Basic information

2008/0238(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Standards of quality and safety of human organs intended for transplantation **Subject** 4.20.05 Health legislation and policy	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	MIKOLÁŠIK Miroslav (PPE)	15/09/2009

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Public Health and Food Safety		

Committee for opinion	Rapporteur for opinion	Appointed
JURI Legal Affairs	WIKSTRÖM Cecilia (ALDE)	02/09/2009
LIBE Civil Liberties, Justice and Home Affairs	The committee decided not to give an opinion.	

Former committee for opinion	Former rapporteur for opinion	Appointed
JURI Legal Affairs		
LIBE Civil Liberties, Justice and Home Affairs		

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	3025	2010-06-29

Key events

Date	Event	Reference	Summary
08/12/2008	Legislative proposal published	COM(2008)0818	Summary
15/12/2008	Committee referral announced in Parliament, 1st reading		
19/10/2009	Committee referral announced in Parliament, 1st reading		
16/03/2010	Vote in committee, 1st reading		Summary
26/03/2010	Committee report tabled for plenary, 1st reading	A7-0106/2010	
18/05/2010	Debate in Parliament		
19/05/2010	Decision by Parliament, 1st reading	T7-0181/2010	Summary
19/05/2010	Results of vote in Parliament		
29/06/2010	Act adopted by Council after Parliament's 1st reading		
07/07/2010	Final act signed		
07/07/2010	End of procedure in Parliament		
06/08/2010	Final act published in Official Journal		

Technical information	
Procedure reference	2008/0238(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Legal basis	Treaty on the Functioning of the EU TFEU 168-p4
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/00139

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE430.898	16/12/2009	
Committee opinion	JURI	PE430.861	29/01/2010	
Amendments tabled in committee		PE439.155	04/03/2010	
Committee report tabled for plenary, 1st reading/single reading		A7-0106/2010	26/03/2010	
Text adopted by Parliament, 1st reading/single reading		T7-0181/2010	19/05/2010	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00019/2010/LEX	07/07/2010	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2008)0818	08/12/2008	Summary
Document attached to the procedure	SEC(2008)2956	08/12/2008	
Document attached to the procedure	SEC(2008)2957	08/12/2008	
Commission response to text adopted in plenary	SP(2010)3805	24/06/2010	
Follow-up document	COM(2015)0123	10/03/2015	Summary
Follow-up document	COM(2016)0809	04/01/2017	Summary
Follow-up document	SWD(2016)0451	04/01/2017	
Follow-up document	COM(2022)0671	30/11/2022	
Follow-up document	SWD(2022)0376	30/11/2022	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	NL_CHAMBER	COM(2008)0818	08/09/2009	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1036/2009	10/06/2009	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Corrigendum to final act 32010L0053R(01)
OJ L 243 16.09.2010, p. 0068

Directive 2010/0053
OJ L 207 06.08.2010, p. 0014 Summary

Standards of quality and safety of human organs intended for transplantation

2008/0238(COD) - 04/01/2017 - Follow-up document

The Commission presents a report on the implementation of Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. The report is based on responses to a survey launched by the Commission in 2014, to which 29 countries replied (i.e. all Member States and Norway).

Implementation of the Directive: In general, the survey shows that the Member States have implemented EU legislation on bodies in an adequate way:

- all Member States have appointed **competent authorities at national level** and have established supervisory mechanisms to ensure standards of safety and quality of human organs;
- all countries reported having an **authorisation scheme** for organ procurement agencies;
- 26 Member States reported that **organ procurement teams** came from overseas on a regular or *ad hoc* basis. For 21 of these, these activities are carried out in a structured collaboration, most often with *Eurotransplant* (Germany, Austria, Belgium, Croatia, Hungary, Luxembourg, Netherlands and Slovenia) or *Scandiatransplant* (Denmark, Finland, Norway and Sweden) or within these organisations;
- **on-site checks, audits or inspections of procurement centres** were carried out in 22 countries. The frequency of such inspections varies from year to year every three to five years, but most frequently every two years (in seven countries);
- all Member States indicated that they applied at least one of these three approaches to assess the **competence of health personnel**: checking of qualifications at recruitment (23 countries), participation in regular training programmes (24 countries) or additional certification (11 countries);
- sixteen Member States and Norway have adopted a **system of tacit consent** at the national level for organ donation (consent is assumed unless declared otherwise before death). Seven Member States have established an **explicit consent system** (donors must expressly agree to organ donation), while four countries have a mixed system;
- most countries have a **register or records for living donors** (23 out of 29). The majority of countries (27 out of 29) monitor donors living after the donation. Sixteen countries offer a lifetime medical check-up, while seven have defined a limited duration for donor monitoring, ranging from one to thirty years;
- all Member States indicated that they have set up authorisation schemes for **transplant centres**.

Additional efforts: given the rather general nature of legal requirements in EU law, the structure of national organisations may be fragmented and vary considerably between countries. As a result, the report highlights the **importance of good coordination** within countries (by means of a strong and well-informed contact point) and between them.

The Commission also recommends that further efforts be made to **improve the monitoring carried out by the Member States**, both as regards recipients and living donors, as well as certain aspects of the quality and safety framework, for example procedures or authorisations.

Indeed, some countries have indicated that they do not have procedures in place to date, such as verifying the identity of the donor, verifying information on consent, or ensuring traceability.

Some of these efforts are already being deployed in the framework of work financed by the Commission. Upcoming implementation surveys and reports will be able to highlight the progress made by Member States.

Standards of quality and safety of human organs intended for transplantation

2008/0238(COD) - 10/03/2015 - Follow-up document

The Commission presents a report on the exercise of the power to adopt delegated acts conferred to the Commission pursuant to Article 24 of Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation.

To recall, the Annex lays down the minimum data set which has to be collected for each donation as well the complementary data set data to be collected in addition, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case.

The Commission is empowered to adopt, delegated acts in order to supplement or amend both the minimum data set and the complementary data set. This power was conferred for a period of five years following 27 August 2010 and it requires the Commission to prepare a report in that respect not later than six months before the end of the five-year period.

The Commission has not yet used the delegated powers conferred by Article 24.

In 2011, the Commission, having consulted experts, concluded that the contents of the data set defined in the Annex to Directive 2010/53/EU were sufficiently detailed to ensure appropriate quality and safety standards, and were in line with current clinical practices in Member States. It considered that delegated powers should not be used at that stage, as there was no specific need for further details in the data set already defined.

The Commission is of the view that the delegated powers conferred by Article 24 of Directive 2010/53/EU should remain in force. Transplantation medicine is evolving quickly. Therefore medical practices and scientific progress may require adaptation of the data set for organ and donor characterisation, for example with the inclusion of tests not previously available on a large enough scale to allow for their mandatory inclusion. Such a need may also arise in an emergency situation related to a new serious risk to human health, where the Commission may be required to adopt delegated acts through the urgency procedure, in accordance with Article 28 of the Directive.

In addition, the EU-funded project FOEDUS will come to an end in 2016 and will deliver guidelines and further consensus positions on organ and donor characterisation. This outcome will further support the Commission in assessing the need to amend the Annex to Directive 2010/53/EU.

Standards of quality and safety of human organs intended for transplantation

2008/0238(COD) - 08/12/2008 - Legislative proposal

PURPOSE: to ensure that human organs used for transplantation in the EU comply with the same quality and safety requirements and to facilitate their exchange between Member States.

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: over the past 50 years organ transplantation has become an established worldwide practice, bringing immense benefits to hundreds of thousands of patients. Organ transplantation is now the most cost-effective treatment for end-stage renal failure, while for end-stage failure of organs such as the liver, lung and heart it is the only available treatment. The shortage of organs is a major factor affecting transplantation programmes. Nearly 56 000 patients are now on waiting lists in the EU. Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30%. Donation rates and availability of organs varies considerably across Europe with achievable good practice delivering far greater benefits in some Member States than in others.

On 31 May 2007, the Commission adopted a Communication on organ donation and transplantation based on that analysis. This Communication proposes what activities the EU should undertake in the field of organ transplantation.

In December 2007, the Council adopted conclusions on organ donation and transplantation which recognised the importance of having high standards with respect to the quality and safety of organs for transplantation, so as to ensure a high level of protection for patients throughout Europe. The Council called on the Commission to consult the Member States, and continue its examination of the need for an EU framework on quality and safety for human organs. The European Parliament resolution adopted on 22 April 2008 recognised that it is vitally important to improve the quality and safety of organ donation and transplantation to reduce transplant risks. It invited the Commission to present a proposal for a directive stipulating requirements to ensure the quality and safety of organ donation across the EU.

CONTENT: this proposal for a Directive covers human organs, that are used for transplantation, during all the phases of the process – donation, procurement, testing, preservation, transport and use – and aims to ensure their quality and safety and hence a high level of health protection. Organs that are transplanted into the human body in clinical trials should comply with the quality and safety standards laid down in this Directive.

The added value of the Directive:

Ensuring quality and safety for patients at EU level: this Directive sets out the basic quality and safety requirements needed in every transplant system. More specifically, the proposal:

- provides for the creation or designation of a competent national authority in each Member State which will ensure compliance with the requirements of the Directive;
- establishes a system for the authorisation of programmes of organ procurement and transplantation based on common quality and safety criteria. This system would provide a complete list of authorised centres throughout the European Union, accessible to the public and professionals alike;
- establishes common quality and safety standards for the processes of evaluating donors and human organs, thus ensuring the health of recipients;
- proposes the introduction of national quality programmes to ensure continuous monitoring of performance and improvement and learning;
- ensures that Member States put in place organ traceability systems. The Commission will adopt procedures for guaranteeing full traceability of organs exchanged between Member States;

- includes measures to capture serious adverse events related to the procurement, testing and transport of organs, as well as any serious adverse reactions observed during or after transplantation which may be connected to the procurement, testing and transport of the organ in the European Union. The Commission will adopt procedures for ensuring interoperability between the reporting systems on adverse events and reactions.

Ensuring the protection of donors: the proposed Directive contains a number of measures to protect living donors. These include correct evaluation of the health of the donor and comprehensive information about the risks prior to donation, the introduction of registers for living donors to follow up their health and measures to ensure the altruistic and voluntary donation of organs by living donors.

Facilitating cooperation between Member States and cross-border exchanges: the Directive will: i) put in place the quality and safety conditions needed to facilitate cross-border exchanges; ii) standardise the collection of the relevant information on the characteristics of the organ needed to make a proper risk assessment; iii) establish a mechanism for transmission of the information; iv) provide for the necessary mechanisms to be put in place for cross-border exchanges of organs to ensure traceability of the organ and pre-empt serious adverse reporting.

Standards of quality and safety of human organs intended for transplantation

2008/0238(COD) - 19/05/2010 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 643 votes to 16 with 8 abstentions a resolution setting out its position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure) with a view to the adoption of on the proposal for a directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. Following agreement with the Council, it made some amendments:

Scope: this Directive shall also apply to the procurement of organs of human origin intended for transplantation.

Definitions: Parliament amends certain definitions, including “donor” and inserts others, including “competent authority””. It also states that the definition of an “organ” includes a part of an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation.

Framework for quality and safety: the resolution states that the framework for quality and safety shall provide for the adoption and implementation of:

- procedures for the verification of donor identity;
- procedures for the verification of the details of the consent, authorisation or absence of any objection of the donor or donor family;
- procedures for the verification of the completion of the organ and donor characterisation;
- procedures for the procurement, preservation packaging and labelling of organs;

- procedures needed to ensure traceability, guaranteeing compliance with the legal requirements on the protection of personal data and confidentiality;
- procedures for the accurate, rapid and verifiable reporting of serious adverse events and reactions;
- procedures for the management of serious adverse events and reaction.

These procedures shall specify, inter alia the responsibilities of procurement organizations, European organ exchange organisations and transplantation centres in this respect. In addition, the framework for quality and safety shall ensure that the healthcare personnel involved at all stages of the chain from donation to transplantation or disposal is suitably qualified or trained and competent, and shall develop specific training programmes for such personnel.

Procurement organisations: Members deleted certain clauses on organisational structure and operational procedures of procurement organisation, stating that such detailed provisions did not belong in the body of the text. They deleted certain provisions on normal standards for operation theatres for the same reasons.

Organ and donor characterisation: the text states that Member States shall ensure that all procured organs and donors thereof are characterised before transplantation through the collection of the information set out in the Annex. Information specified in Part A of the Annex contains a set of minimum data which has to be collected for each donation. Information specified in Part B of the Annex contains a set of complementary information to be collected in addition, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case.

If according to a risk-benefit analysis in a particular case, including life-threatening emergencies, the expected benefits for the recipient outweigh the risks posed by incomplete data, an organ may be considered for transplantation even where not all of the minimum data specified in Part A of the Annex are available.

In order to meet the quality and safety requirements laid down in the Directive, the medical team shall endeavour to obtain all necessary information from living donors and for that purpose shall provide them with the information they need to understand the consequences of donation. In the case of deceased donation, whenever possible and appropriate, the medical team shall endeavour to obtain such information from relatives or other persons. The medical team shall also endeavour to make all parties from whom information is requested aware of the importance of the swift transmission of this information.

Where organs are exchanged between Member States, they shall ensure that the information on organ and donor characterisation, as detailed in the Annex, is transmitted to the other Member State with which the organ is exchanged in conformity with the procedures established by the Commission.

New recitals note that the shortage of organs available for transplantation and the time constraints in the process of organ donation and transplantation makes it necessary to take into account those situations in which the transplantation team lacks some of the information required for donor and organ characterisation as set out in Part A of the Annex, which specifies a minimum mandatory data set of information. In those particular cases, the medical team shall assess the particular risk posed to the potential recipient by the lack of information and by not proceeding with transplantation of the organ in question. Therefore, if a complete characterisation of an organ, according to Part A of the Annex, is not possible in time or due to particular circumstances, such organ may be considered for transplantation where the non-transplantation may pose a greater risk to the potential recipient. Part B of the Annex, referring to a complementary data set of information, will allow performing a more detailed organ and donor characterisation.

Transport of organs: Parliament added to the requirements that the organs transported must be accompanied by the report on the donor and organ characterization.

Traceability: Member States shall ensure the implementation of a donor and recipient identification system that can identify each donation and each of the organs and recipients associated with it. With regard to such system, Member States shall ensure that confidentiality and data security measures are in place in compliance with Union and national rules,

Furthermore, where organs are exchanged between Member States, they shall transmit the necessary information to ensure the traceability of organs, in conformity with the procedures established by the Commission in accordance with Article 29.

Reporting systems and management for serious adverse events and reactions: the text specifies that Member States shall ensure that procedures are in place for: (i) the notification of any serious adverse event and reaction to the competent authority and to the concerned procurement or transplantation organisation in due time; (ii)the notification of the management measures with regards to serious adverse events and reactions to the competent authority in due time.

Principles governing organ donation: the text specifies that the principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and inconveniences related to the donation. For such cases, Member State shall define the conditions under which compensation may be granted, while avoiding any financial incentives or benefit for a potential donor.

Protection of the living donor: Member States shall take all necessary measures to ensure the highest possible protection of living donors in order to fully guarantee the quality and safety of organs for transplantation. They shall endeavour to carry out the follow-up of living donors and shall have a system in place in accordance with national provisions, in order to identify, report, and manage any event potentially relating to the quality and safety of the donated organ, and hence of the safety of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation.

Data protection and confidentiality: the fundamental right to protection of personal data must be fully and effectively protected in all organ donation and transplantation activities, in conformity with Union provisions on the protection of personal data, such as Directive 95/46/EC. Member States must ensure that the data processed are kept confidential and secure and that donors and recipients whose data are being processed within the scope of the Directive are not identifiable, except as permitted by Directive 95/46/EC, and national provisions implementing that Directive. Any use of systems or data that makes the identifications of donors or recipients possible with a view to tracing donors or recipients other than the purposes permitted by Directive 95/46/EC, including medical purposes, and national provisions implementing that Directive should be penalized according to this Directive

Designation and tasks of competent authorities: Member States may delegate, or may allow a Competent Authority to delegate, part or all of the tasks assigned to it under this Directive to another body which is deemed suitable under national provisions. Such a body may also assist a Competent Authority in carrying out its functions.

Exchange of organs with third countries: exchanges from or to third countries must be supervised by the competent authority. For this purpose, the competent authority and European organ exchange organisations may establish agreements with counterparts in third countries. The supervision of organ exchanges with third countries may be delegated by the Member States to European organ exchange organisations.

Delegated acts: there are new provisions on delegated acts, and exercise and revocation of the delegation, as well as objections to delegated acts, in accordance with the new Treaty.

Standards of quality and safety of human organs intended for transplantation

2008/0238(COD) - 07/07/2010 - Final act

PURPOSE: to establish rules on the donation, testing, characterisation, procurement, preservation, transport and transplantation of organs intended for transplantation.

LEGISLATIVE ACT: Directive 2010/45/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation.

CONTENT: the Council adopted this Directive, following a first-reading agreement with the European Parliament. The Directive lays down rules to ensure standards of quality and safety for human organs intended for transplantation to the human body, in order to ensure a high level of human health protection. Where such organs are used for research purposes, the Directive only applies where they are intended for transplantation into the

human body. It aims to minimise the risk for the organ transplant recipients and to facilitate the exchange of human organs between Member States. It indirectly also seeks to contribute to combating organ trafficking and increasing organ availability. In order to ensure a high level of protection for patients receiving a new organ, the Directive obliges Member States to:

- create or designate a competent national authority which has to ensure compliance with the requirements of the Directive;
- establish a system for the authorisation of programmes of organ procurement and transplantation based on common quality and safety criteria. This system would provide a complete list of authorised centres throughout the EU, accessible to the public and professionals alike;
- introduce frameworks of quality and safety to ensure continuous monitoring of performance;
- put in place an organ traceability system while ensuring the anonymity of both the donor and the recipient;
- take measures to gather serious adverse events related to the procurement, testing and transport of organs, as well as any serious adverse reactions observed during or after transplantation;
- ensure that any organ donation is unpaid and voluntary.

With a view to facilitating cooperation between Member States and to improving the prospects of receiving an organ, in particular of recipients in need of a rare match, the Directive provides for:

- the introduction of quality and safety conditions;
- the standardised collection of the organ's characteristics needed to make a proper risk assessment;
- the establishment of a mechanism for the transmission of the information;
- the setting up of a mechanism for cross-border exchanges of organs to ensure traceability of the organ and reporting of serious adverse events.

Although the number of organ donations and transplantations has grown steadily across the EU, saving thousands of lives each year, nearly 56000 patients are currently on a waiting list for a new organ. Almost 12 people die every day in the EU while waiting for a new heart, liver, lung or another organ.

Reports concerning the Directive: Member States shall report to the Commission before 27 August 2013 and every three years thereafter on the activities undertaken in relation to the Directive, and on the experience gained in implementing it. The Commission shall report before 27 August 2014 and every three years thereafter on the implementation of the Directive.

ENTRY INTO FORCE: 26 August 2010.

TRANSPOSITION: 27 August 2012.