

Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010
on standards of quality and safety of human organs intended for transplantation

CHAPTER VI

GENERAL PROVISIONS

Article 22

Reports concerning this Directive

- 1 Member States shall report to the Commission before 27 August 2013 and every three years thereafter on the activities undertaken in relation to the provisions of this Directive, and on the experience gained in implementing it.
- 2 Before 27 August 2014 and every three years thereafter, the Commission shall transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, a report on the implementation of this Directive.

Article 23

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that the penalties are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 27 August 2012 and shall notify it without delay of any subsequent amendments affecting them.

Article 24

Adaptation of the Annex

The Commission may adopt delegated acts in accordance with Article 25 and subject to the conditions of Articles 26, 27 and 28 in order to:

- (a) supplement or amend the minimum data set specified in Part A of the Annex only in exceptional situations where it is justified by a serious risk to human health considered as such on the basis of the scientific progress;
- (b) supplement or amend the complementary data set specified in Part B of the Annex in order to adapt it to scientific progress and international work carried out in the field of quality and safety of organs intended for transplantation.

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Article 25

Exercise of the delegation

1 The power to adopt the delegated acts referred to in Article 24 shall be conferred on the Commission for a period of five years following 27 August 2010. The Commission shall make a report in respect of the delegated powers not later than six months before the end of the five-year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 26.

2 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 26 and 27.

4 Where, in the case of the emergence of new serious risk to human health, imperative grounds of urgency so require, the procedure provided for in Article 28 shall apply to delegated acts adopted pursuant to Article 24(a).

Article 26

Revocation of the delegation

1 The delegation of powers referred to in Article 24 may be revoked at any time by the European Parliament or by the Council.

2 The institution which has commenced an internal procedure for deciding whether to revoke the delegation of powers shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3 The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

Article 27

Objection to delegated acts

1 The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification.

At the initiative of the European Parliament or the Council this period shall be extended by two months.

2 If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3 If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Article 28

Urgency procedure

1 Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act adopted under this Article to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2 The European Parliament or the Council may object to a delegated act adopted under this Article in accordance with the procedure referred to in Article 27(1). In such a case, the act shall cease to apply. The institution which objects to such a delegated act shall state its reasons therefor.

Article 29

Implementing measures

The Commission shall adopt, where organs are exchanged between Member States, detailed rules for the uniform implementation of this Directive in accordance with the procedure referred to in Article 30(2), on the following:

- (a) procedures for the transmission of information on organ and donor characterisation as specified in the Annex in accordance with Article 7(6);
- (b) procedures for the transmission of the necessary information to ensure the traceability of organs in accordance with Article 10(4);
- (c) procedures for ensuring the reporting of serious adverse events and reactions in accordance with Article 11(4).

Article 30

Committee

1 The Commission shall be assisted by the Committee on organ transplantation, hereinafter referred to as 'the Committee'.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof. The period laid down to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

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Article 31

Transposition

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 27 August 2012. They shall forthwith inform the Commission thereof.

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

2 This Directive shall not prevent any Member State from maintaining or introducing more stringent rules, provided that they comply with the provisions of the Treaty on the Functioning of the European Union.

3 Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.