STATUTORY INSTRUMENTS.

S.I. No. 325 of 2012

EUROPEAN UNION (QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION) REGULATIONS 2012

S.I. No. 325 of 2012

EUROPEAN UNION (QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION) REGULATIONS 2012

ARRANGEMENT OF REGULATIONS

Part 1

PRELIMINARY

1. Citation
2. Interpretation
3. Scope
4. Responsibility for functions under Directive

PART 2

AUTHORISATION TO CARRY OUT PRESCRIBED ACTIVITIES

5. Carrying out of prescribed activities
6. Grant of authorisation
7. Removal, variation and addition of conditions
8. Substantial change in prescribed activity
9. Suspension or revocation of authorisation
10. Compliance notice
11. Responsible person

Part 3

QUALITY AND SAFETY OF ORGANS

12. Framework for quality and safety
13. Procurement organisations
14. Organ procurement
15. Organ and donor characterisation

16. Transport of organs

17. Transplantation centres

18. Traceability

19. Reporting system and management concerning serious adverse events and reactions

20. Healthcare personnel

Part 4

Donor and recipient protection and donor selection and evaluation

21. Principles governing organ donation

22. Consent requirements

23. Quality and safety aspects of living donation

24. Protection of personal data, confidentiality and security of processing

Part 5

Recording and reporting of activities under regulations

25. Reporting obligations of HSE

26. Reporting obligations of IMB

27. Reporting to Commission

Part 6

Organ exchange with third countries and European organ exchange organisations

28. Organ exchange with third countries

29. European organ exchange organisations

Part 7

Enforcement, offences and penalties

30. Interpretation of Part 7

31. Inspections and requests for information

32. Authorised officers

33. Taking of samples, etc. by authorised officers

34. Certificate of result of test, etc. of sample, etc.

35. Offences

36. Penalties

37. Defence of due diligence

38. Summary proceedings may be brought by IMB

Schedule

S.I. No. 325 of 2012

EUROPEAN UNION (QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION) REGULATIONS 2012

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 Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010[1], hereby make the following regulations:

Part 1

Preliminary

Citation

1. These Regulations may be cited as the European Union (Quality and Safety of Human Organs intended for Transplantation) Regulations 2012.

Interpretation

2. (1) In these Regulations—

"Act" means the Irish Medicines Board Act 1995, as amended by s. 197 of the Finance Act 1999 (No. 2 of 1999), Regulation 3 of the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001), Regulation 2 of the European Communities (Medical Devices) (Amendment) Regulations 2001 (S.I. 444 of 2001), Regulation 3 of the European Communities (Medical Devices) (Amendment) Regulations 2002 (S.I. 576 of 2002), the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) and the European Communities (Amendment of the Medicines Board Act 1995) Regulations 2007 (S.I. No. 542 of 2007);

"authorisation" means an authorisation granted by the IMB in accordance with Regulation 6;

"authorised officer" means—

(*a*) a person appointed under Regulation 32, or

(*b*) an officer of Customs and Excise;

"Commission" means the Commission of the European Union;

"Data Protection Directive" means Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995[2], as amended by Regulation (EC)

[1]OJ No. L 207, 6.8.2010, p. 14. As affected by Corrigendum (OJ No. L 243, 16.9.2010, p. 68).
[2]OJ No. L 281, 23.11.1995, p. 31.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 31*st August*, 2012.

No. 1882/2003 of the European Parliament and of the Council of 29 September 2003[3]

"Directive" means Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010;

"disposal" means the final placement of an organ where it is not used for transplantation;

"donation" means donating organs for transplantation;

"donor" means a person who donates one or several organs, whether donation occurs during lifetime or after death;

"donor characterisation" means the collection of the relevant information on the characteristics of the donor needed to evaluate his or her suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation;

"European organ exchange organisation" means a non-profit organisation, whether public or private, dedicated to national and cross-border organ exchange, in which the majority of its member countries are Member States of the European Union;

"framework for quality and safety" means the framework established by the HSE pursuant to Regulation 12;

"HSE" means the Health Service Executive established under section 6 of the Health Act 2004 (No. 42 of 2004);

"IMB" means the Irish Medicines Board established under section 3 of the Irish Medicines Board Act 1995 (No. 29 of 1995);

"Member State" means a Member State of the European Union;

"operating procedures" means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end outcome;

"organ" means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be 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;

"organ characterisation" means the collection of the relevant information on the characteristics of the organ needed to evaluate its suitability, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation;

[3]OJ No. L 284, 31.10.2003, p. 1.

"prescribed activity" means any activity relating to the donation, testing, characterisation, procurement, preservation, transport or transplantation of organs intended for transplantation to the human body;

"preservation" means the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of organs from procurement to transplantation;

"procurement" means a process by which the donated organs become available;

"procurement organisation" means a healthcare establishment, a team or a unit of a hospital, a person, or any other body which undertakes or coordinates the procurement of organs, and is authorised to do so by the IMB in accordance with these Regulations;

"recipient" means a person who receives a transplant of an organ;

"responsible person" means a person who has been designated under Regulation 11 as the responsible person for a procurement organisation or transplantation centre;

"serious adverse event" means any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation—

(*a*) that might lead to the transmission of a communicable disease,

(*b*) that might lead to death or life-threatening, disabling or incapacitating conditions for patients, or

(*c*) which results in, or prolongs, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response, including a communicable disease, in the living donor or in the recipient, that might be associated with any stage of the chain from donation to transplantation—

(*a*) that is fatal, life-threatening, disabling or incapacitating, or

(*b*) which results in, or prolongs, hospitalisation or morbidity;

"transplantation" means a process intended to restore certain functions of the human body by transferring an organ from a donor to a recipient;

"transplantation centre" means a healthcare establishment, a team or a unit of a hospital or any other body which undertakes the transplantation of organs and is authorised to do so by the IMB in accordance with these Regulations;

"traceability" means the ability to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, including the ability to—

(*a*) identify the donor and the procurement organisation,

(*b*) identify the recipient(*s*) at the transplantation centre(*s*), and

(*c*) locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ.

(2) In these Regulations, unless otherwise indicated—

(*a*) a word or expression which is also used in the Directive has the same meaning as it has in the Directive,

(*b*) a reference to a Regulation is to a Regulation of these Regulations,

(*c*) a reference to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, and

(*d*) a reference to the Schedule is to the Schedule to these Regulations.

Scope

3. (1) Subject to paragraph (2), the requirements of these Regulations shall apply to the donation, testing, characterisation, procurement, preservation, transport and transplantation of organs intended for transplantation into the human body.

(2) Where the organs referred to in paragraph (1) are used for research purposes, the requirements of these Regulations shall only apply where they are intended for transplantation into the human body.

(3) These Regulations shall apply without prejudice to the Data Protection Acts 1988 and 2003 in so far as those Acts transpose the Data Protection Directive.

Responsibility for functions under Directive

4. (1) The IMB shall perform—

(*a*) the functions of the State under Articles 5(2) and 9(4) of the Directive, and

(*b*) the functions of the competent authority under Articles 9(2), 11(2) and (3) and 17(2)(*b*) and (*c*) of the Directive.

(2) The HSE shall perform—

(*a*) the functions of the State under Articles 4, 6(2), 7(5) and (6), 10, 11(1), 15(3) and (4), 18(1) and (2) and 20 of the Directive, and

(*b*) the functions of the competent authority under Articles 17(2)(*a*), (*d*) and (*g*) and 21 of the Directive.

(3) The IMB and the HSE shall jointly perform—

(*a*) the functions of the State under Articles 11(4), 11(5), 16 and 22(1) of the Directive.

(*b*) the functions of the competent authority under Article 17(2)(*e*), (*f*) and (*h*) of the Directive.

(4) The IMB and the HSE may separately or jointly enter into a contractual arrangement with a person for the purposes of the person assisting them to perform their respective functions under these Regulations and the Directive.

(5) The IMB and the HSE may each delegate part or all of their respective tasks under these Regulations and the Directive.

(6) The IMB and the HSE shall issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal, which may include guidance for the collection of relevant post-transplantation information to evaluate the quality and safety of the organs transplanted.

(7) The IMB may charge fees for its functions under the Directive and these Regulations in accordance with regulations made under section 13(1) of the Act, read in conjunction with section 4(1)(v) of the Act.

Part 2

Authorisation to carry out prescribed activities

Carrying out of prescribed activities

5. (1) A prescribed activity may only be carried out by, in or on behalf of a procurement organisation or transplantation centre acting in accordance with these Regulations and the Directive and an authorisation granted under Regulation 6 (including any conditions to which the authorisation is subject).

(2) Notwithstanding paragraph (1), a procurement organisation or a transplantation centre carrying out a prescribed activity on the coming into force of these Regulations may continue to carry out such prescribed activity provided that it submits an application for authorisation to the IMB no later than 6 weeks after the signing of these Regulations and only until the IMB has made a decision on that application.

Grant of authorisation

6. (1) The IMB may grant an authorisation to a procurement organisation or a transplantation centre to carry out any prescribed activity, having satisfied itself that such prescribed activity shall be carried out by persons complying with the requirements of these Regulations and the Directive.

(2) An application for an authorisation shall—

(*a*) be made in writing to the IMB,

(*b*) be signed by or on behalf of the procurement organisation or transplantation centre making the application, whether in ink or by means of an electronic signature,

(*c*) include all relevant information as determined by the IMB,

(*d*) include the name and qualifications of at least one responsible person designated under Regulation 11, and

(*e*) be accompanied by the appropriate fee.

(3) Where a procurement organisation or a transplantation centre applies, pursuant to paragraph (2), for an authorisation, the IMB may—

(*a*) grant the authorisation,

(*b*) refuse to grant the authorisation,

(*c*) grant the authorisation in respect of particular sites or prescribed activities only, or

(*d*) grant the authorisation subject to conditions.

(4) Where the IMB grants an authorisation, it shall give notice in writing to the procurement organisation or transplantation centre concerned specifying—

(*a*) the prescribed activities which the procurement organisation or transplantation centre may carry out in accordance with these Regulations and the Directive under the authorisation,

(*b*) the particular site(*s*) at which such activities may be carried out,

(*c*) where a prescribed activity is to be carried out by another person on behalf of the procurement organisation or transplantation centre, the names of all persons authorised to carry out such activity, and

(*d*) if the grant is subject to conditions, the conditions which apply to the carrying out of the prescribed activities.

(5) Where the IMB proposes to refuse to grant an authorisation, it shall serve a notice on the procurement organisation or transplantation centre concerned of the proposed refusal and the reasons for same, and shall, if any representations are made by or on behalf of the organisation or centre within 30 days after the date of such notice, consider the representations.

(6) Where the IMB, having considered the representations (if any) made by or on behalf of a procurement organisation or transplantation centre in response to a notice under paragraph (5), decides to refuse to grant an authorisation, it shall notify the organisation or centre stating the reasons on which its decision is based.

Removal, variation and addition of conditions

7. (1) Subject to the requirements of paragraph (2), the IMB may at any time remove or vary a condition attaching to an authorisation pursuant to Regulation 6(3)(*d*) or impose an additional condition to an authorisation.

(2) Where the IMB proposes to remove or vary a condition, or impose an additional condition, to an authorisation, pursuant to paragraph (1), it shall serve a notice on the procurement organisation or transplantation centre concerned which shall—

(*a*) give details of the condition which it proposes to remove, or of the variation which it proposes to make to an existing condition, or of the additional condition which it proposes to impose,

(*b*) give the reasons for its decision, and

(*c*) specify the date, which shall be not less than 14 days from the date on which the notice is served, from which the removal, variation or imposition shall apply.

Substantial change in prescribed activity

8. (1) A procurement organisation or transplantation centre shall not make a substantial change in a prescribed activity which it carries out without the prior written approval of the IMB.

(2) Any application by a procurement organisation or transplantation centre for approval to make a substantial change in a prescribed activity carried out by it shall be—

(*a*) made in writing to the IMB and signed by or on behalf of the procurement organisation or transplantation centre concerned, whether in ink or by means of an electronic signature, and

(*b*) accompanied by the appropriate fee.

(3) For the purpose of this Regulation, "a substantial change in a prescribed activity" means any change to the sites from which the procurement organisation or the transplantation centre concerned operates, or to the prescribed activities to be carried out by the organisation or centre, which would result in a failure to comply with the requirements of—

(*a*) these Regulations and the Directive, or

(*b*) the framework for quality and safety,

and which is likely to have a substantial impact on the conduct of, or might compromise the quality and safety of, the prescribed activity concerned.

Suspension or revocation of authorisation

9. (1) Subject to paragraph (2), the IMB may suspend or revoke an authorisation on one or more of the following grounds—

(*a*) that the procurement organisation or transplantation centre, or procurement or transplant process, concerned is not in compliance with the requirements of these Regulations and the Directive,

(*b*) that the donation, testing, characterisation, procurement, preservation, transport or transplantation of organs by the procurement organisation or transplantation centre concerned cannot be carried out safely,

(*c*) that the information given by the procurement organisation or transplantation centre concerned pursuant to Regulation 6(2)(*c*) or 31(3) was false or incomplete in any material respect,

(*d*) that the procurement organisation or transplantation centre concerned is not carrying out, or has indicated by a notice in writing that it no longer intends to carry out, the prescribed activities to which the authorisation relates, or

(*e*) the procurement organisation or transplantation centre does not have the staff, premises, equipment or facilities necessary for carrying out properly the prescribed activities to which the authorisation relates.

(2) Where the IMB proposes to suspend or revoke an authorisation, it shall serve a notice on the procurement organisation or transplantation centre concerned of the proposal and the reasons for same, and shall, if any representations are made by the organisation or centre within 30 days after the date of such notice, consider such representations.

(3) Where the IMB, having considered the representations (if any) made by or on behalf of a procurement organisation or transplantation centre in response to a notice under paragraph (2), decides to suspend or revoke an authorisation, it shall notify in writing the organisation or centre stating the reasons on which its decision is based.

(4) Where the IMB considers it necessary in the interests of safety, it may, by a notice served on the procurement organisation or transplantation centre concerned, suspend or revoke an authorisation—

(*a*) in a case where the IMB considers that it is necessary in the interests of safety, immediately, or

(*b*) in all other cases, from a date specified in the notice.

(5) A suspension of an authorisation pursuant to this Regulation shall be for such period as the IMB shall consider necessary having regard to the reasons for the suspension.

(6) A suspension or revocation of an authorisation under this Regulation may be total, or may be limited to a particular prescribed activity or to one or more prescribed activities carried out at a particular site or sites, or to a particular organ.

(7) Where, after a suspension has taken effect, the IMB considers that the authorisation should be further suspended or revoked, the IMB shall proceed in accordance with the provisions of this Regulation.

Compliance notice

10. (1) Where—

(*a*) a procurement organisation or transplantation centre has failed, in any material respect, to comply with the requirements of these Regulations, the Directive or the framework for quality and safety, or

(*b*) the information given by a procurement organisation or transplantation centre pursuant to Regulation 6(2)(*c*) or 31(3) was false or incomplete in any material respect,

and the IMB considers that the failure in question is not sufficiently serious to warrant suspension or revocation of the authorisation of the procurement organisation or transplantation centre in the first instance, it may serve a notice on the responsible person of the procurement organisation or transplantation centre in accordance with paragraph (2).

(2) A notice served under this Regulation shall—

(*a*) identify the requirements of these Regulations and the Directive with which the procurement organisation or transplantation centre has failed to comply, or, in the case of false or incomplete information, the further information which is required,

(*b*) identify the action which the procurement organisation or transplantation centre is required to take, and

(*c*) give the timescale within which the procurement organisation or transplantation centre shall take the action identified in subparagraph (*b*).

(3) Where a procurement organisation or transplantation centre fails to comply with the requirements set out in a notice served under this Regulation within the specified timescale, the IMB may, by a further notice served on the procurement organisation or transplantation centre, suspend or revoke the authorisation concerned.

Responsible person

11. (1) A procurement organisation or transplantation centre shall designate at least one responsible person, qualified in accordance with paragraph (3), whose services shall be available to it.

(2) A responsible person designated under paragraph (1) shall ensure that—

(*a*) all authorised prescribed activities are carried out in accordance with the Directive and these Regulations,

(*b*) information is provided to the IMB as required under Regulations 6(2)(*c*) and 31(3),

(*c*) there is a documented system in place for ratifying that organs meet appropriate specifications for safety and quality for release, and for

ensuring that before any exception from the required standards of quality and safety shall occur, a documented risk-benefit analysis is performed which demonstrates that the expected benefits for the recipient outweigh the risks posed by such exception, and

(*d*) there is a reporting system in place to report with respect to serious adverse events and serious adverse reactions as required under Regulation 19.

(3) A procurement organisation or transplantation centre shall not designate a responsible person under paragraph (1) unless that person either—

(*a*) has a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences awarded on completion of a university course of study, or another course of study recognised in Ireland as equivalent, or

(*b*) is otherwise considered by the IMB to be suitably qualified on the basis of academic qualifications and practical experience,

and has at least two years' practical experience which is directly relevant to the prescribed activity to be authorised.

(4) Procurement organisations and transplantation centres shall inform the IMB of the name and qualifications of any additional responsible person designated under paragraph (1) after the grant of the authorisation concerned.

(5) A responsible person may delegate any of the functions specified in paragraph (2) to other persons who shall be suitably qualified by training and experience to perform them.

(6) Procurement organisations and transplantation centres shall inform the IMB of the name of any person to whom functions have been delegated by the responsible person under paragraph (5), and the specific functions which have been delegated to such persons.

(7) Where a responsible person or a person to whom functions have been delegated under paragraph (5) is permanently or temporarily replaced, the procurement organisation or transplantation centre concerned shall without delay provide the IMB with the name of the replacement, details of his or her qualifications and the date on which the replacement began his or her duties.

(8) If the IMB considers that a responsible person does not meet the requirements of paragraph (3), it shall serve a notice to that effect on the procurement organisation or transplantation centre concerned.

(9) If, within 14 days of receiving a notice referred to in paragraph (8), a procurement organisation or transplantation centre is not able to demonstrate to the reasonable satisfaction of the IMB that the responsible person meets the requirements of paragraph (3), it shall, without delay—

(*a*) relieve him or her of the duties of responsible person in respect of the procurement organisation or transplantation centre,

(*b*) appoint a new responsible person in his or her place, and

(*c*) notify the IMB that it has appointed a new responsible person and provide details of the name and qualifications of the person appointed.

Part 3

Quality and safety of organs

Framework for quality and safety

12. (1) The HSE, in consultation with the IMB, shall ensure that a framework for quality and safety is established to cover all stages of the chain from donation to transplantation or disposal, in compliance with the rules laid down in these Regulations and the Directive.

(2) The framework for quality and safety shall provide for, and include details of the roles and responsibilities regarding, the adoption and implementation of operating procedures for—

(*a*) the verification of donor identity,

(*b*) the verification of the details of the donor's or the donor's family's consent,

(*c*) the verification of the completion of the organ and donor characterisation in accordance with Regulation 15 and the Annex to the Directive,

(*d*) the procurement, preservation, packaging and labelling of organs in accordance with Regulations 13, 14 and 16,

(*e*) the transportation of organs in accordance with Regulation 16,

(*f*) ensuring traceability, in accordance with Regulation 18, while guaranteeing compliance with the European Union and national provisions on the protection of personal data and confidentiality,

(*g*) the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with Regulation 19, and

(*h*) the management of serious adverse events and serious adverse reactions in accordance with Regulation 19.

(3) In respect of the operating procedures referred to in paragraph (2)(*f*), (*g*) and (*h*), the framework for quality and safety shall include the responsibilities of procurement organisations, transplantation centres and European organ exchange organisations, as appropriate.

(4) 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 are suitably qualified or trained and competent, and shall develop specific training programmes for such personnel.

(5) In carrying out prescribed activities, procurement organisations and transplantation centres shall comply with the framework for quality and safety.

Procurement organisations

13. (1) The IMB shall indicate in an authorisation granted to a procurement organisation the prescribed activities that the organisation concerned may undertake.

(2) The IMB shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of procurement organisations.

Organ procurement

14. (1) Procurement organisations shall ensure that—

(*a*) medical activities, such as donor selection and evaluation, are performed under the advice and guidance of a doctor of medicine as referred to in Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005[4], and

(*b*) procurement material and equipment are managed in accordance with relevant European Union, international and national legislation, standards and guidelines on the sterilisation of medical devices.

(2) The HSE and procurement organisations shall ensure that procurement takes place in operating theatres, which are designed, constructed, maintained and operated in accordance with adequate standards and best medical practices so as to ensure the quality and safety of the organs procured.

Organ and donor characterisation

15. (1) Procurement organisations shall ensure that all procured organs and donors thereof are characterised before transplantation through the collection of—

(*a*) the set of minimum data set out in Part A of the Annex to the Directive, and

(*b*) the set of complementary data set out in Part B of the Annex to the Directive, based on the decision of the procurement organisation concerned, taking into account the availability of such information and the particular circumstances of the case

(2) Notwithstanding paragraph (1), if according to a risk-benefit analysis in a particular case, including in life-threatening emergencies, the expected benefits for the recipient outweigh the risks posed by incomplete data, an organ may be

[4]OJ L 255, 30.9.2005, p.22

considered for transplantation where not all of the minimum data specified in Part A of the Annex to the Directive are available.

(3) In order to meet the quality and safety requirements laid down in these Regulations and the Directive, procurement organisations shall—

(*a*) in the case of living donation, endeavour to obtain all necessary information from the donor and provide him or her with the information he or she needs to understand the consequences of donation, or

(*b*) in the case of deceased donation, where possible and appropriate, endeavour to obtain all necessary information from relatives of the deceased donor or other persons.

and, in either case, it shall also endeavour to make all parties from whom information is requested aware of the importance of the swift transmission of that information.

(4) The HSE and procurement organisations shall ensure that the tests required for organ and donor characterisation shall be carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment.

(5) The HSE and procurement organisations shall ensure that organisations, bodies and laboratories involved in organ and donor characterisation have appropriate operating procedures in place to ensure that the information on organ and donor characterisation reaches the transplantation centre in due time.

(6) Where organs are exchanged between the State and another Member State, the HSE shall ensure that the information on organ and donor characterisation, as specified in the Annex to the Directive, is transmitted to the procurement organisation or transplantation centre in the other Member State with which the organ is exchanged, in conformity with the procedures established by the Commission pursuant to Article 29 of the Directive.

Transport of organs

16. (1) Subject to paragraph (2), procurement organisations and transplantation centres shall ensure that the following requirements are met—

(*a*) the organisations, bodies or companies involved in the transportation of organs have appropriate operating procedures in place to ensure the integrity of the organs during transport and a suitable transport time,

(*b*) the shipping containers used for transporting organs are labelled with the following information:

(i) identification of the procurement organisation and the establishment where the procurement took place, including their addresses and telephone numbers,

(ii) identification of the transplantation centre of destination, including its address and telephone number,

(iii) a statement that the package contains an organ, specifying the type of organ and, where applicable, its left or right location and marked "HANDLE WITH CARE", and

(iv) recommended transport conditions, including instructions for keeping the container at an appropriate temperature and position, and

(*c*) the organs transported are accompanied by a report on the organ and donor characterisation.

(2) The requirements laid down in paragraph (1)(*b*) need not be met where the transportation is carried out within the same establishment.

Transplantation centres

17. (1) The IMB shall indicate in an authorisation granted to a transplantation centre the prescribed activities that the centre concerned may undertake.

(2) A transplantation centre shall verify before proceeding to transplantation that—

(*a*) the organ and donor characterisation are completed and recorded in accordance with Regulation 15 and the Annex to the Directive, and

(*b*) the conditions of preservation and transport of shipped organs have been maintained.

(3) The IMB shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of transplantation centres.

Traceability

18. (1) The HSE shall, in conjunction with procurement organisations and transplantation centres, ensure that all organs procured, allocated and transplanted in the State can be traced from the donor to the recipient and vice versa in order to safeguard the health of donors and recipients.

(2) The HSE shall, in conjunction with procurement organisations and transplantation centres, 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.

(3) The HSE, procurement organisations and transplantation centres shall ensure that, with regard to the system referred to in paragraph (2), confidentiality and data security measures are in place in compliance with European Union and national provisions, as referred to in Regulation 24.

(4) The HSE, procurement organisations and transplantation centres shall keep the data needed to ensure traceability at all stages of the chain from donation to transplantation or disposal and the information on organ and donor characterisation as specified in the Annex to the Directive, in accordance with the framework for quality and safety, for a minimum of 30 years after donation.

(5) The data referred to in paragraph (4) may be stored in electronic form.

(6) Where organs are exchanged between the State and another Member State, the HSE shall transmit the necessary information to ensure the traceability of organs in conformity with the procedures established by the Commission pursuant to Article 29 of the Directive.

Reporting system and management concerning serious adverse events and reactions

19. (1) The HSE shall, in conjunction with procurement organisations and transplantation centres, ensure that there is an appropriate system in place to collect, collate, report, investigate, register and transmit relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.

(2) A procurement organisation or transplantation centre carrying out a prescribed activity shall—

(*a*) through its responsible person, ensure that operating procedures are in place to ensure compliance with the system established pursuant to paragraph (1),

(*b*) through its responsible person, ensure that operating procedures are in place for the management of serious adverse events and serious adverse reactions as provided for in the framework for quality and safety, and

(*c*) transmit relevant and necessary information simultaneously to the IMB and to the HSE,

(3) Notwithstanding paragraph (2)(*b*) and (*c*), the responsible person in a procurement organisation or transplantation centre carrying out a prescribed activity shall ensure that operating procedures are in place for the notification, in due time, of—

(*a*) any serious adverse event and any serious adverse reaction, to the IMB and the procurement organisation or transplantation centre concerned, and

(*b*) the management measures with regard to serious adverse events and serious adverse reactions, to the IMB.

(4) Where organs are exchanged between the State and another Member State, the procurement organisation or transplantation centre concerned shall ensure that serious adverse events and serious adverse reactions are reported to the IMB and to the HSE, and the IMB and the HSE shall share such reports with the competent authority concerned in any other Member State concerned in conformity with the procedures established by the Commission pursuant to Article 29 of the Directive.

(5) The IMB and the HSE shall ensure the interconnection between the reporting system referred to in paragraph (1) and the notification system established in accordance with Article 11(1) of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004[5] and Regulation 10(3) of the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 (S.I. No. 158 of 2006).

Healthcare personnel

20. Procurement organisations and transplantation centres shall ensure that healthcare personnel directly involved in the chain from donation to the transplantation or disposal of organs are suitably qualified or trained and competent to perform their tasks and are provided with the relevant training, as specified in the framework for quality and safety pursuant to Regulation 12(4).

Part 4

Donor and recipient protection and donor selection and evaluation

Principles governing organ donation

21. (1) Subject to paragraph (2), donation from deceased and living donors shall be voluntary and unpaid.

(2) Living donors may receive compensation for donation, provided it is strictly limited to making good the expenses and loss of income related to the donation. The Minister shall define the conditions under which such compensation may be granted, while avoiding there being any financial incentives or benefit for a potential donor.

(3) Advertising the need for, or availability of, organs, where such advertising is with a view to offering or seeking financial gain or comparable advantage, is prohibited.

(4) Procurement shall be carried out on a non-profit basis.

Consent requirements

22. (1) Organs shall not be procured in the case of a living donor unless the donor has given informed consent to the donation or the donation is otherwise permitted by law.

(2) Organs shall not be procured in the case of a deceased donor unless consent to the donation has been given by the deceased donor's next of kin.

[5]OJ No. L 136, 30.4.2004, p. 85.

Quality and safety aspects of living donation

23. (1) Procurement organisations shall—

(*a*) 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 and

(*b*) ensure that living donors are selected on the basis of their health and medical history, by suitably qualified or trained and competent professionals.

(2) Selection assessments carried out pursuant to paragraph (1)(*b*) may provide for the exclusion of persons whose donation could present unacceptable health risks.

(3) The HSE and transplantation centres shall—

(*a*) ensure that a register or record of the living donors is kept, in accordance with European Union and national provisions on the protection of the personal data and statistical confidentiality,

(*b*) endeavour to carry out the follow-up of living donors, and

(*c*) implement and maintain a system in order to comply with Regulation 19 and 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.

Protection of personal data, confidentiality and security of processing

24. (1) The IMB, the HSE, procurement organisations and transplantation centres shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ donation and transplantation activities, in conformity with European Union provisions on the protection of personal data, such as Articles 8(3), 16, 17 and 28(2) of the Data Protection Directive, and shall take all necessary measures to ensure that—

(*a*) the data processed are kept confidential and secure in accordance with Articles 16 and 17 of the Data Protection Directive,

(*b*) donors and recipients whose data are processed within the scope of these Regulations and the Directive are not identifiable, except as permitted by Article 8(2) and (3) of the Data Protection Directive, and the Data Protection Acts 1988 and 2003, and

(*c*) the principles relating to data quality, as set out in Article 6 of the Data Protection Directive, are met.

(2) The IMB, the HSE, procurement organisations and transplantation centres shall ensure that all information, including genetic information which is

collected for the purposes of these Regulations and the Directive, is held securely so that it is—

(*a*) available for the purpose of tracing donations,

(*b*) not disclosed except—

(i) in accordance with one or more of the requirements of paragraph (3), or

(ii) where it has been rendered anonymous so that donors are no longer identifiable, and

(*c*) subject to safeguards against unauthorised additions, deletions or modifications to donor files or deferral records.

(3) The requirements of this paragraph are as follows:

(*a*) the disclosure is made in accordance with an order of a court or is otherwise required by law,

(*b*) the disclosure is to an authorised officer, or

(*c*) the disclosure is for the purpose of tracing a donation from donor to recipient or recipient to donor.

(4) Where a disclosure is made to an authorised officer pursuant to paragraph (3)(*b*), the authorised officer shall not further disclose the information received unless—

(*a*) the disclosure is made in accordance with an order of a court or is otherwise required by law,

(*b*) the disclosure is to another authorised officer or an officer of the IMB where this is necessary for the proper performance of any function of any such officer, or

(*c*) the information has been rendered anonymous so that the donors are no longer identifiable.

(5) Where a disclosure is made pursuant to paragraph (3), the person to whom the disclosure is made shall not further disclose the information he or she receives other than in accordance with the requirements of that paragraph.

(6) The IMB, the HSE, procurement organisations and transplantation centres shall put in place procedures to ensure that any discrepancies relating to data which are brought to their attention are resolved without delay.

(7) The IMB, the HSE, procurement organisations and transplantation centres shall ensure that the identity of a recipient is not disclosed to the donor or his or her family, or vice versa, without prejudice to legislation which may come into force on the conditions for disclosure.

Part 5

Recording and reporting of activities under regulations

Reporting obligations of HSE

25. (1) The HSE shall—

(*a*) keep a record of the activities of procurement organisations and transplantation centres, including aggregated numbers of living and deceased donors, and the types and quantities of organs procured and transplanted, or otherwise disposed of in accordance with European Union and national provisions on the protection of personal data and statistical confidentiality,

(*b*) draw up and make publicly accessible an annual report on activities referred to in subparagraph (*a*), and

(*c*) establish and maintain an updated record of procurement organisations and transplantation centres.

(2) The HSE shall, upon the request of the Commission or another Member State, provide information on the record of procurement organisations and transplantation centres.

Reporting obligations of IMB

26. (1) The IMB shall keep such records of information which it receives from, or relating to, procurement organisations or transplantation centres as it considers appropriate in accordance with these Regulations and the Directive and shall, in particular, keep records relating to—

(*a*) authorisations under Regulation 6,

(*b*) notifications of serious adverse events and serious adverse reactions by procurement organisations and transplantation centres pursuant to Regulation 19, and

(*c*) inspections or requests for information under Regulation 31.

(2) The IMB shall maintain a publicly accessible register of procurement organisations and transplantation centres, specifying the prescribed activities for which they have been authorised.

Reporting to Commission

27. The IMB and the HSE shall report to the Commission before 27 August 2013 and every three years thereafter on the activities undertaken in relation to the provisions of the Directive, and on the experience gained in implementing it.

Part 6

Organ exchange with third countries and European organ exchange organisations

Organ exchange with third countries

28. (1) The HSE shall supervise organ exchange with third countries and may, for this purpose, conclude agreements with counterparts in third countries.

(2) The supervision of organ exchange with third countries may be delegated by the HSE to European organ exchange organisations.

(3) Organ exchange, as referred to in paragraph (1), shall be allowed only where the organs—

(*a*) can be traced from the donor to the recipient and vice versa, and

(*b*) meet quality and safety requirements equivalent to those laid down in these Regulations and the Directive.

European organ exchange organisations

29. The HSE may conclude agreements with European organ exchange organisations, provided that it is satisfied that such organisations comply with the requirements laid down in these Regulations and the Directive, delegating functions to those organisations, including—

(*a*) the performance of activities provided for under the framework for quality and safety, and

(*b*) specific tasks in relation to the exchange of organs between the State and third countries.

Part 7

Enforcement, offences and penalties

Interpretation of Part 7

30. In this Part—

"inspect" includes search;

"premises" means any place, ship or other vessel, aircraft, railway wagon or other vehicle, and includes a container used to transport relevant things;

"record" includes, in addition to a record in writing—

(*a*) a disc, tape, sound-track or other device in which information, sounds or signals are embodied so as to be capable (with or without the aid of some other instrument) of being reproduced in legible or audible form,

(*b*) a film, tape or other device in which visual images are embodied so as to be capable (with or without the aid of some other instrument) of being reproduced in visual form, and

(*c*) a photograph,

and any reference to a copy of a record includes—

(*d*) in the case of a record to which paragraph (*a*) of this definition applies, a transcript of the sounds or signals embodied therein,

(*e*) in the case of a record to which paragraph (*b*) of this definition applies, a still reproduction of the images embodied therein, and

(*f*) in the case of a record to which paragraphs (*a*) and (*b*) of this definition apply, such a transcript together with such a still reproduction;

"relevant thing" means—

(*a*) an organ, or

(*b*) any article or substance used in the donation, testing, characterisation, procurement, preservation, transport and transplantation of human organs.

Inspections and requests for information

31. (1) The IMB shall conduct a regular inspection of the premises of a procurement organisation or transplantation centre, including any third party facilities used by the organisation or centre, not less than once every 2 years, for the purpose of ensuring that—

(*a*) the procedures and activities carried out by the procurement organisation or transplantation centre and the facilities of any such third party comply with the requirements of the Directive and these Regulations,

(*b*) documents or other records relating to the requirements of the Directive and these Regulations are examined, and

(*c*) problems relating to compliance with those requirements are identified.

(2) The IMB may conduct such additional inspections of the premises of procurement organisations and transplantation centres and the facilities of any third party as it considers necessary for the purpose of ensuring compliance with the requirements of the Directive and these Regulations.

(3) The IMB may serve a notice on a procurement organisation or transplantation centre, or any third party providing facilities to same, requiring that it furnish the IMB with such information concerning its compliance with the

Directive and these Regulations and within such period as shall be specified in the notice.

(4) Any procurement organisation, transplantation centre or third party which receives a request for information in accordance with paragraph (3) shall provide the information requested within the period specified in the notice.

(5) In the event of any serious adverse event or any serious adverse reaction or suspicion thereof, the IMB shall request such information, conduct such inspections, or carry out control measures, in accordance with the Directive and these Regulations, as it shall consider appropriate.

(6) Any reference to an inspection of a site which the IMB is required or empowered to conduct by virtue of this Regulation, shall be construed so as to include an inspection of premises within the State at which any of the prescribed activities are carried out by any person on behalf of, and pursuant to a contractual arrangement with, a procurement organisation or transplantation centre.

(7) For the avoidance of doubt, it is hereby declared that the IMB's functions under this Regulation in relation to a procurement organisation or transplantation centre are also applicable in the case of a procurement organisation or transplantation centre seeking authorisation under Regulation 6.

(8) The IMB, on receipt of a duly justified request from the competent authority in another Member State, shall organise such inspection or other control measures as are reasonably required.

(9) The IMB shall, upon the request of another Member State or the Commission, provide information on the results of inspections and control measures carried out under the Directive and these Regulations.

Authorised officers

32. (1) The IMB—

(*a*) may appoint such and so many persons as the IMB thinks fit to be authorised officers for the purposes of these Regulations, and

(*b*) shall furnish each authorised officer appointed by it with a warrant of the authorised officer's appointment.

(2) An authorised officer (other than an authorised officer who is an officer of Customs and Excise) shall, when performing a function imposed under these Regulations on an authorised officer, produce his or her warrant for inspection if requested to do so by a person affected by the performance of that function.

(3) For the purposes of enforcing compliance with these Regulations, including conducting inspections pursuant to Regulation 31, an authorised officer may—

(*a*) subject to paragraph (5), enter (if necessary by the use of reasonable force), at all reasonable times, any premises which he or she has reasonable grounds to believe that it is necessary to visit, including—

(i) any premises owned or managed by a procurement organisation or a transplantation centre, or at which the procurement organisation or transplantation centre carries out any prescribed activities, or any premises that is connected to the management, procurement, transplantation or any supply, storage, import or export of the relevant thing,

(ii) any premises of any person who carries out any prescribed activity on behalf of, and pursuant to a contractual arrangement, with a procurement organisation or transplantation centre,

(iii) where any facilities for donor evaluation and testing are in the premises of any person or body other than a procurement organisation or transplantation centre, those facilities in that person's premises, and

(iv) any premises at which books, records or other documents (including financial documents and documents stored in non-legible form) relating to any prescribed activity are stored or kept,

(*b*) at such premises inspect, and take copies of, any books, records, other documents (including documents stored in non-legible form) or extracts therefrom, which he or she finds in the course of his or her inspection,

(*c*) remove any such books, records or other documents from such premises and detain them for such period as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,

(*d*) carry out, or have carried out, such tests, examinations, analyses, inspections and checks of—

(i) the premises,

(ii) any relevant thing at the premises, or

(iii) any equipment, machinery or plant at the premises,

as he or she reasonably considers to be necessary for the purposes of his or her functions under these Regulations,

(*e*) require any person at the premises or the owner or person in charge of the premises, and any person employed there, to give to him or her such assistance and information and to produce to him or her such books, records or other documents (and in the case of documents stored in non-legible form, produce to him or her a legible reproduction thereof) that are in that person's power or procurement, as

he or she may reasonably require for the purposes of his or her functions under these Regulations,

(*f*) without payment, take samples of any relevant thing found at the premises for the purposes of any test, examination or analysis,

(*g*) direct that such relevant thing found at the premises as he or she, upon reasonable grounds, believes does not comply with the requirements of these Regulations not be sold or distributed or moved from the premises, without his or her consent,

(*h*) secure for later inspection any premises or part of any premises in which a relevant thing is found or ordinarily kept, or books, records or other documents are found or ordinarily kept, for such period as may reasonably be necessary for the purposes of his or her functions under these Regulations,

(*i*) without payment, take possession of and remove from the premises for any test, examination or analysis any relevant thing found there, and detain it for such period as he or she considers reasonably necessary for the purposes of his or her functions under these Regulations,

(*j*) without payment, take samples of any relevant thing, detained pursuant to subparagraph (i), for the purposes of any test, examination, or analysis, or

(*k*) where the taking of samples of any relevant thing pursuant to subparagraph (*f*) or (*j*) is, for whatever reason, not practicable, without payment take the relevant thing concerned for the purposes of any test, examination or analysis.

(4) When performing a function under these Regulations, an authorised officer may, subject to any warrant issued under paragraph (6), be accompanied by such number of—

(*a*) other authorised officers,

(*b*) members of the Garda Síochána, or

(*c*) persons with expertise relating to any relevant thing,

as he or she considers appropriate in the circumstances of the case.

(5) An authorised officer shall not enter a dwelling, other than—

(*a*) with the consent of the occupier, or

(*b*) in accordance with a warrant issued under paragraph (6).

(6) Upon the application of an authorised officer, a judge of the District Court, if satisfied that there are reasonable grounds for believing that—

(*a*) a relevant thing is to be found in any dwelling, or is being or has been subjected to any process or stored in any dwelling,

(*b*) books, records or other documents (including documents stored in non-legible form) referred to in paragraph (3)(*a*)(iv) are being stored or kept in any dwelling, or

(*c*) a dwelling is occupied in whole or in part by an undertaking carrying out any prescribed activity,

may issue a warrant authorising a named authorised officer, accompanied by such other authorised officers, members of the Garda Síochána, or persons with expertise relating to any relevant thing as may be necessary, at any time or times, within one month of the date of issue of the warrant, to enter the dwelling and perform any of the functions of an authorised officer under paragraph (3)(*b*) to (*k*).

(7) Where an authorised officer, upon reasonable grounds, believes that a person has committed an offence under these Regulations, he or she may require that person to provide him or her with his or her name and the address at which he or she ordinarily resides.

(8) A statement or admission made by a person pursuant to a requirement under paragraph (3)(*e*) shall not be admissible as evidence in proceedings brought against that person for an offence (other than an offence under Regulation 35(2)(*g*)).

(9) Nothing in this Regulation shall be taken to compel the production by any person of a document which he or she would be exempt from producing in proceedings in a court on the ground of legal professional privilege.

Taking of samples, etc. by authorised officers

33. (1) Subject to paragraph (3), where an authorised officer takes a sample of a relevant thing, he or she shall—

(*a*) divide the sample into 3 approximately equal parts,

(*b*) place each part into separate containers, and

(*c*) forthwith seal and mark each such container in such a manner as to identify it as part of the sample taken by that authorised officer.

(2) Where an authorised officer has complied with paragraph (1), he or she shall—

(*a*) offer one of the sealed containers to the owner or person for the time being in charge or possession of the relevant thing from which the sample concerned was taken,

(*b*) retain one of the sealed containers, and

(c) forward, or cause to be forwarded, one of the sealed containers for test, examination or analysis of the sample concerned by a person mentioned in Regulation 34(1)(a),(b) or (c).

(3) Where a relevant thing is contained in a container and its division into parts pursuant to paragraph (1) is, for whatever reason, not practicable, an authorised officer, who wishes to take samples of the relevant thing for the purposes of any test, examination or analysis, shall take possession of 3 such containers belonging to the same batch, and each such container shall be deemed to be part of a sample for the purposes of paragraph (1), and the provisions of paragraphs (1) and (2) shall apply thereto accordingly.

(4) Where an authorised officer takes a relevant thing pursuant to Regulation 32(3)(*k*), he or she shall—

(*a*) place the relevant thing in a container,

(*b*) forthwith seal and mark the container in such a manner as to identify it as a relevant thing taken pursuant to that section, and

(*c*) forward, or cause to be forwarded, the sealed container for test, examination or analysis of the relevant thing by a person mentioned in Regulation 34(1)(*a*), (*b*) or (*c*).

Certificate of result of test, etc. of sample, etc

34. (1) In any proceedings for an offence under these Regulations, a certificate in the form specified in the Schedule to these Regulations signed by—

(*a*) either—

(i) the State Chemist, or

(ii) another chemist employed or engaged at the State Laboratory and authorised by the State Chemist to sign the certificate,

(*b*) either—

(i) a public analyst appointed under section 10 of the Sale of Food and Drugs Acts 1875 to 1936, or

(ii) another analyst authorised by such a public analyst to sign the certificate, or

(*c*) a chemist or analyst appointed by the IMB,

stating the result of any test, examination or analysis of a sample of any relevant thing, or of a relevant thing, as the case may be, forwarded under Regulation 33(2)(*c*) or (4)(*c*) shall, with regard to that sample of the relevant thing, or the relevant thing, as the case may be, be evidence of the matters stated in the certificate unless the contrary is proved.

(2) In proceedings for an offence under these Regulations, a relevant thing, or a package containing a relevant thing, that purports to bear the name of the manufacturer or importer of that thing, or of the person who placed that thing on the market, shall, unless the contrary is proved, be evidence that the relevant thing was manufactured or imported, or placed on the market, as the case may be, by the person so named.

(3) In proceedings for an offence under these Regulations, a relevant thing, or a package containing a relevant thing, that bears a trademark shall, unless the contrary is proved, be evidence that the thing was manufactured by the person who at the time of the alleged commission of the offence owned that trademark.

(4) In this Regulation "trademark" has the same meaning as it has in the Trade Marks Act 1996 (No. 6 of 1996).

Offences

35. (1) A person who contravenes Regulation 5(1), 8(1), 11(1), 14(1), 15(4) or (5), 16(1)(*b*), 17(2), 18, 19(2) or (3), 20, 21(1), (2) or (4), 22, 23(1)(*b*) or 24 is guilty of an offence.

(2) A person—

(*a*) who fails to comply with a notice of suspension or revocation of an authorisation, served pursuant to Regulation 9, except where the operation of that notice has been suspended or has been withdrawn or revoked by the IMB,

(*b*) knowingly supplies an organ which is not labelled in accordance with the requirements of Regulation 16(1)(*b*),

(*c*) discloses any information referred to in Regulation 24(2) to which he or she has access by virtue of these Regulations, otherwise than in accordance with the provision of Regulation 24(3) and (4),

(*d*) obstructs or interferes with an authorised officer, a member of the Garda Síochána or a person with expertise relating to any relevant thing, in the course of performing a function conferred on him or her by these Regulations or a warrant under Regulation 32(6),

(*e*) impedes the performance by the officer, member, or person with expertise, as the case may be, referred to in subparagraph (*d*), of such function or fails or refuses to comply with a request or requirement of, or to answer a question asked by, the officer, member, or person with expertise, as the case may be, pursuant to Regulation 32,

(*f*) in purported compliance with a request or requirement referred to in subparagraph (*e*), or in answer to a question referred to in subparagraph (*e*), gives information to the officer, member, or person with expertise, as the case may be, that he or she knows to be false or misleading in any material respect,

(*g*) falsely represents himself or herself to be an authorised officer,

(*h*) imports into the State an organ from a country or territory outside the European Union which does not meet standards of quality and safety equivalent to those laid down pursuant to Regulation 12,

(*i*) procures or sells, including brokering the procurement or sale, for exchange of money or value an organ contrary to these Regulations and the Directive, or

(*j*) trafficks, harbours, imports or exports an organ contrary to these Regulations and the Directive,

(*k*) who fails to comply with the directions of an authorised officer pursuant to Regulation 32(3)(*g*),

is guilty of an offence.

(3) Where a body corporate, or a person acting on behalf of a body corporate, commits an offence under these Regulations and the offence is committed with the consent, connivance or approval of, or is attributable to any neglect or default on the part of, any director, manager, secretary or any other officer of such body, or a person purporting to act in any such capacity, such person is also guilty of an offence and is liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(4) Where the affairs of a body corporate are managed by its members, paragraph (3) applies as if the reference to a director in that subsection were a reference to a member of the body corporate.

Penalties

36. (1) A person guilty of an offence under these Regulations is liable—

(*a*) on summary conviction to a class C fine or imprisonment for a term not exceeding one year or both, or

(*b*) on conviction on indictment—

(i) in the case of a first offence, to a fine not exceeding €120,000 or imprisonment for a term not exceeding 3 years or both, and

(ii) in the case of any subsequent offence, to a fine not exceeding €300,000 or imprisonment for a term not exceeding 3 years or both.

(2) On conviction for an offence under these Regulations, the court may, in addition to any other penalty—

(*a*) order any relevant thing to which the offence relates to be forfeited to the IMB for destruction or disposal as the IMB thinks fit, and

(*b*) upon application made to it by or on behalf of the IMB, order the person convicted of the offence to pay to the relevant person all or part of the costs of the test, examination or analysis of such relevant thing, or its such destruction or disposal subject to such conditions, if any, as are specified in the order.

(3) In any proceedings for an offence under these Regulations, where no conviction is recorded, the court may, upon application made to it by or on behalf of the IMB, order any relevant thing to which the offence relates to be forfeited to the IMB for destruction or disposal.

Defence of due diligence

37. (1) In any proceedings for an offence under these Regulations, it shall be a defence for the person charged to prove that he or she took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

(2) Where evidence is adduced which is sufficient to raise an issue with respect to a defence under paragraph (1), the court or jury shall assume that the defence is satisfied unless the prosecution proves beyond all reasonable doubt that it is not.

Summary proceedings may be brought by IMB

38. Summary proceedings for an offence under these Regulations may be brought and prosecuted by the IMB.

Regulation 34

Schedule

EUROPEAN UNION (QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION) REGULATIONS 2012

Certificate stating results of test, examination or analysis

This certificate is issued by me, the undersigned, for the purpose of Regulation 34 of the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012, being—

[1] _____ .

I hereby certify that I received, on the ____ day of _____, from

[2] _____ of _____a sample of the relevant thing/the relevant thing*, being [3] _____ for test, examination or analysis; which was undamaged, duly sealed and marked [4] _____.

I further certify that the said sample/relevant thing* has been tested, examined or analysed by me or under my direction and that the results are as follows—

[5]

Signature _____

Date _____

Address _____

_____

_____

1. Here insert official title of person signing the certificate.

2. Here insert the name of the authorised officer who submitted the sample of the relevant thing, or the relevant thing, as the case may be.

3. Here insert the name or description of the relevant thing.

4. Here insert distinguishing mark on the sample of the relevant thing, or the relevant thing, as the case may be, and the date shown on its container as the date of sampling, or the date on which the relevant thing was taken into possession, as the case may be.

5. Here insert the relevant results as appropriate.

* Delete whichever is inapplicable

L.S.

GIVEN under my Official Seal,
27 August 2012.

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 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.

These Regulations may be cited as the European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,
AONAD 20 PÁIRC MIONDÍOLA COIS LOCHA, CLÁR CHLAINNE MHUIRIS,
CONTAE MHAIGH EO,
(Teil: 01 - 6476834 nó 1890 213434; Fax: 094 - 9378964 nó 01 - 6476843)
nó trí aon díoltóir leabhar.

———————

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased directly from the
GOVERNMENT PUBLICATIONS SALE OFFICE
SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2,
or by mail order from
GOVERNMENT PUBLICATIONS, POSTAL TRADE SECTION,
UNIT 20 LAKESIDE RETAIL PARK, CLAREMORRIS, CO. MAYO,
(Tel: 01 - 6476834 or 1890 213434; Fax: 094 - 9378964 or 01 - 6476843)
or through any bookseller.

———————

ISBN 978-1-4064-9864-6

€8.89

9 781406 498646

Wt. (B29393). 285. 8/12. Clondalkin Pharma & Healthcare (Glasnevin) Ltd. Gr 30-15.