EXPLANATORY MEMORANDUM TO

THE QUALITY AND SAFETY OF ORGANS INTENDED FOR TRANSPLANTATION REGULATIONS 2012

2012 No. 1501

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 These Regulations transpose Directive 2010/53/EU on the standards of quality and safety of human organs intended for transplantation. The United Kingdom (UK) is required to be compliant with the Directive from 27 August 2012. The Regulations set out the legal framework for organ procurement and transplantation in the UK, based on the requirements of the Directive. They cover the donation, testing, characterisation, procurement, preservation, transport, transplantation and disposal of an organ intended for transplantation. The ultimate aim is to set minimum standards for the quality and safety of organs intended for transplantation to the human body. The intention of the Regulations is to transpose by imposing minimum burdens on the procurement and transplantation sector whilst continuing to ensure patient safety.

2.2 The Regulations also establish a national competent authority to ensure compliance with European Union quality and safety standards; require the establishment of a traceability system for human organs; a reporting system for serious adverse events and reactions and to facilitate the safe use and exchange of human organs. Data collection on specific organ characteristics will be standardised.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 Implementation under section 2(2) of the European Communities Act 1972 in relation to health protection measures regulating the use of material of human origin.

5. Territorial Extent and Application

5.1 These Regulations extend to all of the United Kingdom apart from Regulation 25 (2),(3),(4) and (7) that extends to England and Wales and Northern Ireland only and Part 7 that extends to Scotland only. Gibraltar will implement the Directive separately. The Directive does not apply to the Channel Islands or the Isle of Man.

6. European Convention on Human Rights

Anne Milton has made the following statement regarding Human Rights:

In my view the provisions of *The Quality And Safety Of Organs Intended for Transplantation Regulations 2012* are compatible with the Convention Rights

7. Policy background

- What is being done and why

7.1 Despite rapid advances in transplantation medicine and increased use of human organs for transplantation, there is a shortage of organs available for transplantation across the European Union (EU). Member States decided in July 2010 to adopt Organ Directive 2010/53/EU to try and improve the quality and safety of organs for transplantation, enhance the efficiency and accessibility of transplantation systems and increase organ availability across the EU. The Directive must be transposed into UK law by 27 August 2012.

7.2 The UK is broadly compliant with the Directive's requirements, but to implement in full and avoid infraction the UK needs to set up a new licensing regime for the authorisation of procurement and transplantation activities. In doing so, a regulatory approach has been chosen that will build on existing arrangements where possible to minimise the costs and burdens involved. We have appointed a single UK-wide competent authority and, in relation to the licensing of procurement activities, have focused on the licensing of approximately 40 organisations undertaking procurement and/or transplant activities, rather than requiring every donating Trust to have a licence. We have also taken the opportunity to strengthen the UK's procedures in relation to the traceability of donors and organs and likewise standardise the reporting of serious adverse events and reactions.

7.3 These Regulations, transposing the Directive, set out a legal framework for organ procurement and transplantation in the UK. The Regulations cover the donation, testing, characterisation, procurement, preservation, transport, transplantation and disposal of an organ intended for transplantation. They primarily impact on NHS Blood and Transplant and some 30 NHS and 10 private hospitals undertaking procurement and transplant activity. The Regulations have taken account of the Secretary of State's duty to have regard to the need to reduce inequalities with respect to the benefits they can receive from the Health Service.

7.4 The Directive requires the appointment of a national competent authority (or authorities) in every Member State to ensure compliance with EU quality and safety standards. In the UK, the Human Tissue Authority has been designated the Competent Authority.

- Consolidation

7.5 As part of its reform programme, the Government has made a commitment to reduce significantly the number of health arms length bodies. *Liberating the NHS: Report of the arm's-length bodies review (2010)* set out proposals for how functions might be carried out in the future, including those currently undertaken by the Human Tissue Authority. These proposals will be subject to consultation shortly. Subject to the outcome of that, we will be in a position to consider consolidation.

8. Consultation outcome

8.1 Consultation on the Regulations was conducted between 26 October and 21 December 2011. A decision was made to go for an 8 week rather 12 week consultation because the transplant community had already been contacted with regard to implementation of the Directive's requirements and because the consultation was broadly directed at a discrete group of interested stakeholders. Furthermore, there was a need to give the Human Tissue Authority as much time as possible to invite, consider and determine applications for a procurement and or transplantation licence.

8.2 In total we sent the consultation document to over 400 people or organisations and had 37 responses to the consultation. A summary of consultation comments can be found at:
http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_134203
In brief, comments received recognised that the UK already has a high quality and safe organ donation programme and that to a large extent we are already implementing the Directive. Therefore, consultation respondents strongly preferred to rely on existing arrangements, or alternatively the introduction of a lighter regulatory regime. They were very concerned about cost burdens – both the licensing fee and the costs of implementation within their organisations and the potential for duplication or overlap with other regulators.

8.3 In view of the consultation comments, and the Secretary of State's duty to promote autonomy in the provision of health services, the regulatory approach within the consultation document was significantly reviewed to make the approach more light-touch and less costly. This was done by developing national operating procedures, (rather than requiring each organisation to develop their own) for example on serious adverse events and reactions reporting; using existing training requirements and building regulations; dispensing with the need for organisations to appoint a designated individual; and looking to work with other regulators to identify core safety and quality standards to avoid duplication. New criminal sanctions were limited to that of undertaking procurement and/or transplantation activities without a licence. We will also increase Human Tissue Authority Grant-in-Aid for 2012/13 to subsidise organ directive licence fees in the first year of implementation.

9. Guidance

9.1 A detailed guidance note for those organisations who will be licensed under these Regulations has been prepared by the Human Tissue Authority and will be available on their website. It will be available to licence applicants, stakeholders and the public. In addition, workshops are being held in May and June to take relevant organisations through the requirements necessary to comply with the Regulations.

10. Impact

An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk

In summary, it is estimated that the overall cost over a 10 year period for the implementation of the Directive in the UK will be £13.680 million. This includes an estimated set-up cost of £200k and an annual ongoing cost to the private sector of £354k.

11. Regulating small business

11.1 The legislation does apply to small business but no organisations undertaking procurement or transplant activity come within the small business category.

12. Monitoring & review

12.1 The UK's implementing Regulations will be reviewed in five years in August 2017. The review objective will be to ascertain whether in implementing the Directive's requirements we have been successful in minimising the costs and burdens involved in setting up a new licensing regime for the authorisation of organ procurement and transplantation activities. We will also examine whether the implementation of the Directive has been an incentive to organ donation and transplantation and whether the UK's procedures for traceability and the reporting of severe adverse events and reactions have improved over the 5-year period.

13. Contact

Triona Norman**,** Head of Policy, Organ and Tissue Transplantation at the Department of Health, telephone 020 7972 4921 or email triona.norman@dh.gsi.gov.uk can answer any queries regarding the instrument.

Transposition Note: The Quality and Safety of Organs Intended for Transplantation Regulations 2012

The Organ Directive

This Transposition Note, in tabular form, explains how the Quality and Safety of Organs Intended for Transplantation Regulations 2012 transpose Directive 2010/53/EC of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (the 'Organ Directive').

The Directive sets quality and safety standards for transplantation, which cover the process from procurement to transplantation. It requires the appointment of a competent authority, which must carry out the tasks set out in the Directive. It also requires the authorisation of procurement organisations and transplantation centres (which are defined in Article 3).

Member States are required to ensure various quality and safety standards, and carry out specified actions to ensure the standards are met. Although obligations are placed on Member States, the Directive specifically requires the competent authority to ensure certain requirements or to carry out certain actions. For example, Article 4 provides that Member States shall ensure the establishment of a Framework, but Article 17(2)(a) makes clear that this is the competent authority's duty.

Further, the Directive requires Member States to ensure that procurement and transplantation takes place in procurement organisations and transplantation centres that meet the requirements of the Directive (see article 5(1) and 9(1)). This means that many requirements, even when they are imposed on a Member State, are actually best implemented by the creation of a licensing regime. This is because the Directive requires penalties, and the most appropriate penalties are licensing sanctions e.g. suspension, withdrawal, etc of a licence. This is preferable to a sanction in legislation, as there is flexibility for the Authority to liaise with the relevant organisations to help to ensure compliance.

UK implementing regulations

One of the reasons why obligations are placed on Member States is to give Member States maximum flexibility about the type of authorisation / licensing scheme which they implement. This structure means that the Directive cannot simply be copied out in full in the implementing regulations. The structure used in the Directive needs to be revised in the implementing regulations so that the functions of the competent authority and the requirements of the licensing regime are separated. It should be noted, however, that although a copy out of the Directive has not been possible, the actual wording of the obligations, in so far as possible, has remained unchanged.

Proper implementation of the Directive requires clarity and precision. Policy decisions are needed to determine the requirements that apply to procurement organisations and transplantation centres. This is because the Directive defines procurement and transplantation as a process, without clarifying exactly what this process covers. It has been decided that the best approach, for the sake of clarity and identification, would be to define the activities covered in the procurement and transplantation process, and to require organisations that carry out one or more of these activities to be licensed. This will ensure that all appropriate

organisations are licensed and avoid having to licence all hospitals where retrieval takes place. Despite an overlap between procurement and transplantation activities, we have opted to distinguish between procurement activities and transplantation activities to mirror the Directive's split between procurement and transplantation. To not do so might increase the risk of infraction.

Further, there is a need for legal certainty in many obligations being placed on those who will be licensed. To maintain maximum flexibility, the competent authority has been given a power to give directions which specify how unclear obligations should be met.

In so far as it is not appropriate to place obligations on persons who carry out procurement or transplantation activities, the obligations are placed on the competent authority.

Therefore, the implementing regulations do two key things – they create a licensing regime, which imposes obligations on those who carry out procurement and transplantation, and they impose obligations on the competent authority. These Regulations designate the Human Tissue Authority (the HTA) as the UK-wide Competent Authority for the Organ Directive.

The authorisation requirement in the Directive is met by the creation of a licensing regime. An organisation undertaking procurement or transplantation activity will apply to the HTA to be the licence holder and will ensure that arrangements are made within the organisation for the operational management of the licence to ensure that the licence holder complies with the requirements of the Directive. The Directive does not specify what type of authorisation regime is required; it leaves this detail to the Member States to determine.

It should be noted that certain requirements in the Directive are already implemented in the UK and are therefore not covered in these Regulations in order to avoid regulatory duplication. For example, in relation to Article 6.2, standards for operating theatres are already in place in the UK and are therefore not covered under these implementing Regulations. A fuller explanation is provided in the table below for this and other instances where the UK already meets some of the Directive's requirements which are not included in these Regulations.

A description of each article, whether copy out has been used, a justification if necessary, and a description of the regulations is provided in the table below.

ANNEX – TRANSPOSITION TABLE

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

TRANSPOSITION TABLE

Article	**Copy out (yes/ no)**	**If no - justification**	**National Provision**
Article 2 This sets out the scope of the Directive, prescribing that it applies to the donation, testing, characterisation, procurement, preservation, transport and transplantation of organs intended for transplantation: **Scope** 1. This Directive applies to the donation, testing, characterisation, procurement, preservation, transport and transplantation of organs intended for transplantation. 2. Where such organs are used for research purposes, this Directive only applies where they are intended for transplantation into the human body.	N/A	N/A	Does not require express implementation.
Article 3 This defines terms used in the Directive. **Definitions** For the purposes of this Directive, the following definitions apply: (a) 'authorisation' means authorisation, accreditation, designation, licensing or registration, depending on the concepts used and the practices in place in each Member State;	Yes where possible, but no for some definitions a) - No b) –	The following definitions in Article 3 have not been copied out for the following reasons: a) 'authorisation': it is not necessary to define authorisation, because the regulations implement the requirement by creating a licensing regime. The licensing regime is set out in Part 3 of the regulations, and Schedules 1 and 2. b) 'competent authority': it is unnecessary to include this definition in UK regulations; instead we designate the Human Tissue Authority as the 'competent authority' in regulation 4. (e) donation: We have amended donation for transplantation to donation "for the purposes of transplantation" for clarity – the meaning of	<u>Explanation</u> Regulation 3 defines terms that will be used in the Regulations. Most of these mirror article 3, and further definitions of national legislation and the Directive have been included. <u>UK implementing regulations – definitions in Regulation 3</u> a) 'authorisation' – not defined. b) 'competent authority' – not defined.

(b) 'competent authority' means an authority, body, organisation and/or institution responsible for implementing the requirements of this Directive; (c) 'disposal' means the final placement of an organ where it is not used for transplantation; (d) 'donor' means a person who donates one or several organs, whether donation occurs during lifetime or after death; (e) 'donation' means donating organs for transplantation; (f) 'donor characterisation' means the collection of the relevant information on the characteristics of the donor needed to evaluate his/her suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation; (g) '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; (h) '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	No c) – Yes d) – Yes e) – Yes f) – No g) – No h) – Yes i) - No j) – Yes k) – No l) – Yes m) – Yes n) – Yes o) – Yes	donation is unaffected. f) 'donor characterisation: we are required to use gender neutral drafting so we have replaced "his/her" with "the donor's". g) definition of 'European organ exchange organisation' is not required as we do not use a European organ exchange organisation in the UK. h) definition of 'organ' has been copied out. We have also taken this opportunity to ensure that this definition is used consistently across all relevant UK legislation to ensure clarity – see regulation 26(a) and 27. It is important that the same definition of "organ" is used in all relevant legislation: this will assist the HTA and stakeholders in being clear where the requirements of the Directive apply. Any lack of clarity could create confusion for the HTA and stakeholders. Ensuring consistency in definition of an organ would not add any burdens but could help potentially reduce them. i) organ characterisation: we have inserted the words "for transplantation" after suitability so that it is clear that the organ is being evaluated for transplantation. This ensures legal certainty and clarity. k) 'procurement organisation' has not been defined in the regulations because the regulations require procurement activities to be licensed. See the covering letter for an explanation of the licensing regime proposed for the UK. q) transplantation: this is defined as a process; we have inserted the words "which is" before copying "intended to restore certain functions of the human body by transferring an organ from a donor to a recipient" for clarity; the meaning of the definition is not changed. r) 'transplantation centre' is not defined in the regulations because we are licensing transplantation activities. See the covering letter for an explanation about the licensing regime proposed for the UK. s) we have attempted to copy-out the definition of 'traceability' as far as possible. However, as we have required activities to be licensed rather than organisations (see explanation in covering letter and under Article 5 below), it was necessary to amend procurement organisations and transplantation centres to state expressly which activity should be recorded. To ensure traceability, it is essential that the licence holder that retrieves and implants the organ is identified, so this is what the definition provides for. It also provides for the recipient to be identified at the premises the organ is implanted, as this is what the Directive requires. If we did not amend the wording in this way, then all licence holders who carry out procurement and transplantation would need to be recorded, which would be burdensome. This change therefore creates clarity and helps to reduce the burden of collection of traceability data.	c) 'disposal – copied out. d) 'donor' – copied out. e) 'donation' – copied out. f) 'donor characterisation' reads – "donor characterisation" means the collection of relevant information on the characteristics of the donor needed to evaluate *the donor's* suitability for donation, in order to undertake a proper risk assessment and to minimise the risks for the recipient, and optimise organ allocation" g) 'European organ exchange organisation' – not necessary to include. h) 'organ' – copied out except that the definition in the Directive is in two separate sentences which are linked in the domestic provision by "and". i) 'organ characterisation' reads – "organ characterisation" means the collection of the relevant information on the characteristics of the organ needed to evaluate its suitability *for transplantation*, in order to undertake a risk assessment and minimise the risks for the recipient, and optimise organ allocation" j) 'procurement' – reads- "procurement" means a process by which a donated organ becomes available for transplantation". k) 'procurement organisation' – not defined. l) 'preservation' – copied out m) 'recipient' – copied out. n) 'serious adverse event' – copied out except that for the word "patients" used in the Directive the word "patient" is

structure and vascularisation; (i) '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; (j) 'procurement' means a process by which the donated organs become available; (k) '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 competent authority under the regulatory framework in the Member State concerned; (l) '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; (m) 'recipient' means a person who receives a transplant of an organ; (n) 'serious adverse event' means any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or	p) – Yes q) – Yes r) – No s) - No		used in the domestic provision o) 'serious adverse reaction' – copied out. p) 'operating procedures' – copied out. q) 'transplantation' – reads "transplantation" means a process which is intended to restore certain functions of the human body by transferring an organ from a donor to a recipient. r) 'transplantation centre' – not defined. s) 'traceability' reads: "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 licence holder who retrieved the organ from the donor, (b) identify the licence holder who implanted the organ in the recipient, (c) identify the recipient at the premises that the organ is implanted into the recipient, and (d) locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ; <u>Further definitions included in Regulation 3</u> (necessary because the words are used elsewhere in the Regulations): - 'the 2004 Act' means the Human Tissue Act 2004

morbidity; (o) '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 that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;EN L 207/18 Official Journal of the European Union 6.8.2010 (p) '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; (q) 'transplantation' means a process intended to restore certain functions of the human body by transferring an organ from a donor to a recipient; (r) '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 competent authority under the regulatory framework in the Member State concerned; (s) '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: — identify the donor and the procurement organisation, — identify the recipient(s) at the transplantation			- 'the 2006 Regulations' means the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 - 'the 2006 Scotland Act' means the Human Tissue (Scotland) Act 2006 - 'the 2006 Scotland Regulations' means the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 - 'the 2007 Regulations' means the Human Tissue (Quality and Safety for Human Application) Regulations 2007 - 'the Authority' means the Human Tissue Authority established under section 13 of the 2004 Act. - 'the Directive' means Directive 2010/53/EU of the European Parliament and Council of 7th July 2010 on standards of quality and safety of human organs intended for transplantation. - 'consent', in respect of a donor, means - a) in England, Wales and Northern Ireland, appropriate consent as defined in the 2004 Act; or b) in Scotland, the authorisation referred to in Part 1 (transplantation etc.) of the 2006 Scotland Act or, as the case may be, the authorisation or lack of willingness of the donor referred to in the 2006 Scotland Regulations - 'licence holder' means a person who holds a licence under Schedule 1 - 'licensed activity', in relation to a licence, means an activity which the licence authorises under Schedule 1. - 'procurement activity' means any of the following activities, undertaken for the purposes of procurement - (a) donor characterisation, (b) organ characterisation,

centre(s), and — locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ.			(c) preservation of an organ, (d) making arrangements to transport an organ, or (e) retrieval of an organ. - 'transplantation activity' means any of the following activities, undertaken for the purposes of transplantation - (a) organ characterisation, (b) preservation of an organ, (c) making arrangements to transport an organ, or (d) implantation of an organ
Article 4 4(1) – this requires the establishment of a Framework for quality and safety, which covers the entire chain for donation to transplantation, and complies with the Directive requirements. 4(2) – this prescribes what must be included in that Framework. In particular, it makes provision for the implementation of operating procedures for matters prescribed. It also requires operating procedures to specify, inter alia, the responsibilities of procurement organisations, European organ exchange organisations and transplantation centres. 4(3) – this requires the framework for quality and safety to 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 to develop specific training programmes for such personnel. **Framework for quality and safety** 1. Member States	4.1 - No 4.2 - No	Article 4, paragraphs (1) and (2). Paragraph (1) has not been copied out because the obligation is for Member States to ensure the establishment of a Framework. Regulation 13 requires the HTA to establish and keep updated a Framework, which covers all stages of the chain from donation to transplantation or disposal. Paragraph (2) is not copied out because the policy intention is for operating procedures to be set by individual organisations, rather than the Member State or the competent authority. Operating procedures, as defined in article 3(p), require detailed written instructions about how to carry out steps in a specific process and we are of the view that it would not be appropriate for either the regulations or the Authority to prescribe one set of operating procedures for all persons who carry out a transplantation of a procurement activity because this would limit the ability of organisations to work in a manner that they consider appropriate and efficient. This is supported by stakeholders we have consulted. Therefore, persons who apply for licenses are required to establish and maintain their own operating procedures in respect of the matters in Article 4.2. This is dealt with in Schedule 1 to the Regulations – see paragraphs 2(g), 3(b), 6(b) and 8(d). Article 4.3 has not been copied out because this requirement is ensured as part of the licensing regime; it is implemented in the licensing conditions in Schedule 1, paragraph 2(c) and by existing training programmes developed and provided by NHS Blood and Transplant (NHSBT), professional organisations (eg the Royal Colleges) and by transplantation centres themselves. This ensures flexibility because the HTA can amend who is considered suitably qualified or trained and competent in directions.	<u>Explanation</u> Article 4.1 is implemented by regulation 13.1 and 13.2, which requires the Authority to establish and keep updated a Framework for quality and safety. Article 4.2 and 4.3 is implemented by creating licensing conditions, and placing an obligation on the HTA to clarify licensing conditions that are unclear. See in particular Schedule 1, paragraphs 2(g), 3(b), 6(b) and 8(d) – which require licence holders to establish operating procedures for the matters in article 4.2. 4.3 is implemented by Schedule 1, paragraph 2(c) and by existing training programmes developed and provided by NHSBT, professional organisations (eg the Royal Colleges) and by transplantation centres themselves. <u>UK implementing regulations</u> Article 4.1 implemented by regulation 13(1) and 13(2) to read: '13 - (1) The Authority shall establish and keep updated a framework which shall specify how the requirements for the quality and safety of organs for transplantation shall be ensured to secure compliance with the Directive. (2) The Framework shall cover all stages of the chain from donation to transplantation or disposal and shall include information about the – (a) procurement activities

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 this Directive. 2. The framework for quality and safety shall provide for 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, authorisation or absence of any objection, in accordance with the national rules that apply where donation and procurement take place; (c) the verification of the completion of the organ and donor characterisation in accordance with Article 7 and the Annex; (d) the procurement, preservation, packaging and labelling of organs in accordance with Articles 5, 6 and 8; (e) the transportation of organs in accordance with Article 8; (f) ensuring traceability, in accordance with Article 10, guaranteeing compliance with the Union and national provisions on the protection of personal data and confidentiality;	4.3 - No		and transplantation activities that are required to be carried on under the authority of a licence under Schedule 1; (b) licensing application process; (c) requirements that licenses must comply with, including the licensing conditions and any directions that the Authority has given under section 23(1) of, or paragraph 2(4)(c) to (f) of Schedule 3 to, the 2004 Act, as applied by regulation 6; and (d) guidance that the Authority has given under regulation 12.' Article 4.2 implemented by Schedule 1 (licenses for the purposes of regulation 5), as follows: 4.2.a) – implemented by Schedule 1, paragraph 6 to read: 'It shall be a condition of a licence for the transplantation activity of implantation for the licence holder- (a) to ensure that, subject to paragraph 7, the following have been verified before proceeding to implant an organ in a recipient – (i) identification of the donor; (ii) the collection of information prescribed in paragraph 5(b); and (iii) compliance with conditions in paragraph 8 about the preservation and transportation of shipped organs; and (b) to have in place operating procedures demonstrating how the requirements in sub-paragraph (a)(i) and (ii) shall be complied with.' 4.2.b) – implemented by Schedule 1, paragraph 6– see above. 4.2.c) – implemented by Schedule 1, paragraph 6 – see above. 4.2.d) – implemented by Schedule 1, paragraph 3(b) to

(g) the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with Article 11(1); (h) the management of serious adverse events and reactions in accordance with Article 11(2). The operating procedures referred to in points (f), (g) and (h) shall specify, inter alia, the responsibilities of procurement organisations, European organ exchange organisations and transplantation centres. 3. 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 are suitably qualified or trained and competent, and shall develop specific training programmes for such personnel.			read: 'It shall be a condition of a licence for a procurement activity for the licence holder– b) to have in place operating procedures demonstrating how the requirements in sub-paragraph a) shall be complied with' The requirements in Schedule 1, paragraph 2(f) and 3(a) are that the licence condition for a procurement activity must require medical activities to be performed under the advice and guidance of a registered medical practitioner and that procurement material and equipment is managed in accordance with relevant legislation and standards on the sterilisation of medical devices. In respect of transport conditions in article 8, see 4.2.e. 4.2.e – implemented by Schedule 1, paragraph 8(d) to read: 'It shall be a condition of a licence for a procurement activity or a transplantation activity of making arrangements to transport an organ – (d) to have in place operating procedures demonstrating how the requirements in sub-paragraphs (a) to (c) shall be complied with' The requirements in Schedule 1, paragraph 8(a) to (c) implement the requirements in Article 8 (transport of organs). Though not a copy-out of the requirements of Article 8 (reasons given under Article 8 below), Schedule 1, paragraph 8(a) to (c) implement Article 8 requirements. 4.2.f – implemented in part by Schedule 1, paragraph 2(d) , (e) and (g) to read: 'It shall be a condition of a licence for a procurement activity or a transplantation activity for the licence holder – (d) to ensure that the data required to ensure the traceability of organs is kept for 30 years from the date of the retrieval of the

			organ; (e) to keep information on organ and donor characterisation for a period specified by the Authority in directions given under regulation 11; (g) to have in place operating procedures demonstrating how the requirements in sub-paragraphs (b) and (d) to (f) shall be complied with.' The remainder relating to the protection of personal information and data implemented by the Data Protection Acts 1998 and 2003. 4.2.g – implemented by Schedule 1, paragraph 2(b) and (g) to read as above. Paragraph 2(b) reads as follow: 'b) to rapidly report to the Authority– (i) 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; and (ii)the management measures taken with regard to such a serious adverse event or reaction' 4.2.h – implemented by Schedule 1, paragraph 2(a) to read: 'It shall be a condition of a licence for a procurement activity or a transplantation activity for the licence holder– (a) to have in place operating procedures for the management of a serious adverse event or a serious adverse reaction' 4.2 (last paragraph) – implemented by Schedule 1 as a whole. 4.3 – implemented by Schedule 1, paragraph 2(c) to read: 'It shall be a condition of a licence

			for a procurement activity or a transplantation activity for the licence holder – (c) to ensure that the healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are - i) competent, ii) suitably qualified or trained, and iii) provided with the training necessary to perform their tasks. 4.3 is also implemented by existing training programmes developed and provided by NHS Blood and Transplant (NHSBT), professional organisations (eg the Royal Colleges) and by transplantation centres themselves.
Article 5 This requires procurement to be carried out by procurement organisations and to comply with the rules in the Directive. It also requires the UK to provide the Commission information about the authorisation of procurement organisations. **Procurement organisations** 1. Member States shall ensure that the procurement takes place in, or is carried out by, procurement organisations that comply with the rules laid down in this Directive. 2. Member States shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of procurement	5.1 - No 5.2 - No	It is not appropriate to copy out this article because the Directive leaves the manner of implementation to the Member State. We have implanted in the way described below. The Authority is required, in Part 3 of the regulations, to authorise organisations and natural persons who carry out a procurement activity (it should be noted that the Regulations use the term "person", which covers both natural persons and organisations). The licensing conditions in Schedule 1 ensure that these organisations will carry out procurement in a way that is consistent with the Directive. Instead of defining a 'procurement organisation' (see article 3(k)) or a 'transplant centre (see article (3(r)), we have decided to prescribe the activities involved in the process of 'procurement' (see article 3(j)) and the process of 'transplantation' (see article 3(q)), which we have defined in regulation 3. This is because this approach will help to limit the regulatory burden. Requiring activities to be licensed means that all hospitals where organs are procured will not need to be licensed; only those organisations that directly carry out the procurement or transplant activities will need to be licensed – in effect NHS Blood and Transplant and some 30 NHS Trusts and 10 private hospitals. In relation to the licensing of procurement activities, we intend to license NHSBT and the organ retrieval teams operating out of a transplant centre. By taking this approach, we aim to avoid requiring every donating Trust to have a procurement licence as this would have imposed onerous costs and burdens and would have been a considerable disincentive to donation. Regulation 5 requires procurement activities and transplantation activities to be carried out under the	<u>Explanation</u> Part 3 of the Regulations create a licensing regime, which ensures that those who carry out any activities within the procurement process, are licensed and meet the requirements of the Directive. Article 5.1 is implemented by regulation 5 which requires procurement activities and transplantation activities to be carried out under a licence granted under Schedule 1. Article 5.2 is implemented by regulation 20 which requires the Competent Authority to provide information. <u>UK implementing regulations</u> Article 5.1 is implemented by regulation 5 to read: '5 – (1) No person shall carry out a procurement activity or a transplantation activity otherwise than under the authority of a licence under Schedule 1 (2) The authority conferred by a licence extends to the licence holder, any person designated by the licence holder and any person acting under the

organisations.		authority of a licence granted under Schedule 1 of the draft regulations. Regulation 8 makes it an offence to carry out a procurement activity or a transplantation activity without a licence from the Competent Authority, which is required to meet article 23, which requires effective, proportionate and dissuasive penalties. Schedule 1 sets out the conditions that licence holders must comply with to obtain either a licence for a procurement or a transplantation activity. It should be noted that the licensing regime is based on the one established in the Human Tissue Act 2004, and followed when implementing Directive 2004/23/EC on tissues and cells. This licensing regime is well understood in the field, and would allow the HTA to take advantage of synergies by having similar licensing systems for organs and tissues and cells. Article 5.2. This imposes an obligation on the Member States to provide information to the Commission. This does not require implementation in legislation, but to ensure that the UK has the necessary information, regulation 20 places an obligation on the Authority to provide information to the SofS if requested to do so. With the advent of the Organ Directive, a greater proportion of HTA's work will involve Scotland. Scottish Ministers have therefore requested that they be given a similar power to enable them to hold the HTA to account by requesting information should they feel this to be necessary.	supervision of either of them. (3) The Authority shall specify in the licence which procurement activity or transplantation activity a person may undertake under the licence. (4) The Authority shall permit a person making an application for two or more- (a) procurement activities, (b) transplantation activities, or (c) procurement activities and transplantation activities, to make a single application in respect of the activities.' Article 5.2 is implemented by regulation 20 to read: '20 – (1) The Secretary of State may serve a notice upon the Authority requiring it to provide within a specified period any information which the notice specifies about the carrying out of its functions under these Regulations in relation to England and Wales and Northern Ireland. (2) The Scottish Ministers may serve a notice upon the Authority requiring it to provide within a specified period any information which the notice specifies about the carrying out of its functions under these Regulations in relation to Scotland. (3) The Authority shall, upon receipt of a notice under paragraphs (1) or (2), provide the information requested within the period specified in the notice.'
Article 6 This sets out requirements for procurement organisations, which include requirements about medical activities, operating theatres and procurement material and equipment. **Organ procurement** 1. Member States	6.1 – No	The Directive leaves it to Member State to determine how to ensure that the requirements in this Article are met. Given that Article 5 requires procurement organisations to meet the requirements of the Directive, it has been decided that this is best done by making these requirements part of the licensing regime. The requirements for procurement organisations in article 6 are therefore implemented by creating licensing conditions in Schedule 1. This means that the Directive wording is restructured where necessary, but obligations have not been changed. Article 6.1 – the same obligation is created in Schedule 1, paragraph 2(f). We have clarified the definition of a doctor of medicine to mean a	<u>Explanation</u> The requirements are imposed as licensing conditions on those who will carry out the relevant procurement activity – see Schedule 1, paragraphs 2(f) and 3(b). Obligations are placed on the HTA to clarify the conditions in Schedule 2, paragraphs 1(d), (e). <u>UK implementing regulations</u> Article 6.1 is implemented by Schedule 1, paragraph 2(f) to

shall ensure that medical activities in procurement organisations, such as donor selection and evaluation, are performed under the advice and the 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 on the recognition of professional qualifications (1).EN 6.8.2010 Official Journal of the European Union L 207/19 (1) OJ L 255, 30.9.2005, p. 22. 2. Member States 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. 3. Member States shall ensure that procurement material and equipment are managed in accordance with relevant Union, international and national legislation, standards and guidelines on the sterilisation of medical devices.	6.2 – No 6.3 - No	"registered medical practitioner". This is a defined terms in the Interpretation Act 1978, and ensures legal certainty and clarity for licence holders. The HTA has a duty, under Schedule 2, paragraph 1(d) to specify which medical activities, or types of activities, this requirement applies to. This is required to ensure legal certainty and clear and precise implementation. Further, it will be helpful to licence holders because they will know exactly what they need to do to comply with the licence requirements. It is not necessary to include the wording "such as donor selection and evaluation" because the HTA can determine what activities this applies to. Article 6.2 –standards for operating theatres are already in place in the UK. For example, in England, hospitals must adhere to theatre operating standards laid down by NHS Estates, an Executive Agency of the Department of Health – eg Health Building Note (HBN) 26 volume 1 sets standards for facilities for surgical procedures. These standards are regulated by the Care Quality Commission (CQC) in England. Some of these standards, eg HBN 26 vol 1 mentioned above, also apply to Wales and Northern Ireland who also have additional standards of their own and their own separate healthcare regulators (eg the Regulation and Quality Improvement Agency in Northern Ireland and Healthcare Inspectorate Wales). Scotland has its own separate healthcare regulatory arrangements. Article 6.3 – the same obligation is created in Schedule 1, paragraph 3(a), and an obligation is placed on the HTA in Schedule 2, paragraph 1(e) to specify the relevant legislation. This will be helpful to licence holders so they know exactly what the relevant legislation is. This licensing regime ensures legal certainty and clear and precise implementation whilst maintaining flexibility because the HTA can change directions given under Schedule 2 as necessary to reflect changes and the manner in which activities are carried out.	read: '2. It shall be a condition of a licence for a procurement activity or a transplantation activity for the licence holder – (f) to ensure that medical activities are performed under the advice and guidance of a registered medical practitioner;' To ensure legal clarity and certainty for licence holders, the HTA must under Schedule 2, paragraph 1(d): 'For the purposes of ensuring consistent compliance with the licensing conditions prescribed in Schedule 1, the Authority shall give directions under section 23(1) (conduct of licensed activities) of the 2004, as applied by regulation 6, Act specifying – d) the medical activities, or the types of medical activities, that must be performed under the advice and guidance of a registered medical practitioner;' Article 6.2 is already implemented by existing standards for operating theatres in the UK (see previous column). Article 6.3 is implemented by Schedule 1, paragraph 3(a) to read: '3. It shall be a condition of a licence for a procurement activity for the licence holder – (a) to ensure that procurement material and equipment which could affect quality and safety of an organ are managed in accordance with relevant European Union, international and national legislation, standards and guidelines on the sterilisation of medical devices;' To ensure legal clarity and certainty for licence holders, the HTA must under Schedule 2, paragraph 1(e):

			'For the purposes of ensuring consistent compliance with the licensing conditions prescribed in Schedule 1, the Authority shall give directions under section 23(1) (conduct of licensed activities) of the 2004 Act, as applied by regulation 6, specifying – e) the European Union, international and national legislation and standards on the sterilisation of medical devices which shall be complied with (and the guidelines on the sterilisation of medical devices which shall be taken into account) in respect of procurement material and equipment which could affect the quality and safety of an organ, or the health of the donor or recipient.'
Article 7 7.1 – This requires organs and donors to be characterised. The information to be collected is set out in the Annex to the Directive. The information in part A of the Annex is mandatory, it must be collected. In respect of the information in part B, it is up to the medical team to determine whether to collect it, taking into account the availability of information and circumstances of the case. 7.2 – Where all the information in part A cannot be collected, article 7.2 creates an obligation to carry out a risk-benefit assessment to determine whether the organ should be used for transplantation. 7.3 – this creates obligations about the information that must	7.1 – No	It should be noted that the Commission is given a power in article 24 of the Directive to amend the Annex to the Directive. Part A of the Annex to the Directive can only be amended in exceptional situations where it is justified by a serious risk to human health considered on the basis of scientific progress. The Commission has said that it has no intention of amending part A now. The Commission can amend part B of the Annex to the Directive 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. The Commission has indicated that they do not intend to make any amendments to part B of the Annex to the Directive prior to the Directive's transposition deadline of 27 August 2012. It is possible however that the Commission may amend part B of the Annex at some time in the future and the regulations therefore refer to part B of the annex at the time when an organ is sent to another country (see regulation 18(1)(b) and paragraph 5(b)(ii) of Schedule 1 to the regulations). Article 7 cannot be copied out because the Member State needs to determine how to ensure the requirements in this Article are met. Given that Articles 5 and 9 require procurement organisations and transplantation centres to meet the requirements of the Directive, it has been decided that this is best done by making most of these requirements part of the licensing regime. With the exception of paragraphs (3) and (6) of this article, these requirements are implemented as licensing conditions or by directions from the Competent Authority which are mandatory. They apply to the procurement or transplantation activity of organ and	<u>Explanation</u> Requirements in Article 7(1), (2) are implemented as licensing conditions in Schedule 1, paragraphs 5 and 7. They are about the characterisation of organs and donors. Requirements in Article 7(4) and (5) are implemented in paragraph 2 of Schedule 2. Requirements in article 7(3) are implemented in respect of deceased donors in the licensing conditions in Schedule 1, paragraph 5(a), and in respect of live donors in regulation 26(b), which makes amendments to the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006. Requirements in article 7(6) are implemented by regulation 18(1)(a) and (b), which sets out the requirements that the Authority must ensure when an organ is being sent to another country. <u>UK implementing regulations</u> Article 7.1 is implemented by Schedule 1, paragraph 5(b) to read:

be collected from donors. 7.4 – this requires tests for organ and donor characterisation to be carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment. 7.5 – this requires all those involved in organ and donor characterisation to have operating procedures (which are defined in article 3(p)) to ensure the information collected reaches the transplantation centre in due time. 7.6 – this imposes obligations in respect of organ and donor characterisation when organs are exchanged between Member States. **Organ and donor characterisation** 1. 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. The 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 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	7.2 – No 7.3 – No 7.4 – No 7.5 – No 7.6 - No	donor characterisation. See below for further details. Article 7(1): this is implemented by Schedule 1, paragraph 5(b). A medical team is not a defined term in English law, and therefore, this has been amended to a registered medical practitioner or a person acting under their supervision. This gives maximum flexibility to licence holders, whilst also giving them certainty, and means we are meeting the requirement for clear and precise implementation. We refer to the Annex of the Directive, instead of copying it out, but this achieves the same result. As explained above, when we refer to part B of the Annex, we have included the words "as amended by amendments that have been adopted and have come into force" because the Commission has the power to amend part B, and intends to use that power. This is preferable to copying out part B and then laying new regulations every time part B is amended. Article 7(2): this is implemented by paragraph 7 of Schedule 1 to the Regulations. The wording "including in life-threatening emergencies" is not included because we do not wish to limit in any way the types of situations that the organ can be transplanted once a risk-benefit analysis has been conducted. Article 7(4): this is implemented by paragraph 2(a) of Schedule 2 to the Regulations. For the legal certainty, the Authority is required, in paragraph 2(a) of Schedule 2 to specify, in directions, the requirements that apply to the carrying out of donor and organ characterisation by laboratories, the suitable qualification, training and competence of laboratory personnel and the adequacy of laboratory facilities and equipment. Article 7(5): this is implemented by paragraph 2(b) of Schedule 2. "Due time" is used in the Directive but is not leally clear and precise, so the implementing regulations say "a time period that would not compromise the quality and safety of the organ". This is preferable to prescribing exactly what a "due time" is in every case. Article 7(3): To ensure that there are minimal changes to existing practice, article 7(3) is implemented in respect of a live donor in regulation 26(b), in particular the insertion of a new paragraph (b) (the insertion of paragraph (a) implements article 15(2)). Although article 7(3) is restructured to ensure clarity and ease of understanding, the obligations are unchanged. It is sensible for all requirements in respect of live donation to be in the same regulations, which are the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006. In respect of deceased donation, this is implemented by the licensing condition in Schedule 1, paragraph 5(a). The obligations have not been amended. Article 7(6): The HTA will be responsible for ensuring that requirements of the directive, as set out in various articles, are met when an organ is sent to another EU/non-EU country. The main	'5. It shall be a condition of a licence for the procurement activity of donor characterisation, and the procurement or transplantation activity of organ characterisation, for the licence holder to ensure – (b) subject to paragraph 7, that donors and organs are characterised before implantation by – (i) the collection of information specified in part A of the Annex to the Directive, and (ii) where considered appropriate by the registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, the collection of the information specified in part B of the Annex to the Directive, as amended by amendments that have been adopted and have come into force.' Article 7.2 is implemented by Schedule 1, paragraph 7 to read: '7. Where any of the information specified in part A of the Annex to the Directive is not available, it shall be a licensing condition for the transplantation activity of implantation for the licence holder to conduct a risk-benefit analysis to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.' In respect of deceased donors, Article 7.3 is implemented by Schedule 1, paragraph 5(a) to read: '5. It shall be a condition of a licence for the procurement activity of donor characterisation, and the procurement or transplantation activity of organ characterisation for the licence holder to ensure- (a) that where a donor is deceased, a registered medical practitioner, or a person acting

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 considered for transplantation even where not all of the minimum data specified in Part A of the Annex are available. 3. In order to meet the quality and safety requirements laid down in this 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, where possible and appropriate, the medical team shall endeavour to obtain such information from relatives of the deceased donor 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 that information. 4. The tests required for organ and donor characterisation shall be carried out by laboratories with suitably qualified or trained and competent personnel and		amendment is to not use the word "exchange" because that would mean a direct swap. However, the Commission made clear in negotiations that the obligation would apply even in cases when there is not a direct swap. The obligations are set out in regulation 18. Article 7(6) is implemented in regulation 18(1)(a) and (b); the obligation created is the same.	under the supervision of a registered medical practitioner, has endeavoured to obtain information from relatives of the deceased donor or other persons about the donor and has explained to such persons the importance of swift transmission of that information.' In respect of living donors, Article 7.3 is implemented by regulation 26(b) – '26. In the 2006 Regulations – b) in regulation 11 (cases in which restriction on transplants involving a live donor is disapplied), at the end of paragraph 2 insert - ", and where that referral concerns an organ, the referral must state that the registered medical practitioner, or a person acting under the supervision of that registered medical practitioner - a) is satisfied that the donor's health and medical history are suitable for the purposes of donation, and b) has – i) provided the donor with the information the donor requires to understand the consequences of donation; and ii) endeavoured to obtain information from the donor that is relevant to transplantation. Article 7.4 is implemented by Schedule 2, paragraph 2(a) to read: '2. For the purpose of ensuring consistent standards in relation to the procurement activity of donor characterisation and the procurement or transplantation activity of organ characterisation, the Authority shall specify in directions given under section 23(1) of the 2004 Act - (a) the requirements that apply to laboratories carrying out tests for donor

adequate facilities and equipment. 5. Member States 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 Member States, those Member States shall ensure that the information on organ and donor characterisation, as specified 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 pursuant to Article 29.			and organ characterisation, to ensure that those tests are carried out by laboratories with suitably qualified, trained and competent personnel and with adequate facilities and equipment'; Article 7.5 is implemented by Schedule 2, paragraph 2(a) to read: '2. For the purpose of ensuring consistent standards in relation to the procurement activity of donor characterisation and the procurement or transplantation activity of organ characterisation, the Authority shall specify in directions given under section 23(1) of the 2004 Act - (a) the requirements that apply to laboratories carrying out tests for donor and organ characterisation, to ensure that those tests are carried by laboratories with suitably qualified, trained and competent personnel and with adequate facilities and equipment.' Article 7.6 is implemented by regulation 18(1)(a) and (b) to read: '18 – (1) Where an organ is sent to another country in the European Union, the Authority shall ensure that – (a) information on organ and donor characterisation that is specified in Part A of the Annex to the Directive; (b) information that has been collected by a registered medical practitioner or a person acting under their supervision that is required by Part B of the Annex at the time when the organ is sent to another country in the European Union; and (c) information to ensure the traceability of the organ, is transmitted to that country in conformity with procedures established by the Commission under article 29 of the

			Directive.'
Article 8 This sets out transport conditions that must be met when transporting organs. **Transport of organs** 1. Member States 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'; (iv) recommended transport conditions, including instructions for keeping the container at an appropriate temperature and	8.1 – No 8.2 - No	The Directive leaves it to Member State to determine how to ensure that the requirements in this Article are met. Given that Articles 5 and 9 require procurement organisations to meet the requirements of the Directive, it has been decided that this is best done by making these requirements part of the licensing regime. Paragraph 8 of Schedule 1 places requirements on persons who arrange for the transport of organs, and make the requirements in article 8 licensing conditions. It should be noted that NHS Blood and Transplant will be providing clarity in relation to a suitable transport time and recommended transport conditions for transporting organs in their national operating procedures. In respect of article 8(1)(b)(i), we cannot state "the establishment where procurement takes place" because we have licensed procurement activities rather than a procurement organisation (see explanation for this under article 5 and the covering letter). The same applies to the wording "identification of the transplantation centre of destination" in article 8(1)(b)(ii). If the regulations said procurement activities and transplantation activities, this would be too wide. Therefore, instead of requiring the identification of the procurement organisation in article 8(1)(b)(i), the Regulations require the identification of the licensed person who retrieved the organ. Similarly, instead of requiring the identification of the transplantation centre of destination in article 8(1)((b)(ii), the Regulations require the identification of the place where implantation will take place. This does not impose a greater burden; it simply reflects the licensing approach we have taken when creating the licensing regime.	<u>Explanation</u> The requirements in Schedule 1, paragraph 8(a) to (c) implement the requirements in Article 8.1 (transport of organs). Though not a copy-out of the requirements of Article 8.1, Schedule 1 paragraph 8(a) to (c) implement very closely what Article 8 requires. It should be noted that paragraph 8(d) of Schedule 1, which requires licence holders to have operating procedures in place to demonstrate how the requirements of paragraph 8(a) to (c) have been met, implements article 4(2)(e) of the Directive as explained under article 4. Article 8.2 has been implemented by paragraph 9 of Schedule 1. <u>UK implementing regulations:</u> Article 8.1 implemented by Schedule 1, paragraph 8(a) to (c) to read: 'It shall be a condition of a licence for a procurement activity or a transplantation activity of making arrangements to transport an organ are made by the licence holder– (a) to maintain the integrity of the organ is ensured during transport and that the transport time is suitable to ensure the quality and safety of the organ; (b) that, subject to paragraph 9, the shipping containers used for transporting organs are labelled with the following information - (i) identification of the licence holder responsible for retrieved the organ and the place where the retrieval took place, including an address and telephone number for that place, (ii) identification of the place that an organ will be implanted in a recipient, including its address and telephone number, (iii) a statement that the

position; (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. EN L 207/20 Official Journal of the European Union 6.8.2010.			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; (c) to ensure that the organs transported are accompanied by a report on the organ and donor characterisation' Article 8.2 has been implemented by paragraph 9 of Schedule 1 to read: '11. The conditions in paragraph 8(b) do not apply where transportation is carried out in the same establishment.'
Article 9 This requires Member States to ensure that transplantation takes placed in transplantation centres that meet the requirements of the Directive and requires the authorisation of transplantation centres to specify which activities the transplantation centre may undertake. It also requires transplantation centres to verify that organ and donor characterisation and the condition of preservation and transport have been met. Lastly, it requires Member States to provide information to the Commission, if requested, about authorisation. **Transplantation centres** 1. Member States shall ensure that transplantation takes place in, or is carried out by, transplantation centres that comply with the rules laid down	9.1 – No 9.2 – No 9.3 – No 9.4 - No	Article 9, paragraphs (1) and (2): it is not appropriate to copy the Directive; Member States need to create regulations which ensure transplantation centres meet the requirements of the Directive. The approach we have taken is described below. The Authority is required, in Part 3 of the regulations, to authorise organisations and natural persons who carry out a transplantation activity (it should be noted that the Regulations use the term "person", which covers both natural persons and organisations). There is a specific requirement in article 9(2) to specify in the authorisation which activities a transplantation centre may undertake. The regulations do this by requiring transplantation activities to be licensed. The licensing conditions in Schedule 1 ensure that these organisations will carry out procurement in a way that is consistent with the Directive. In so far as legal certainty is required in respect of the requirements in the directive, the Authority is given a duty in Schedule 2 to specify how the requirements shall be complied with. Article 9, paragraph (3): this is implemented in Schedule 1, paragraph 6(a)(ii) and (iii). The exact wording has not been used because Schedule 1 requires organ and donor characterisation and imposes conditions about preservation, and it is clearest (and is in accordance with good drafting techniques) to refer to these licensing conditions when imposing a requirement to verify these. It should be noted that the obligations remain unchanged. Article 9, paragraph (4): This imposes an obligation on the Member States to provide information to the	<u>Explanation</u> Article 9.1 is implemented by regulation 5 as a whole which, with Schedule 1, sets out the licensing regime. Article 9.2 is implemented by regulation 5(3) which requires the HTA to specify which transplantation activity or procurement activity a licence holder may undertake. Article 9.3 is implemented by Schedule 1, paragraph 6(a)(ii) and (iii) Article 9.4 is implemented by regulation 20. <u>UK implementing regulations</u> Article 9.1 implemented by regulation 5 to read: '5 – (1) No person shall carry out a procurement activity or a transplantation activity otherwise than under the authority of a licence under Schedule 1. (2) The authority conferred by a licence extends to the licence holder, any person designated by the licence holder and any person acting under the supervision of either of them. (3) The Authority shall specify in the licence which

in this Directive. 2. The competent authority shall indicate in the authorisation which activities the transplantation centre concerned may undertake. 3. The transplantation centre shall verify before proceeding to transplantation that: (a) the organ and donor characterisation are completed and recorded in accordance with Article 7 and the Annex; (b) the conditions of preservation and transport of shipped organs have been maintained. 4. Member States shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of transplantation centres.		Commission. This does not require implementation in legislation, but to ensure that the UK has the necessary information, regulation 20 places an obligation on the Authority to provide information to the Secretary of State if requested to do so. With the advent of the Organ Directive, a greater proportion of HTA's work will involve Scotland. Scottish Ministers have therefore requested that they be given a similar power to enable them to hold the HTA to account by requesting information should they feel this to be necessary.	procurement activity or transplantation activity a person may undertake under the licence. (4) The Authority shall permit a person making an application for two or more- (a) procurement activities, (b) transplantation activities, or (c) procurement activities and transplantation activities, to make a single application in respect of the activities.' Article 9.2 is implemented by regulation 5(3) – see above. Article 9.3 is implemented by Schedule 1, paragraph 6(a)(ii) and (iii) to read: '6. It shall be a condition of a licence for the transplantation activity of implantation for the licence holder – (a) to ensure that, subject to paragraph 7, the following have been verified before proceeding to implant an organ in a recipient - (ii) the collection of information prescribed in paragraph 5(b); and (iii) compliance with the conditions in paragraph 8 about the preservation and transportation of shipped organs.' Paragraph 7 refers to the requirement to conduct a risk-benefit analysis as a condition to carry out the transplantation activity of implantation. Paragraph 5(b) refers to information collected for organ and donor characterisation, namely information included in part A and, if appropriate, part B of the Annex to the Directive. Paragraph 8 sets out the transport conditions. Article 9.4 is implemented by regulation 20 to read: '20 – (1) The Secretary of State may serve a notice upon the Authority requiring it to provide within a specified period any information which the notice specifies about the carrying out

			of its functions under these Regulations in relation to England and Wales and Northern Ireland. (2) The Scottish Ministers may serve a notice upon the Authority requiring it to provide within a specified period any information which the notice specifies about the carrying out of its functions under these Regulations in relation to Scotland. (3) The Authority shall, upon receipt of a notice under paragraphs (1) or (2), provide the information requested within the period specified in the notice.'
Article 10 This requires Member States to ensure that all organs can be traced and requires Member States to put in place a traceability system. It also requires the competent authority or other bodies involved in the chain from procurement to transplantation to keep data on traceability and organ and donor characterisation, and to retain the data on traceability for 30 years. Lastly, where organs are exchanged, it requires traceability information to be transmitted in accordance with procedures that the Commission develops under powers given in Article 29 (comitology powers). **Traceability** 1. Member States shall ensure that all organs procured, allocated and transplanted on their territory can be traced from the donor to the recipient and vice versa in order to safeguard the health of donors and recipients. 2. Member States shall ensure the implementation of a donor and recipient	10.1 – No 10.2 – No 10.3 – No 10.4 - No	Article 10 cannot be copied out as the duty is placed upon the Member State; it is for Member States to determine how to implement the requirements. Article 10(1), (2) and (3): These create overlapping obligations. For example, the requirement in paragraph (1) to ensure traceability of organs is partly ensured by the obligation in paragraph (2) to have a donor and recipient identification system, and the requirement in paragraph (3) to keep traceability data for 30 years. The implementing regulations overcome this overlap by prescribing clear duties to the HTA and to licence holders. The implementing regulations also ensure that obligations are legally clear and precise. It should be noted that to inform relevant organisations of serious adverse events and reactions, as required by Article 11(3)(a), the competent authority, or licensed organisations themselves, would need to hold traceability data about organs they have carried out activities on. It has been decided that the competent authority should be responsible for putting in place a traceability system and a reporting system for serious adverse events and reactions (SAE/R), in view of the link between the two. Regulation 17 therefore requires the competent authority to ensure a traceability system is established to ensure that the Authority can comply with the serious adverse events and reactions duty. In respect of Article 10(1), Member States need to determine how to ensure traceability. This is achieved in the implementing regulations by requiring licensed organisations to keep traceability information – see Schedule 1, paragraph 2(d). This also ensures compliance with article 10(3)(a) and the requirement to keep the data collected for 30 years complies with article 10(3)(b). Where licensed persons are no longer licensed, but have traceability information, the Authority is required to ensure that the data is kept for 30 years from the date it was	<u>Explanation</u> Article 10.1, 10.2 and 10.3 is implemented by regulation 17 and the licensing conditions in Schedule 1 paragraph 2(d) and (e). Article 10.4 is implemented by regulation 18(1)(b). <u>Uk implementing regulations</u> Article 10.1 and 10.2 implemented by regulation 17 to read: '17 – (1) The Authority shall ensure that a traceability system is established for the purposes of ensuring notification of serious adverse events or reactions in accordance with regulation 16(1)(a). (2) Where any person who is licensed to carry out a procurement activity or a transplantation activity ceases to be licensed, the Authority shall make arrangements to ensure that the data collected by that person under the licensing condition in paragraph 2(d) of Schedule 1 to these Regulations is kept for 30 years from the date of the retrieval of the organ.' Article 10.1 also implemented by Schedule 1, paragraph 2(d) which reads as follows: '2. It shall be a condition of a licence for a procurement activity or a transplantation

identification system that can identify each donation and each of the organs and recipients associated with it. With regard to such a system, Member States shall ensure that confidentiality and data security measures are in place in compliance with Union and national provisions, as referred to in Article 16. 3. Member States shall ensure that: (a) the competent authority or other bodies involved in the chain from donation to transplantation or disposal 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, in accordance with the framework for quality and safety; (b) data required for full traceability is kept for a minimum of 30 years after donation. Such data may be stored in electronic form. 4. Where organs are exchanged between Member States, those Member States shall transmit the necessary information to ensure the traceability of organs, in conformity with the procedures established by the Commission pursuant to Article 29.		collected by regulation 17(2). This is important because the obligation to keep traceability data applies to the Member States and it is important that the Regulations do not leave any gaps in respect of persons who cease to be licensed. Article 10(2) requires a traceability system that ensures compliance with confidentiality and data security provisions.. The Authority is already required to comply with data protection provisions under the Data Protection Act 1998. As explained above, to ensure compliance with Article 10(3)(a) and (b), the organisations that are licensed are required to keep the data for 30 years. Organisations that are licensed are also required to keep information on organ and donor characterisation for a period prescribed by the Authority in paragraph 2(e) of Schedule 1 to the Regulations. Article 10(3)(a) only requires that information on organ and donor characterisation is kept, it does not specify a time period. To ensure legal certainty, we need to specify how long information must be kept for. Allowing the HTA to do this by Directions would permit the requirement to be changed as necessary, and to take into account concerns from organisations that are licensed. NHS Blood and Transplant (NHSBT), the organ donation organisation for the UK, currently operates a traceability system, and likewise a system for the reporting of SAE/R. It should be noted that the traceability and serious adverse events and reactions requirements do not therefore require the UK to set up a new traceability system and SAE/R reporting system, only to amend the systems that we already have in place to ensure compliance with the Directive. The Directive gives us the opportunity to make improvements to our existing systems, which is welcome by the Department. Article 10(4): We have decided to place the obligation in Article 10(4) on the HTA, who will be responsible for ensuring that requirements of the Directive, as set out in various articles, are met when an organ is sent to another EU/non-EU country. The wording is revised to reflect this in regulation 18(1)(c). The other main amendment in implementing regulation 18(1)(b) is that we have not used the word “exchange” because that would mean a direct swap, which might not happen in many cases, although the obligations in the Directive would still apply (the Commission made clear in negotiations that the obligations would apply to any giving or receiving of organs from another Member State).	activity for a licence holder– (d) to ensure that the data required to ensure the traceability of organs is kept for 30 years from the date of the retrieval of the organ’ Article 10.3 (a) and (b) are implemented by regulation 17 and schedule 1, paragraph 2(d) (see above) and (e): 2. It shall be a condition of a licence for a procurement activity or a transplantation activity for the licence holder – (e) to keep information on organ and donor characterisation for a period specified by the Authority in directions given under regulation 11. Article 10.4 is implemented by regulation 18(1)(c) to read: ’18 – (1) Where an organ is sent to another country in the European Union, the Authority shall ensure that – c) information to ensure the traceability of the organ is transmitted to that country in conformity with any procedures established by the Commission under article 29 of the Directive.’
Article 11 This is about the serious adverse events and reactions reporting system. Article 11(1), (2) and (3) – the requirement is for the Member State to ensure that there is a reporting system that		These cannot be copied out because the Member States need to determine how to ensure the requirements are met, and in particular, which obligations to place on persons carrying out procurement and transplantation activities and on the competent authority. Schedule 1, paragraph 2(a) requires organisations who are carrying out any procurement or transplantation activity to have operating procedures for the management of a serious adverse even or	<u>Explanation</u> The structure of Article 11 has required considerable restructuring but the obligations have not been amended. The requirements under article 11.1 have been implemented as follows: • in relation to the

reports, investigates, registers and transmits information prescribed in Article 10(1). There is a requirement to put in place operating procedures for the management of serious adverse events and reactions in Article 10(2). Article 10(3) requires operating procedures for the notification of matters prescribed in paragraph (3)(a) and)b). Article 11(4) is about the serious adverse events and reactions obligations when organs are exchanged, and article 11(5) requires the interconnection between the reporting system required by article 11 and the reporting system required in the Tissues and Cells Directive (Directive 1004/23/EC). **Reporting system and management concerning serious adverse events and reactions** 1. Member States shall ensure that there is a reporting system in place to 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. Member States shall ensure that an operating procedure is in place for the management of serious adverse events	11.1 – No 11.2 – No 11.3 – No 11.4 – No 11.5 - No	reaction, as required by Article 11(2). Schedule 1, paragraph 2(b)(i) requires such organisations to notify to the authority any serious adverse event that may influence the quality and safety of an organ, or any serious adverse reactions observed during or after transplantation, which may be attributed to the testing, characterisation, procurement, preservation and transport of an organ. This meets the requirement in Article 11(1) in respect of reporting, and combined with the requirement in Schedule 1, paragraph 2(g), which requires operating procedures for such a notification, it meets the requirement in Article 11(3)(a) too. Similarly, Schedule 1, paragraph 2(b)(ii), combined with the requirement in Schedule 1, paragraph 2(g) meets the requirements in article 11(3)(b) in respect of operating procedures for the notification of management measures to the competent authority. Regulation 16(1) imposes obligations on the Authority to take action when it is notified of information by licence holders. It requires the Authority to notify other organisations/persons who may be affected, which meets the requirement in article 11(3)(a). The requirement in regulation 16(1)(a) to "rapidly" notify information to persons meets the requirement in article 4(2)(g) to ensure the accurate, rapid and verifiable reporting of serious adverse events and reactions. The Authority is also required to investigate and register that information – which meets the requirements under Article 11(1). It should be noted that although the structure of Article 11 has required amendment, so that different duties can be placed on licence holders and the Authority, the obligations themselves have not been amended. This method of implementation is made necessary by the requirement on Member States to ensure requirements are met, rather than placing obligations on the relevant organisations. Article 11(4): Regulation 18(2) requires the HTA to ensure that requirements of the directive, as set out in various articles, are met when an organ is sent to another EU country. The main amendment is to not use the word "exchange" because that would mean a direct swap, which won't happen in most cases. Article 11(5): It has not been possible to copy out because the obligation is on the Member State to ensure the interconnection of the reporting system, leaving it to the Member State to determine how to meet the requirement. Regulation 16(2) requires the Authority to ensure the interconnection of the reporting systems, as they are also responsible for the system under Directive 2004/23/EC, as implemented by the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The obligation imposed on the Authority has not been amended. It should be noted that the regulations that implement Directive 2004/23/EC are referred to instead of the Directive itself because this is where the notification system for tissues and cells, as required by that Directive, is established –	requirement for Member States to ensure that information received in a SAE/R reporting system is investigated and registered, this has been implemented by regulation 16(1) – in particular regulation 16(1)(b) and (c). • in relation to the requirements to ensure that reporting of SAE/R takes place, this is implemented by Schedule 1, paragraph 2(b)(i) and Schedule 2, paragraph 1(a) Article 11.2 has been implemented by Schedule 1, paragraph 2(a). The requirements under article 11.3 have been implemented as follows: • in relation to the requirements for reporting under article 11.3.a, this has been implemented by Schedule 1, paragraph 2(b)(i) in combination with Schedule 1, paragraph 2(g) which requires operating procedures for such reporting / notification. Regulation 16(1) also implements the requirements under article 11.3.a for action to take place when notification of an SAE/R is received. • in relation to the requirements under article 11.3.b for operating procedures to ensure notification of management measures relating to SAE/R to the competent authority, these requirements are implemented by Schedule 1, paragraph 2(b)(ii) in combination with Schedule 1, paragraph 2(g). Article 11.4 has been implemented by regulation 18(2). Article 11.5 has been implemented by regulation 16(2). <u>UK implementing regulations</u> Article 11.1 implemented by regulation 16(1) to read: '16 – (1) When a licence holder

and reactions as provided for in the framework for quality and safety. 3. In particular, and with regard to paragraphs 1 and 2, Member States shall ensure that operating procedures are in place for the notification, in due time, of: (a) any serious adverse event and reaction to the competent authority and to the concerned procurement organisation or transplantation centre; (b) the management measures with regard to serious adverse events and reactions to the competent authority. 4. Where organs are exchanged between Member States, those Member States shall ensure the reporting of serious adverse events and reactions in conformity with the procedures established by the Commission pursuant to Article 29. 5. Member States shall ensure the interconnection between the reporting system referred to in paragraph 1 of this Article and the notification system established in accordance with Article 11(1) of Directive 2004/23/EC.		and this is easier for persons reading the legislation in the UK to understand.	reports a serious adverse event or a serious adverse reaction to the Authority, or the Authority is otherwise made aware of such an event or reaction, the Authority shall – (a) rapidly notify that information to such persons that the Authority considers may be affected by that information; (b) investigate the matter where the Authority considers that an investigation will promote the quality and safety of organs; and (c) register that information.' Article 11.1 is also implemented by Schedule 1, paragraph 2(b)(i) to read: '2. It shall be a condition of a licence for a procurement activity or transplantation activity for a licence holder – (b) to rapidly report to the Authority- (i) 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' And by Schedule 2, paragraph 1(a) to read- 1. For the purposes of ensuring consistent compliance with the licensing conditions prescribed in Schedule 1, the Authority shall give directions under section 23(1) of the 2004 Act, as applied by regulation 6, specifying— (a) the serious adverse events or serious adverse reactions that must be notified to the Authority, including the time period for such notification;

			Article 11.2 has been implemented by Schedule 1, paragraph 2(a) to read: '2. It shall be a condition of a licence for a procurement activity or a transplantation activity for the licence holder – a) to have in place operating procedures for the management of a serious adverse event or a serious adverse reaction' Article 11.3 is implemented as follows. In relation to article 11.3.a, this is implemented by Schedule 1, paragraph 2(b)(i) (see above) in combination with Schedule 1, paragraph 2(g), which reads: '2. It shall be a condition of a licence for a procurement activity or a transplantation activity – g) to have in place operating procedures demonstrating how the requirements in sub-paragraphs (b) and (d) to (f) shall be complied with.' Regulation 16.1 (see above) also implements the requirements under article 11.3.a for action to take place when notification of an SAE/R is received. In relation to article 11.3.b, this is implemented by Schedule 1, paragraph 2(b)(ii) in combination with Schedule 1, paragraph 2(g) (see above). Schedule 1, paragraph 2(b)(ii) to read: '2. It shall be a condition of a licence for a procurement activity or a transplantation activity for the licence holder – b) to rapidly report to the Authority- (ii) the management measures taken with regard to such a serious adverse event or reaction' Article 11.4 has been implemented by regulation 18(2)

			to read: '18 – (2) Where an organ is sent to, or received from, a country in the European Union, the Authority shall ensure the reporting of serious adverse events and reactions in conformity with any procedures established by the Commission under Article 29 of the Directive.' Article 11.5 has been implemented by regulation 16(2) to read: '16 – (2) In carrying out its duties under paragraph (1), the Authority shall ensure the interconnection with the reporting systems established under regulation 20 (duties of the Authority in relation to serious adverse events and serious adverse reactions) of the 2007 Regulations.'
Article 12 This requires the UK to ensure that all healthcare personnel directly involved in the chain from donation to transplantation are suitably qualified or trained and competent. **Healthcare personnel** Member States 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 referred to in Article 4(3).EN 6.8.2010 Official Journal of the European Union L 207/21	12 - No	This article has not been copied out as the duty is placed upon the Member State, who needs to determine how to ensure the requirements are met. It is implemented by Schedule 1, paragraph 2(c) whose wording mirrors closely the wording in article 12.	Article 12 has been implemented by Schedule 1, paragraph 2(c) to read: '2. It shall be a condition of a licence for a procurement activity or a transplantation activity for the licence holder – c) to ensure that the healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are – i) competent, ii) suitably qualified or trained, and iii) provided with the training necessary to perform their tasks.
Article 13 This requires donation to be voluntary and unpaid, and procurement to be carried out on a non-profit basis. It does not prevent however living		It is for Member States to determine how they ensure that the donations of organs are voluntary and unpaid, so the provisions could not be copied out. Given that we already have section 32 of the Human Tissue Act, which requires organs to be donated voluntarily and prohibits financial gain, including advertising, we do not need to implement this provision in the Regulations. We have, however, amended section 32 to remove the HTA's	<u>Explanation</u> *Implementation in England, Wales and NI* Article 13 is implemented by Section 32 of the 2004 Act. Regulation 25(3) also implements Article 13.1 by

donors from receiving reimbursement for out of pocket expenses such as loss of income related to their donation. **Principles governing organ donation** 1. Member States shall ensure that donations of organs from deceased and living donors are voluntary and unpaid. 2. The principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and loss of income related to the donation. Member States 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. Member States shall prohibit advertising the need for, or availability of, organs where such advertising is with a view to offering or seeking financial gain or comparable advantage. 4. Member States shall ensure that the procurement of organs is carried out on a non-profit basis.	13.1 – No 13.2 - ? 13.3 – N/A 13.4 – N/A	power to appoint a person who could carry out an organ transplantation activity for profit. This is in regulation 25(3). In Scotland, the requirements are implemented by the Human Tissue (Scotland) Act 2006 and the Human Organ and Live Transplants (Scotland) Regulations 2006. Section 20 of the Act makes it an offence to obtain financial gain from the supply of body parts and also prohibits advertisements for such a supply. In addition, the 2006 Regulations require the Scottish Ministers to be satisfied that no reward has been given in cases of transplants between living persons, donation by adults with incapacity and child donors.	making amendments to the 2004 Act. Article 13.2 is implemented by Section 32 of the 2004 Act. Article 13.3 is implemented by Section 32 of the 2004 Act. Article 13.4 is implemented by Section 32 of the 2004 Act. *Implementation in Scotland* This is a devolved matter, but we have powers to implement EU obligations on behalf of Scotland with consent. Article 13 is already implemented by section 20 of the Human Tissue (Scotland) Act 2006 (the 2006 Act) so implementing provisions are not required. <u>UK implementing legislation</u> Article 13 is implemented in England, Wales and Northern Ireland by Section 32 of the 2004 Act, as follows: **32 Prohibition of commercial dealings in human material for transplantation** (1) A person commits an offence if he— (a) gives or receives a reward for the supply of, or for an offer to supply, any controlled material; (b) seeks to find a person willing to supply any controlled material for reward; (c) offers to supply any controlled material for reward; (d) initiates or negotiates any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any controlled material; (e) takes part in the management or control of a body of persons corporate or

			unincorporate whose activities consist of or include the initiation or negotiation of such arrangements. (2) Without prejudice to subsection (1)(b) and (c), a person commits an offence if he causes to be published or distributed, or knowingly publishes or distributes, an advertisement— (a) inviting persons to supply, or offering to supply, any controlled material for reward, or (b) indicating that the advertiser is willing to initiate or negotiate any such arrangement as is mentioned in subsection (1)(d). (3) A person who engages in an activity to which subsection (1) or (2) applies does not commit an offence under that subsection if he is designated by the Authority as a person who may lawfully engage in the activity. (4) A person guilty of an offence under subsection (1) shall be liable— (a) on summary conviction— (i) to imprisonment for a term not exceeding 12 months, or (ii) to a fine not exceeding the statutory maximum, or (iii) to both; (b) on conviction on indictment— (i) to imprisonment for a term not exceeding 3 years, or (ii) to a fine, or

			(iii) to both. (5) A person guilty of an offence under subsection (2) shall be liable on summary conviction— (a) to imprisonment for a term not exceeding 51 weeks, or (b) to a fine not exceeding level 5 on the standard scale, or (c) to both. (6) For the purposes of subsections (1) and (2), payment in money or money's worth to the holder of a licence shall be treated as not being a reward where— (a) it is in consideration for transporting, removing, preparing, preserving or storing controlled material, and (b) its receipt by the holder of the licence is not expressly prohibited by the terms of the licence. (7) References in subsections (1) and (2) to reward, in relation to the supply of any controlled material, do not include payment in money or money's worth for defraying or reimbursing— (a) any expenses incurred in, or in connection with, transporting, removing, preparing, preserving or storing the material, (b) any liability incurred in respect of— (i) expenses incurred by a third party in, or in connection with, any of the activities mentioned in paragraph (a), or

			(ii) a payment in relation to which subsection (6) has effect, or (c) any expenses or loss of earnings incurred by the person from whose body the material comes so far as reasonably and directly attributable to his supplying the material from his body. (8) For the purposes of this section, controlled material is any material which— (a) consists of or includes human cells, (b) is, or is intended to be removed, from a human body, (c) is intended to be used for the purpose of transplantation, and (d) is not of a kind excepted under subsection (9). (9) The following kinds of material are excepted— (a) gametes, (b) embryos, and (c) material which is the subject of property because of an application of human skill. (10) Where the body of a deceased person is intended to be used to provide material which— (a) consists of or includes human cells, and (b) is not of a kind excepted under subsection (9), for use for the purpose of transplantation, the body shall be treated as controlled material for the purposes of this section.

			(11) In this section— "advertisement" includes any form of advertising whether to the public generally, to any section of the public or individually to selected persons; "reward" means any description of financial or other material advantage. In relation to Article 13.1, regulation 25(3) amends the 2004 Act as follows: '25 – (1) The 2004 Act is amended as follows. (3) In section 32 (prohibition of commercial dealings in human material for transplantation), after subsection (3) insert – (3A) The Authority may not designate a person under subsection (3) to engage in any activity relating to an organ (within the meaning given by Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation) for use for the purpose of transplantation.'
Article 14 This requires that organs can only be procured after all national consent requirements have been met **Consent requirements** The procurement of organs shall be carried out only after all requirements relating to consent, authorisation or absence of any objection in force in the Member State concerned have been met.	14 – N/A	Article 14 refers to national consent requirements. National consent requirements already prohibit transplantation when consent requirements have not been met, so no further implementation is necessary. The Human Tissue (Scotland) Act 2006 and the Human Organ and Live Transplants (Scotland) Regulations 2006 set out the requirements in Scotland for authorisation or, in some cases, absence of objection.	<u>Explanation</u> Article 14 already implemented by the Human Tissue Act 2004 Act for England, Wales and Northern Ireland. In Scotland it is implemented by the Human Tissue (Scotland) Act 2006 and the Human Organ and Live Transplants (Scotland) Regulations 2006.
Article 15 This concerns living donation. It requires living donors to be		It is for Member States to determine how they ensure the highest possible protection of living donors. Therefore, Article 15.1 could not be copied out. The protection of living donors is already ensured by the Human Tissue Act 2004 (Persons	<u>Explanation</u> Article 15.1 already implemented into UK law by the 2006 Regulations (for England,

selected on the basis of their health and medical history, a record / register of living donors to be kept, requires the follow-up of living donors and requires a system to identify, report and manage any event potentially relating to the quality and safety of the donated organ, as well as any serious adverse reaction in the living donor that may result from the donation. **Quality and safety aspects of living donation** 1. 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. 2. Member States shall ensure that living donors are selected on the basis of their health and medical history, by suitably qualified or trained and competent professionals. Such assessments may provide for the exclusion of persons whose donation could present unacceptable health risks. 3. Member States shall ensure that a register or record of the living donors is kept, in accordance with Union and national provisions on the protection of the personal data and statistical confidentiality. 4. Member States 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	15.1 – N/A 15.2 – No 15.3 – No 15.4 - No	who Lack Capacity to Consent and Transplants) Regulations 2006 ("the 2006 Regulations) for England, Wales and NI. Copy out is therefore not required in the implementing regulations. In Scotland protection of living donors is ensured by the Human Organ and Live Transplants (Scotland) Regulations 2006. Article 15.2 has also been implemented by regulation 26(b), in particular the insertion of the new (a), which copies out the requirement in Article 15.2, except that suitably qualified or trained and competence professionals are clarified to mean a registered medical practitioner or a person acting under his supervision. This is important to ensure legal clarity and certainty. It offers sufficient flexibility and is in line with the current practice of selecting donors. Similar amendments have been made to the Scottish 2006 Regulations by regulation 29. Copy out Article 15.3 is not possible because the obligation is placed on Member States. We have decided to place this obligation on the HTA in regulation 15(1). Regulation 15(1) requires the HTA to keep a record of living donors for the purposes of ensuring that a living donor is followed up. It would not have been legally clear and precise to state that a "record" should be kept, without indicating what should be included in that record or what the purpose of that record should be, which is why the words "for the purposes of ensuring that the living donor is followed up" are included. Copy out of article 15.4 has not been possible because it places the duty on the Member State, and we need to determine how to ensure the requirements are met. Article 15.4 is implemented by regulation 15(2) and (3) and Schedule 1, paragraph 4(b). The obligations in Article 15.4 are placed on a person licensed for the retrieval of an organ in paragraph 4(b) of Schedule 1. Article 15.4 is copied out, but restructured so that paragraph 4(b) of Schedule 1 requires the follow up of living donors, and requires the identification, reporting to the Authority, and management of a serious adverse event and reaction. Because of the possibility that a person who is licensed to carry out retrieval can stop being licensed for that activity (e.g. because they lose their licence, or stop carrying out that activity), an obligation is placed on the HTA in regulation 15(2) and (3) to carry out the requirements in article 15.4 where licensed persons stop being licensed. This is important because the obligations are placed on Member States and our system must ensure that endeavours are made to follow up all living donors even when a person stops being licensed and is therefore under no obligation to continue to carry out follow-up.	Wales and NI and by the Human Organ and Live Transplants (Scotland) Regulations 2006 in Scotland. Article 15.2 already implemented by the 2006 Regulations and also by regulation 26(b) which amends these Regulations. Article 15.3 is implemented by regulation 15(1) Article 15.4 is implemented by regulation 15(2) and (3) and Schedule 1, paragraph 4(b). <u>UK implementing regulations</u> Article 15.1 already implemented into UK law by the 2006 Regulations (for England, Wales and NI and by the Human Organ and Live Transplants (Scotland) Regulations 2006 in Scotland. Article 15.2 is implemented by regulation 26(b), which amends the 2006 Regulations as follows: '26. In the 2006 Regulations – (b) in regulation 11 (cases in which restriction on transplants involving a live donor is disapplied), at the end of paragraph (2) insert - " and where that referral concerns an organ, the referral must state that the registered medical practitioner, or a person acting under the supervision of that registered medical practitioner – (a) is satisfied that the donor's health and medical history are suitable for the purposes of donation, and…" In Scotland Article 15.2 is implemented by regulation 29, which amends the 2006 Regulations as follows: **29.**—(1) The 2006 Scotland Regulations are amended as follows. (2) In regulation 2 (cases in which restriction on transplants of organs are disapplied), at the end of paragraph (3) insert—

the recipient, as well as any serious adverse reaction in the living donor that may result from the donation.			", and that referral must state that the medical practitioner is satisfied that the donor's health and medical history are suitable for the purposes of donation, and that the medical practitioner, or a member of that practitioner's team, has— (a) provided the donor with the information required to understand the consequences of donation; and (b) endeavoured to obtain information from the donor that is relevant to transplantation.". (3) In regulation 3 (cases in which restriction on transplants of organs are disapplied), at the end of paragraph (5), at the end of sub-paragraph (a) omit "and" and insert— "(ab) stated in that referral that the medical practitioner is satisfied that the donor's health and medical history are suitable for the purposes of donation, and that the medical practitioner, or a member of that practitioner's team, has— (i) provided the donor, or one or more of the individuals referred to in paragraph 6(b),

			with the information required to understand the consequences of donation; and (ii) endeavoured to obtain from the donor, or one or more of the individuals referred to in paragraph 6(b), information that is relevant to transplantation; and" (4) In regulation 5 (cases in which restriction on transplants of organs or tissue are disapplied), in paragraph 7, at the end of sub-paragraph (a) omit "and" and insert after that sub-paragraph — "(ab) stated in that referral that the medical practitioner is satisfied that the donor's health and medical history are suitable for the purposes of donation, and that the medical practitioner, or a member of that practitioner's team, has—

			(i) provided the donor, or the person referred to in paragraph (8)(b) with the information required to understand the consequences of donation; and (ii) endeavoured to obtain from the donor or the person mentioned in paragraph 8(b) information that is relevant to transplantation; and" Article 15.3 implemented by regulation 15(1) to read: '15 – (1) The Authority shall keep a record of living donors for the purposes of ensuring the follow-up of living donors.' Article 15.4 implemented by regulation 15(2) and (3) to read: '15(2) In cases where a person licensed to carry out the procurement activity of retrieving an organ ceases to be licensed by the Authority, the Authority shall make arrangements which – a) ensure that reasonable endeavours are made

			to follow-up all relevant donors for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation; and b) identify and manage any event or reaction identified under sub-paragraph (a).' (3) In paragraph (2), a relevant donor means a living donor from whom the person who has ceased to be licensed retrieved an organ. Article 15.4 is also implemented by Schedule 1, paragraph 4(b) to read: '4. It shall be a condition of a licence for the procurement activity of retrieval of an organ for a licence holder to ensure that – b) endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation; and to identify, report to the Authority, and manage any event or reaction.'
Article 16 This requires compliance with the Data Protection Directive, which is implemented in UK law by the Data Protection Act 1998 **Protection of personal data, confidentiality and security of processing** Member States shall ensure that the fundamental right to protection of personal	16 - No	We have not copied out this article because it places duties on Member States to ensure the protection of personal data. This is already ensured by the Data Protection Act 1998. Part 1 of Schedule 1 of the Data Protection Act 1998 lays down the principles which data controllers must follow. Section 2 of the Data Protection Act 1998 also ensures that the information on the physical or mental health or condition of an individual is given additional protection by being treated as 'sensitive personal data'. In respect of the requirement in Article 16(a) to ensure that unauthorised accessing of data or systems is penalised in accordance with Article 23 of the Directive, this is implemented by the Data Protection Act 1998 which is enforced by the Information Commissioner. Failure to follow his	Article 16 is implemented by the Data Protection Act 1998.

data is 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, and in particular Article 8(3), Articles 16 and 17 and Article 28(2) thereof. Pursuant to Directive 95/46/EC, Member States 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 Directive 95/46/EC. Any unauthorised accessing of data or systems that makes identification of donor or recipients possible shall be penalised in accordance with Article 23 of this Directive; (b) donors and recipients whose data are processed within the scope of this Directive are not identifiable, except as permitted by Article 8(2) and (3) of Directive 95/46/EC, and national provisions implementing that Directive. Any use of systems or data that makes the identification of donors or recipients possible with a view to tracing donors or recipients other than for the purposes permitted by Article 8(2) and (3) of Directive 95/46/EC, including medical purposes, and by national provisions implementing that Directive shall be penalised in accordance with Article 23 of this Directive; (c) the principles relating to data quality, as set out in Article 6 of Directive 95/46/EC, are met.		decisions may be punished by criminal sanctions including unlimited fines on conviction on indictment.	
Article 17			Explanation

Requires the appointment of a Competent Authority and sets out the duties the Competent Authority must undertake. Allows Member States or the Competent Authority to delegate tasks to another body or allow that body to assist the Competent Authority in carrying out its functions. **Designation and tasks of competent authorities** 1. Member States shall designate one or more competent authorities.EN L 207/22 Official Journal of the European Union 6.8.2010 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 the competent authority in carrying out its functions. 2. The competent authority shall, in particular, take the following measures: (a) establish and keep updated a framework for quality and safety in accordance with Article 4; (b) ensure that procurement organisations and transplantations centres are controlled or audited on a regular basis to ascertain compliance with the requirements of this Directive; (c) grant, suspend, or withdraw, as appropriate, the authorisations of procurement organisations or transplantation centres	17.1 – No 17.2 - No	Article 17.1 is implemented by regulation 4. It is not possible to copy out article 17.1 because the Member State needs to determine who to designate as a competent authority. Although the Directive permits competent authorities to delegate functions (see article 17.1), we have not been able to permit the Authority to delegate its functions to another body because this is prohibited by common law. We have, however, permitted other bodies to assist the HTA to carry out its functions; such assistance can include the carrying out of the HTA's functions by another body (see regulation 21 of the Regulations). We have excluded the giving of directions and regulations from this power. This is because the power that we have given the HTA to give directions and regulations is only permitted by the European Communities Act 1972 (which we are relying on to implement the Directive) because we are relying on an existing power that the HTA has to give directions in the Human Tissue Act 2004; we cannot permit the Authority to ask another body to carry out that function. Further, we have not copied the exact wording as we needed to state clearly what assistance the HTA can arrange. We needed to specify what body is suitable under national provisions. To allow maximum flexibility, we have provided that a suitable body under national provisions is "a body that the Authority determines will carry out functions effectively, efficiently and economically". It has not been possible to copy out Article 17.2 because it brings together various obligations elsewhere in the Directive. For example, article 17.2(a) requires the competent authority to establish and keep updated a Framework, which is also required by Article 4. We have not, however, created any additional obligations. Please see below further details. (a) – this is implemented by regulation 13. Please see explanation for Article 4 for more details. (b) The licensing regime is provided for in Part 3 of the regulations. In particular, regulation 13(3) places an obligation on the HTA to audit licensed persons. Under article 4(2)(b), we could choose to place a duty on the HTA to "control" or "audit" procurement organisations and transplantation centres, and have chosen to specify "audit" as we think this would offer maximum flexibility to the HTA to determine how to exercise that duty. Also, we are not licensing procurement organisations and transplantation centres, but activities, and the wording used reflects that. The wording "regular basis" is not used because it is not clear and precise. We did not want to prescribe a period because that may become unduly burdensome for licensed persons and costly. We have therefore given a power to the HTA to determine the intervals. (c) Regulation 6(2)(d) applies Schedule 3 of the Human Tissue Act 2004, which gives the HTA powers to revoke, vary and suspend licenses if the designated individual is not ensuring that the	Article 17.1 is implemented by regulation 4, which appoints the HTA as a competent authority. It is also implemented by regulation 21. The sub-paragraphs in Article 17.2 are implemented as follows: a) regulation 13(1) and (2) b) regulation 13(3) c) Part 3 of the Regulations, in particular regulation 6(2)(d), which applies Schedule 3 of the Human Tissue Act 2004, which gives the HTA powers to vary, suspend and revoke licenses d) regulation 16, 17(1) and paragraph 2(a), (b) and (g) of Schedule 1 e) regulation 12 f) regulation 19 g) regulation 18 h) already implemented by requirements in the Data Protection Act 1998 which is enforced by the Information Commissioner. Failure to follow his decisions may be punished by criminal sanctions including unlimited fines on conviction on indictment. <u>UK implementing regulations</u> Article 17.1 is implemented by regulation 4 to read: '4. The Authority is designated the competent authority for the purposes of the Directive.'. Provisions about the competent authority being able to request assistance from other bodies is implemented in regulation 21: 21 - (1) Subject to paragraph (5), the Authority may make arrangements with a body in the United Kingdom for that body to assist the Authority in relation to any of its functions under these Regulations. (2) Assistance under such arrangements may take the form of the carrying out by the body of the Authority's functions. (3) Before making arrangements under paragraph (1) the Authority must be satisfied that the body it is proposing to make arrangements with is a suitable body, as defined in paragraph

or prohibit procurement organisations or transplantation centres from carrying out their activities where control measures demonstrate that such organisations or centres are not complying with the requirements of this Directive; (d) put in place a reporting system and management procedure for serious adverse events and reactions as provided for in Article 11(1) and (2); (e) 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; (f) participate, whenever possible, in the network of competent authorities referred to in Article 19 and coordinate at national level input to the activities of that network; (g) supervise organ exchange with other Member States and with third countries as provided for in Article 20(1); (h) ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ transplantation activities, in conformity with Union provisions on the protection of personal data, in particular Directive 95/46/EC.		licensing conditions are being met. There is also a power to enter and inspect premises. (d) this is not copied out because article 11 sets out the specific obligations in respect of serious adverse events and reactions, which the regulations implement in regulation 16, 17(1) and paragraph 2(a), (b) and (g) of Schedule 1 to the Regulations. (e) this has been implemented by regulation 12. It is not appropriate to copy out "to healthcare establishments, professionals and other parties involved" because we would need to specify who these persons are to ensure legally precise and clear implementation. The licensing regime applies to persons involved in all stages of the chain from donation to transplantation and it is appropriate for the HTA to give guidance to these persons. Otherwise, the guidance would be given to too many people, or an unclear group of people which could cause confusion and be overly burdensome. Further, we have included an obligation to keep the guidance under review and to revise it when necessary. This is important to ensure that the Guidance continues to be in accordance with established practices, and does not become out of date and burdensome. (f) this is implemented in regulation 19. Article 17(2)(f) requires participation "whenever possible" but this is not clear and precise, so regulation 19 states "whenever reasonably practicable". This does not involve a greater burden on the HTA. (g) requirements about organ exchange with third countries are in article 20, and are implemented by regulation 18. See below an explanation of how article 20 is implemented. Requirements about organ exchange with Member States are throughout the Directive and have been implemented in Article 18. In particular, article 7(6), 10(4) and 11(4). As those provisions have been implemented by placing an obligation on the competent authority, a copy out of this obligation was not necessary (it would be inappropriate and cause confusion to place the same obligation on the HTA in twice). (h) this is not copied out because procurement organisations and transplant centres are already required to comply with the requirements of the Data Protection Act 1998. Following public consultation, in order to reduce costs and burdens on licence holders still further, the Competent Authority (the HTA) will no longer develop training standards for staff working in the donation – transplantation chain: instead, existing training requirements developed by NHSBT will be used. Similarly, the HTA will no longer specify theatre operating standards and building requirements as these standards already exist currently (eg the Care Quality Commission in England already sets theatre operating standards which procurement organisations and transplantation centres already comply with).	(4). (4) A suitable body is a body that the Authority determines will carry out functions effectively, efficiently and economically. (5) Arrangements under paragraph (1) shall not affect the Authority's responsibility for the carrying-out of its functions. (6) The Authority may not make arrangements under paragraph (1) in respect of the giving of a) directions under section 23(1) (conduct of licensed activities) or 24(1) (changes of licence circumstances)of, or paragraph 2(4)(c) to(f) (characteristics of licence) of Schedule 3 to, the 2004 Act, or b) the giving of Regulations under Section 21(5) (procedure on reconsideration) of, or paragraphs 10(5) (procedure in relation to licensing decisions) or 13(1) (applications under Schedule 3 to the 2004 Act) of Schedule 3 to, the 2004 Act, as applied by regulation 6. Article 17.2 is implemented as follows: Article 17.2(a) implemented by regulation 13 (1) and (2) to read: '13 – (1) The Authority shall establish and keep updated a Framework which shall specify how the requirements for the quality and safety of organs for transplantation shall be ensured to secure compliance with the Directive. (2) The Framework shall cover all stages of the chain from donation to transplantation or disposal and shall include information about the – a) procurement activities and transplantation activities that are required to be carried on under the authority of a licence under Schedule 1; b) licensing application process; c) requirements that licence holders must comply with, including

			the licensing conditions and any directions that the Authority has given under section 23(1) (conduct of licensed activities) of, or paragraph 2(4)(c) to (f) (characteristics of licence) of Schedule 3 to, the 2004 Act, as applied by regulation 6; and d) guidance that the Authority has given under regulation 12.' Article 17.2(b) is implemented by regulation 13(3), which reads: '(3) The Authority shall ensure that license holders are audited for the purposes of ensuring compliance with — (a) the licensing conditions in Schedule 1 to these Regulations; and (b) any requirements imposed by directions given under section 23(1) or 24(1) (change of licence circumstances) of, or paragraph 2(4) of Schedule 3 to, the 2004 Act, as applied by regulation 6 at such intervals that the Authority considers will ensure compliance with such licensing conditions and directions.' Article 17.2 (c) is implemented by Part 3 of the Regulations, which creates the licensing regime. In particular, regulation 6(2)(d) applies Schedule 3 of the Human Tissue Act 2004, which gives the HTA a power to revoke, suspend and vary licenses. Article 17.2.d – see explanation for article 11 above. See also regulation 16, which reads 16(1) When a licence holder reports a serious adverse event or a serious adverse reaction to

			the Authority, or the Authority is otherwise made aware of such an event or reaction, the Authority shall— (a) rapidly notify that information to such persons that the Authority considers may be affected by that information; (b) investigate the matter where the Authority considers that an investigation will promote the quality and safety of organs; and (c) register that information. (2) In carrying out its duties under paragraph (1), the Authority shall ensure the interconnection with the reporting systems established under regulation 20 (duties of the Authority in relation to serious adverse events and serious adverse reactions) of the 2007 Regulations. Article 17.2.e is implemented by regulation 12 to read: '12 – (1) The Authority shall publish such guidance to license holders as it considers necessary to ensure compliance with the Directive. (2) The Authority shall keep the guidance published under paragraph (1) under review and prepare revised guidance when it considers necessary to do so. (3) The Authority shall publish the guidance under this regulation in such a way as, in its opinion, is likely to bring it to the attention of licence holders.' Article 17.2(f) is implemented by regulation 19 to read: '19 The Authority shall, whenever reasonably practicable – a) participate in the network of competent authorities established

			by the European Commission; and b) co-ordinate United Kingdom input into the activities of that network.' Article 17.2(g) is implemented by regulation 18 to read: '18 (1) Where an organ is sent to another country in the European Union, the Authority shall ensure that – (a) information on organ and donor characterisation that is specified in Part A of the Annex to the Directive; (b) information that has been collected by a registered medical practitioner or a person acting under their supervision that is required by Part B of the Annex at the time when the organ is sent to another country in the European Union; and (c) information to ensure the traceability of the organ is transmitted to the country that the organ is sent to in conformity with procedures established by the Commission under article 29 of the Directive. (2) Where an organ is sent to, or received from, a country in the European Union, the Authority shall ensure the reporting of serious adverse events and reactions in conformity with any procedures established by the Commission under article 29 of the Directive. (3) The Authority shall ensure that any organs sent to, or received from, countries which are not in the European Union can – (a) be traced from the donor to the recipient; and (b) meet quality and safety standards that are equivalent to those required by these Regulations. (4) For the purposes of paragraph (3), the Authority may conclude agreements with countries that are not in the European Union.'

			Article 17.2(h) is implemented by the Data Protection Act 1998 which is enforced by the Information Commissioner. Failure to follow his decisions may be punished by criminal sanctions including unlimited fines on conviction on indictment.
Article 18 Requires the UK to keep a record of all activities of procurement and transplantation organisations including numbers of living and deceased donors, numbers of organs procured and transplanted or otherwise disposed. It also requires the UK to make publicly accessible a report on these activities. **Records and reports concerning procurement organisations and transplantation centres** 1. Member States shall ensure that the competent authority: (a) keeps 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 Union and national provisions on the protection of personal data and statistical confidentiality; (b) draws up and makes publicly accessible an annual report on activities referred to in point (a); (c) establishes and maintains an updated record of procurement organisations and transplantation centres. 2. Member States shall, upon the request of the	18.1 – No 18.2 - No	It has not been possible to copy out article 18 as it refers to procurement organisations and transplantation centres, whilst the proposed implementing regulations refer to licence holders and procurement activities and transplantation activities. Nevertheless, regulation 14 closely follows the structure and content of Article 18.1 Article 18.2 does not require legislative implementation because the Member State is obliged to provide the information. Therefore this has not been copied out. However, regulation 20 gives the Secretary of State or Scottish Ministers the power to require the HTA to provide information, in this case information on the record of procurement organisations and transplantation centres. This is important to ensure that the Member State has the information needed to send to the Commission or another Member State if requested.	<u>Explanation</u> Article 18.1 is implemented by regulation 14. Article 18.2 is implemented by regulation 20. <u>UK implementing regulations</u> Article 18.1 is implemented by regulation 14 to read: '14 – (1) The Authority shall – (a) keep a record of - (i) the aggregate number of living and deceased donors, and (ii) the types and quantities of organs procured and transplanted, or otherwise disposed of; (b) publish an annual report on the activities referred to in paragraph (a); and (c) establish and keep updated a record of licence holders.' Article 18.2 is implemented by regulation 20 to read: '20 – (1) The Secretary of State may serve a notice upon the Authority requiring it to provide within a specified period any information which the notice specifies about the carrying out of its functions under these Regulations in relation to England and Wales and Northern Ireland. (2) The Scottish Ministers may serve a notice upon the Authority requiring it to provide within a specified period any information which the notice specifies about the carrying out of its functions under these Regulations in relation to Scotland. (3) The Authority shall, upon receipt of a notice under paragraphs (1) or (2), provide the information requested within the period specified in the notice.'

Commission or another Member State, provide information on the record of procurement organisations and transplantation centres.			
Article 19 Requires the Commission to set up a network of competent authorities, in which the UK competent authority must participate **Exchange of information** 1. The Commission shall set up a network of the competent authorities with a view to exchanging information on the experience acquired with regard to the implementation of this Directive. 2. Where appropriate, experts on organ transplantation, representatives from European organ exchange organisations, as well as data protection supervisory authorities and other relevant parties may be associated with this network.	19.1 – No 19.2 - No	It has not been possible to copy out this article because it places a duty on the Commission to set up a network of competent authorities, which does not require implementation in domestic legislation. Regulation 19 places a duty on the HTA to participate in this network, whenever reasonably practicable, to comply with article 17(f).	<u>Explanation</u> Article 19 does not require implementation in domestic legislation. However, it is closely linked with regulation 19, which implements article 17.2(f). <u>UK implementing regulations</u> Article 19 is implemented by regulation 19 to read: '19 The Authority shall, whenever reasonably practicable – a) participate in the network of competent authorities established by the European Commission; and b) co-ordinate United Kingdom input into the activities of that network.'
Article 20 Article 20 requires the UK to ensure that when an organ is exchanged with a country outside the EU, that organ can be traced from the donor to the recipient, and meets quality and safety requirements equivalent to those in the Directive. There are also requirements about organ exchange between EU countries through the Directive. **Organ exchange with third countries** 1. Member States shall ensure that organ exchange with third countries is supervised by the competent authority. For this	20.1 – No 20.2 – N/A 20.3 - No	Article 20.1 has not been copied out because Member States need to determine how to implement it. Regulation 18(3) requires the HTA to supervise organs sent to or received from third countries (ie countries not in the EU). We have not used the term exchange because there will not necessarily be direct swaps, and the Commission has made it clear that the requirements will still apply. Further, we have not included the wording "European organ exchange organisation" as we do not use these in the UK. Article 20.2 is not relevant to the UK because we do not use European organ exchange organisations. We are not able to give the HTA a power to delegate the supervision of exchange of organs with non-EU countries to a European organ exchange organisation because that would be sub-delegation, which is not permitted by common law and by section 2(2) of the European Communities Act 1972 (we have used section the power in the 1972 Act to implement the Directive). Therefore, we have been unable to copy-out article 20.2. Article 20.3 sets the criteria that must be adhered to when organs are exchanged with countries outside	<u>Explanation</u> Article 20.1 and 20.3 implemented by regulation 18(3) Article 20.2 is not implemented as it is not relevant to the UK. <u>UK implementing regulations</u> Article 20.1 and 20.3 implemented by regulation 18(3) to read: '18(3) The Authority shall ensure that any organs sent to, or received from, countries which are not in the European Union can – a) be traced from the donor to the recipient; and b) meet quality and safety standards that are equivalent to those

purpose, the competent authority and European organ exchange organisations may conclude agreements with counterparts in third countries 2. The supervision of organ exchange with third countries may be delegated by the Member States 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; (b) meet quality and safety requirements equivalent to those laid down in this Directive		the EU. These are closely followed in regulation 18(3). However, Article 20.3 refers to the Directive whilst regulation 18(3) refers to the implementing Regulations.	required by these Regulations.'
Article 21 **European organ exchange organisations** Member States may conclude or allow a competent authority to conclude agreements with European organ exchange organisations, provided that such organisations ensure compliance with the requirements laid down in this Directive, delegating to those organisations, inter alia: (a) the performance of activities provided for under the framework for quality and safety; (b) specific tasks in relation to the exchanges of organs to and from Member States and third countries.	21 – N/A	Article 21 is not mandatory. The UK does not have any agreements with European organ exchange organisations. Therefore, this article has not been copied out.	<u>Explanation</u> Article 21 is permissive and is not included in the Regulations because the UK does not have any agreements with European exchange organisations.
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	22.1 – N/A 22.2 – N/A	It is not necessary to implement Article 22.1 into UK implementing regulations. The requirements of this article 22.1 can be met by administrative action. The Department of Health and the HTA will report to the Commission as required by article 22.1 of the Directive Article 22.2 is not relevant as it places a duty on the Commission, not Member States	<u>Explanation</u> Article 22.1 can be met by administrative action. Article 22.2 is not relevant to Member States, including the UK. No implementing regulations are therefore required.

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 This sets out the penalties for infringements of the provisions that implement the Directive. **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.	23 - No	It has not been possible to copy out the requirements of article 23 as Member States need to determine and set out precise penalties, ensuring that they are effective, proportionate and dissuasive. The Regulations create an offence for a failure to be licensed. Regulation 8 sets out the penalties applicable to a person or organisation that carried out a licensable activity without a licence. Regulation 22 provides that an officer of a body corporate, or a partner in Scottish partnership, commits an offence when it is proved that such a body or partnership committed an offence under the Regulations with the consent or connivance of that officer or partner, or it was attributable to neglect on the part of that officer or partner. This follows the approach taken when implementing similar Directives (for example, the Directive regulating tissues and cells). In relation to criminal offences set out in the proposed implementing Regulations, we have made significant changes in response to our public consultation: we have limited the introduction of new criminal sanctions to that of undertaking procurement and/or transplantation activities without a licence and will rely on existing police powers for enforcement. Should a licence holder fail to provide information to the Competent Authority, this will put their licence in jeopardy through regulatory and not criminal sanction. As a result, the search of premises (for which we now rely on the police exercising their powers under the Police and Criminal Evidence Act) is not envisaged as the initial enforcement option. The Ministry of Justice has given Gateway clearance in respect of the one new criminal sanction of operating without a licence. As we do not intend to introduce new powers of entry, the Home Office have confirmed that their Gateway clearance is not required. Other penalties are to be licensing sanctions, for example, suspending, varying, or revoking a licence. The HTA is given these powers in regulation 6(2)(d), which applies the relevant paragraphs of Schedule 3 to the 2004 Act.	Explanation Article 23 is implemented by regulation 8 and 22. Regulation 6 applies relevant provisions on Schedule 3 to the 2004 Act. UK implementing regulations Article 23 is implemented by regulation 8 to read: ‘8 – (1) A person who contravenes regulation 5(1) commits an offence unless that person reasonably believes that – a) the activity being undertaken is not an activity to which regulation 5(1) applies; or b) they are acting under the authority of a licence under Schedule 1. (2) A person guilty of an offence under paragraph (1) shall be liable – a) on summary conviction to a fine not exceeding the statutory maximum; or b) on conviction on indictment - i) to imprisonment for a term not exceeding 2 years, or ii) to a fine, or iii) to both.’ Article 23 is also implemented by regulation 22 to read: **Offences by bodies corporate**

			22 – (1). Where an offence under regulation 8 is committed by a body corporate and is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of— (d) any director, manager, secretary or other similar officer of the body corporate; or (e) any person who was purporting to act in any such capacity, that person (as well as the body corporate) commits the offence and shall be liable to be proceeded against and punished accordingly. (2) Where the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and defaults of a member in connection with that member's functions of management as if that member were a director of the body corporate. (3) Where an offence under this Act is committed by a Scottish partnership and is proved to have been committed with the consent or connivance of a partner, or to be attributable to any neglect on the part of a partner, that partner (as well as the partnership) commits the offence and shall be liable to be proceeded against and punished accordingly. (4) In subsection (3), partner includes a person purporting to act as a partner. Article 23 is also implemented by regulation 6(2)(d), which applies relevant provisions in Schedule 3 to the 2004 Act. We have not copied these implementing regulations here in view of their length.
Article 24 **Adaptation of the**	24 – N/A	Article 24 does not require UK implementing regulations: a power is given to the Commission to amend or supplement part A or part B of the Annex	<u>Explanation</u> No implementing regulations

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.		to the Directive. As explained under article 7, the power to amend part A of the Annex to the Directive is very limited. Therefore, we have implemented Annex A as it stands now. In respect of Part B of the Annex, the Commission has decided not to amend Part B at this time, though this may be amended at some time in the future after the Directive is transposed on 27 August 2012. It should be noted that Part B of the Annex is not mandatory; it is complementary data to be collected based on the decision of the medical team, taking into account the availability of the data and the particular circumstances of the case. The implementing regulations refer to Part B of the Annex as amended by amendments that have been adopted and have come into force. This means that amendments to Part B of the Annex will automatically apply. The HTA will ensure, in its Framework document, that licence holders are aware of the latest version of the Annex. Please refer to the explanation of the implementation for article 7 for more information about how the annex is implemented.	required as article 24 places the duty on the Commission. Part B of the Annex has been referred to as amended in regulation 18(1)(b) and paragraph 5(b)(ii) of Schedule 1 to the Regulations.
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	25 – N/A	Article 25 does not require implementation because it is about how the Commission should exercise the power given to it in article 24.	<u>Explanation</u> Article 25 does not require implementation.

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.EN L 207/24 Official Journal of the European Union 6.8.2010 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.	26 – N/A	Article 26 is does not require implementation because it is about the Commission's exercise of the power given to it in article 24.	<u>Explanation</u> Article 26 does not require implementation.
Article 27 **Objection to delegated**	27 – N/A	Article 27 does not require implementation because it sets out the objection procedure that the European Parliament or the Council may resort to if they are	<u>Explanation</u> Article 27 does not require

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.		not content with a delegated act that has been published by the Commission using its powers under article 24.	implementation.
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.	28 – N/A	Article 28 does not require implementation because it deals with the urgency procedure in relation to delegated acts that the Commission makes using the power in article 24.	<u>Explanation</u> Article 28 does not require implementation.

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 therefore.			
Article 29 Where organs are exchanged between Member States, article 29 gives the Commission powers to make rules for the uniform implementation of the transmission of information on organ and donor characterisation, procedures for the transmission of information on traceability, and procedures for the reporting of serious adverse events and reactions. **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	29 – Cannot copy out	Where organs are exchanged between Member States, article 29 places a duty on the Commission to publish implementing measures in relation to a) organ and donor characterisation, b) traceability and c) SAE/R reporting. As the duty is placed upon the Commission, and the Commission has not yet published the implementing measures, this provision cannot be implemented yet. The Commission have indicated that they do not intend to publish any implementing measures in relation to a) organ and donor characterisation. In relation to b) traceability and c) SAE/R reporting, the Commission has not yet published any implementing measures though it is likely that they will publish these measures (called Comitology Directives) at some point after the transposition deadline of 27 August 2012. We will need to lay separate regulations dealing with this at some point after 27 August 2012. We cannot delay the laying of these Regulations in Parliament because the HTA needs powers to start to invite licence applications to ensure that all relevant organisations are licensed by 27th August 2012. For present purposes only, regulation 18(1) and (2) refers to "procedures established by the Commission under article 29 of the Directive".	<u>Explanation</u> The implementing measures have not yet been published by the Commission. When implementing measures are published, we will need to implement them.

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.	30 – N/A	Article 30 does not require implementation. The Committee referred to will be comprised of experts in organ transplantation. The UK will send its representatives to sit on this Committee.	<u>Explanation</u> Article 30 does not require implementation.
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.EN 6.8.2010 Official Journal of the European Union L 207/25 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	31.1- No 31.2 – N/A 31.3 – N/A	It has not necessary to copy out Article 31 because it creates a general obligation to implement the Directive. In relation to article 31.1, it is proposed that UK implementing Regulations come into force by 27 August 2012, as required by the Directive. Regulation 1(2) makes this clear. The exception to this is regulation 1(3), which provides that the regulations come into force the day after they are made to enable the HTA to invite, consider and grant applications from persons and organisations seeking to carry out procurement activities, transplantation activities, or both by the transposition deadline of 27 August 2012. Article 31.2 does not require UK implementing regulations. It should be noted that these regulations do not require more stringent measures. Article 31.3 does not, of itself, require UK implementing regulations as it can be dealt with by administrative action when the Department of Health sends a copy of the implementing Regulations to the Commission.	<u>Explanation</u> Article 31.1 implemented by regulation 1, and generally by the Regulations as a whole. Article 31.2 and 31.3 do not require UK implementing regulations. <u>UK implementing regulations</u> Article 31.1 implemented by regulation 1 to read: '1 – (1) These Regulations may be cited as the Quality and Safety of Organs Intended for Transplantation Regulations 2012. (2) Except as provided under paragraph (3), these Regulations shall come into force on 27 August 2012. (3) These Regulations shall come into force on 12th of July 2012 so far as necessary to enable anything to be done for the purposes of granting, refusing or reconsidering licence applications, or varying, suspending or revoking licences, in respect of activities required by virtue of these Regulations to be authorised by a licence from 27 August 2012, including but not limited to – a) giving directions under

communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.			Section 23(1) of, or paragraph 2(4) of Schedule 3 to, the 2004 Act; b) publishing guidance under regulation 12; c) establishing the Framework under regulation 13; and d) the fixing of fees.' Article 31.2 and 31.3 do not require UK implementing regulations.
Article 32 **Entry into force** This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Union.	32 – N/A	This Directive entered into force on 26 August 2010 (and must be transposed by Member States into national law by 27 August 2012). Article 32 of itself does not require implementation.	Explanation Article 32 does not require implementation.
Article 33 **Addressees** This Directive is addressed to Member States	33 – N/A	Article 33 does not require implementation.	Explanation Article 33 does not require implementing.
ANNEX – Part A **Organ and Donor Characterisation** **Minimum Data Set**	Annex – Part A YES	Part A of the Annex to the Directive sets out the minimum data set required for organ and donor characterisation. The Commission only has powers to amend it in exceptional circumstances, and therefore, it is unlikely to be changed by the Commission. We have referred to Annex A of the Directive as it stands now in the regulations in regulation 18(1)(a) and in paragraph 5(b)(i) of Schedule 1 to the Regulations (which implement article 7 of the Directive – see explanation above for further details).	Explanation See implementation of article 7 of the Directive.
ANNEX – Part B **Organ and Donor Characterisation** **Complementary Data Set**	Annex – Part B YES	See comments under Article 7.	Explanation See implementation of article 7 above.