



STATUTORY INSTRUMENTS.

**S.I. No. 198 of 2014**

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EUROPEAN UNION (QUALITY AND SAFETY OF HUMAN ORGANS  
INTENDED FOR TRANSPLANTATION) (AMENDMENT)  
REGULATIONS 2014

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I, JAMES REILLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Commission Implementing Directive 2012/25/EU of 9 October 2012<sup>1</sup> and for the purpose of giving further effect to Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010<sup>2</sup>, hereby make the following regulations:

1. (1) These Regulations may be cited as the European Union (Quality and Safety of Human Organs Intended for Transplantation) (Amendment) Regulations 2014.

(2) The Principal Regulations and these Regulations may be cited together as the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012 and 2014.

2. In these Regulations, “Principal Regulations” means the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012 (S.I. No. 325 of 2012).

3. The Principal Regulations are amended, in the “Arrangement of Regulations” by inserting after “38. Summary proceedings may be brought by IMB” the following:

“Part 8

ORGAN EXCHANGE BETWEEN MEMBER STATES OF THE EUROPEAN ECONOMIC  
AREA

39. Interpretation of this Part

40. Responsibility for functions under Directive 2012/25/EU

41. Common procedural rules

42. Information on organ and donor characterisation

43. Information to ensure the traceability of organs

44. Reporting of serious adverse events and reactions”

<sup>1</sup>OJ No. L 275, 10.10.2012, p. 27.

<sup>2</sup>OJ No. L 207, 6.8.2010, p. 14. As affected by Corrigendum (OJ No. L 243, 16.9.2010, p. 68).

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 9th May, 2014.*

4. Regulation 2 of the Principal Regulations is amended—

(a) in the definition of “European organ exchange organisation”, by deleting “of the European Union”,

(b) by substituting for the definition of “Member State” the following definition:

“‘Member State’ means a State which is a contracting party to the Agreement on the European Economic Area signed in Oporto on 2 May 1992;”, and

(c) in the definition of “transplantation centre”, by inserting “, in the case of a transplantation centre in the State,” after “transplantation of organs and”.

5. Regulation 4 of the Principal Regulations is amended—

(a) in paragraph (2)(a), by substituting “11(1) and (4)” for “11(1)”, and

(b) in paragraph (3)(a), by deleting “11(4),”.

6. Regulation 15 of the Principal Regulations is amended by deleting paragraph (6).

7. Regulation 18 of the Principal Regulations is amended by deleting paragraph (6).

8. Regulation 19 of the Principal Regulations is amended by deleting paragraph (4).

9. Regulation 35(2)(h) of the Principal Regulations is amended by substituting “European Economic Area” for “European Union”.

10. The Principal Regulations are amended by inserting after Part 7 the following Part:

“Part 8

ORGAN EXCHANGE BETWEEN MEMBER STATES OF THE EUROPEAN  
ECONOMIC AREA

*Interpretation of this Part*

39. In this Part—

‘delegated body’ means—

(i) a body to which tasks have been delegated in accordance with Regulation 4(5), or Article 17(1) of the Directive, or

- (ii) a European organ exchange organisation to which tasks have been delegated in accordance with Regulation 29, or Article 21 of the Directive;

‘Directive 2012/25/EU’ means Commission Implementing Directive 2012/25/EU of 9 October 2012<sup>1</sup>;

‘Member State of destination’ means the Member State to which the organ is sent for the purpose of transplantation;

‘Member State of origin’ means the Member State where the organ is procured with the purpose of transplantation;

‘National donor identification number’ means the identification code attributed to a donor in accordance with the identification system established pursuant to Regulation 18(2);

‘National recipient identification number’ means the identification code attributed to a recipient in accordance with the identification system established pursuant to Regulation 18(2);

‘Specification of the organ’ means—

- (i) the anatomical description of an organ including: its type (e.g. heart, liver),
- (ii) where applicable, its position (left or right) in the body, and
- (iii) whether it is a whole organ or a part of an organ, mentioning the lobe or segment of the organ.

#### *Responsibility for functions under Directive 2012/25/EU*

40. (1) The HSE shall perform the functions of the competent authority under Articles 5, 6 and 7 of Directive 2012/25/EU.

(2) Where information is received by the HSE or the appropriate delegated body pursuant to Article 7 of Directive 2012/25/EU, the HSE or the appropriate delegated body shall forward it to the IMB.

#### *Common procedural rules*

41. (1) Information transmitted pursuant to this Part to another Member State shall:

- (a) be transmitted in writing either electronically or by fax,
- (b) be written in a language mutually understood by the sender and the addressee or, in absence thereof, in a mutually agreed language, or, in absence thereof, in English,
- (c) be transmitted without undue delay,

- (d) be recorded and capable of being made available upon request,
- (e) indicate the date and time of the transmission,
- (f) include the contact details of the person responsible for the transmission, and
- (g) contain the following reminder:

“Contains personal data. To be protected against unauthorised disclosure or access.”.

(2) Notwithstanding paragraph (1), in case of urgencies, information transmitted pursuant to this Part may be exchanged in a verbal form, in particular for exchanges pursuant to Articles 5 and 7 of Directive 2012/25/EU, and Regulations 42 and 44, provided that such verbal contacts are followed by a transmission in writing in accordance with those Articles and Regulations.

(3) Where information is transmitted to the State in accordance with Directive 2012/25/EU, the receiving authority or body shall ensure that the receipt of the information is confirmed to the sender, in accordance with the requirements set out in paragraph (1).

(4) The HSE or the appropriate delegated body, in conjunction with procurement organisations and transplantation centres, shall ensure that designated personnel—

- (a) are available 24 hours a day and 7 days a week, for urgent situations, and
- (b) are able to receive and transmit information pursuant to this Part and Directive 2012/25/EU without undue delay.

*Information on organ and donor characterisation*

42. (1) Where the State is to be the Member State of origin, prior to the organ being sent to the Member State of destination for the purpose of transplantation, the HSE, or the appropriate delegated body, shall transmit the information collected to characterise the procured organ and the donor, as specified in Regulation 15 and in the Annex to the Directive, to the competent authority or delegated body of the potential Member State of destination.

(2) Notwithstanding paragraph (1), where some of the information to be transmitted in accordance with that paragraph is not available at the time of the initial transmission and becomes available later, it shall be transmitted—

- (a) by the HSE, or the appropriate delegated body, to the competent authority or delegated body of the Member State of destination, or
- (b) directly by the procurement organisation to the transplantation centre in the Member State of destination,

in due time to allow for medical decisions.

(3) Procurement organisations and transplantation centres shall transmit to the HSE, or the appropriate delegated body, a copy of the information transmitted to or from them pursuant to this Regulation and Article 5 of Directive 2012/25/EU.

*Information to ensure the traceability of organs*

43. (1) Where the State is the Member State of origin, the HSE shall inform the competent authority or delegated body of the Member State of destination of—

- (a) the specification of the organ,
- (b) the national donor identification number of the donor,
- (c) the date of procurement, and
- (d) the name and contact details of the relevant procurement organisation.

(2) Where the State is the Member State of destination, the HSE shall inform the competent authority or delegated body of the Member State of origin of—

- (a) the national recipient identification number of the recipient or, if the organ was not transplanted, the final use to which it was put,
- (b) the date of transplantation, if applicable, and
- (c) the name and contact details of the relevant transplantation centre.

*Reporting of serious adverse events and reactions*

44. (1) Where the HSE, or the appropriate delegated body, is notified of a serious adverse event or reaction that it suspects to relate to an organ that was received from another Member State, it shall immediately inform the competent authority or delegated body of the Member State of origin and transmit without undue delay to that competent authority or delegated body an initial report containing the information set out in Annex I to Directive 2012/25/EU, in so far as that information is available.

(2) Where the HSE, or the appropriate delegated body, is notified of a serious adverse event or reaction that it suspects to be related to a donor whose organs were sent to other Member States, it shall immediately inform the competent authorities or delegated bodies of each concerned Member State of destination and transmit to each of them an initial report containing the information set out in Annex I to Directive 2012/25/EU.

(3) When additional information becomes available following an initial report by the HSE, or the appropriate delegated body, under this Regulation, it shall be transmitted by the HSE, or the appropriate delegated body, without undue delay to the relevant competent authorities or delegated bodies.

(4) The HSE, or the appropriate delegated body, shall, within three months of transmitting an initial report pursuant to paragraph (1) or (2), transmit to the competent authorities or delegated bodies of all Member States of destination concerned, a common final report containing the information set out in Annex II of Directive 2012/25/EU, after collecting relevant information from all such Member States.

(5) Where the HSE, or the appropriate delegated body, receives an initial report from a competent authority or delegated body under Article 7 of Directive 2012/25/EU, it shall provide relevant information in a timely manner to that authority or delegated body of the Member State of origin.”



GIVEN under my Official Seal,  
1 May 2014.

JAMES REILLY,  
Minister for Health.

EXPLANATORY NOTE

*(This note is not part of the Instrument and does not purport to be a legal interpretation.)*

These Regulations give effect to Commission Implementing Directive 2012/25/EU of 9 October 2012 and give further effect to Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010.

These Regulations amend the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012.

These Regulations may be cited as the European Union (Quality and Safety of Human Organs Intended for Transplantation) (Amendment) Regulations 2014.



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