorities and to establish accreditation/designation/authorisation/licensing systems of tissue establishments;
- pinspections systems;
- registries of tissue establishments;
- systems to report, investigate, register and transmit information about serious adverse events and reactions; and
- testing requirements.

The degree of implementation of some other measures suggests that further efforts and actions by Member States are needed. This concerns the following:

- the development of specific systems for authorising the tissue and cell preparation process;
- finalisation of the accreditation/designation/authorisation/licensing process in respect of each individual establishment;
- the carrying out of inspections in all Member States;
- monitoring of imports/exports;
- fulfilment of the reporting requirements (tissue establishments' annual reports on activities, register of accredited/designated/authorised/licensed tissue establishments at the level of the Member States and at EU level -EUROCET-);
- preparation of annual reports on adverse events and reactions for the Commission.

The Commission is working with the Member States to help them develop operational solutions in response to the remaining challenges.

In July 2009 there were five infringement procedures open for failure to achieve full transposition of the Directives in two Member States.

The report also notes that some of the difficulties identified by Member States were linked to the implementation of testing requirements, in particular in the Medically Assisted Reproductive Technologies (MART) sector. The interpretation of the air quality standards that tissue establishments need to apply while tissues and cells are being processed is also a matter of concern among Member States. More guidance on coding systems, inspections, import/export and vigilance requirements was also sought by Member States. The report states that an efficient coding system is a crucial, but not exclusive, element in the traceability chain and ultimately in any vigilance system for human tissues and cells. The human tissue and cell chain is dependent on a robust codification system, which will secure the information flow from donation to transplantation and vice versa. The European coding system should ensure that the pre-existing traceability/coding systems can be maintained and further developed by the Member States, whilst ensuring a minimum level of compatibility between them.

The Commission is endeavouring to provide Member States and competent authorities with appropriate support in these areas.

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The Commission presents its Second Report on Voluntary and Unpaid Donation of Tissues and Cells in accordance withDirective 2004/23/EC. The report is based on the Members States' responses to a report template on voluntary and unpaid donation of tissues and cells. All Member States submitted a report to the Commission. In addition, Liechtenstein and Norway submitted a report (in total 29 reporting countries).

The report aims to provide an overview of the practice of voluntary and unpaid donation of tissues and cells, focusing on 1) legislative provisions, guidelines and policies; 2) compensation and incentives; 3) promotion and advertising, and 4) procurement and supply.

Compliance: the report shows that Member States overall comply with Article 12 of Directive 2004/23/EC, requiring Member States to take the necessary measures to endeavour to ensure voluntary and unpaid donations of tissues and cells. Largely in line with the findings of the first report on voluntary and unpaid donation of tissues and cells (issued in 2006), this report shows that legislative provisions and guidelines on voluntary and unpaid donation of tissues and cells are well established across the EU. 27 out of the 29 reporting countries have such legislative provisions or guidelines in place.

Compensation: 19 of the reporting countries have some form of compensation or incentive structures for donors of tissues and cells (excluding reproductive cells), such as reimbursement of travel and medical costs. For reproductive cells, about half of the countries provide some forms of compensation or incentives, including reimbursement of travel costs, refreshments and compensation linked to loss of earnings. In addition, four countries give some form of compensation or incentives to relatives of deceased donors.

Promotion: 19 countries have undertaken some form of measures to promote voluntary and unpaid donation of tissues and cells, such as awareness raising and information campaigns. In addition, 23 countries have 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 (in line with article 12 of Directive 2004/23/EC).

Procurement and supply of tissues and cells: the report shows that the majority of the countries have public collectors/suppliers or a dual system of public and private collectors/suppliers. With regards to supply, 11 countries report having policies in place to endeavour to promote self-sufficiency of tissues and cells, and 17 countries have bilateral or other forms of agreements/collaboration structures to ensure national

supply of tissues and cells. However, almost half of the countries report some form of shortages of tissues and cells, including bone marrow and gametes.

As set out in Article 12 of Directive 2004/23/EC, the Commission shall inform the European Parliament and the Council of any necessary further measures it intends to take in the field of voluntary and unpaid donation of tissues and cells. Based on the findings of this report, the Commission will now, together with the Member States, reflect on the potential need for further measures, keeping in mind that the Commission's legal mandate is limited to quality and safety of tissues and cells.

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The Commission presented a report on the implementation of Directives 2004/23/EC, 2006/17/EC and 2006/86/EC setting standards of quality and safety for human tissues and cells.

The report is based on the replies to questionnaires that the Commission sent to Member States in 2012 (verification of the completeness of transposition), 2013 (implementation survey) and 2014 (implementation of the voluntary and unpaid donation (VUD) principle) and follows up on the Commission communication published in January 2010 as well as the two reports on the application of the principle of VUD for tissues and cells issued in 2006 and 2011.

Overall application of the Directives: this Report reveals an overall adequate application of the current quality and safety requirements of the EU tissues and cells legislation in most of the responding EU Member States and EEA countries.

Significant progress has been made in many areas, also through the active support by Commission funded projects and other initiatives:

- since 2003, a number of projects have been funded under the multi-annual programmes for Union action in the field of health addressing the area of human tissue and cells for clinical application. These actions allowed for the development of guidelines and manuals in areas of common interest such as inspections and vigilance, included training courses for Member States Competent Authorities and their inspectors and brought together professionals in the tissue banking sector for the development of detailed technical guidance in line with the EU legal requirements;
- an additional support on training of tissue establishment personnel was given through EU-funded projects such as European Quality System for Tissue Banking (EQSTB) and European Good Tissue Practices (EuroGTPs). Good practices developed by the EU-funded initiatives were also included by the Council of Europe in a dedicated Guide to the Quality and Safety of Tissues and Cells;
- as regards the risk of transmission of communicable diseases thorough tissues and cells, the collaboration with ECDC proved extremely valuable. In addition to providing regular updates during the bi-annual meeting of the tissue and cell expert sub-group on the epidemiological situation relevant to the tissue and cell sector, the development of risk assessments (e.g. for HTLV, malaria, dengue and chikungunya) and preparedness plans (e.g. for WNV outbreaks) provided a valuable contribution to policy and decision making in this sector at both national and EU level;
- the Commission developed - in close cooperation with Member States - a Rapid Alert Platform for Tissues and Cells (RATC) which facilitates web-based communications between Member States in case of alerts relating to human tissues or cells transferred across borders

However, the report points to some gaps and difficulties in relation to the application and enforcement of the existing provisions (e.g. definitions, requirements on the safety aspects regarding living donors, inspections framework), some of them owing to the different approaches taken by the Member States when transposing and implementing the current EU legislation and others due to the scientific and technologic developments since the adoption of the Directives.

Another important issue highlighted by some Member States was the need to foster harmonisation of the inspection practices in the Member States. Even though most of the Member States reported using the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments, there is no common agreement on the classification of shortcomings identified during inspections (e.g. classification of minor, major and critical deficiencies).

The Commission will follow-up with Member States to address situations where the legislation might not have been fully or correctly implemented.

Voluntary and unpaid donation (VUD) principle: as regards the implementation of the VUD principle, the Commission survey showed that Member States overall comply with Article 12 of Directive 2004/23/EC requiring them to take the necessary measures to encourage VUD. However, Member States interpretation of what is considered compensation and incentive vary.

Only 17 Member States reported having guiding principles regarding the possibility to compensate tissue and cell donors, but in many cases these principles were just a description of the practices allowed at national level. An important issue is how and by whom the decision concerning the value and form of compensations for tissue and cell donors is taken.

In conclusion, the gaps and difficulties identified suggest that a further in-depth evaluation might be useful. The Commission will consider the need for an evaluation in order to assess the relevance, effectiveness, efficiency, coherence and the EU added value of Directive 2004/23/EC and its implementing Directives.