EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Directive 2010/53/EC of the European Parliament and of the Council of 7th July 2010 on standards of quality and safety of human organs intended for transplantation ("the Directive"). These Regulations impose quality and safety requirements in relation to the procurement and transplantation of organs intended for transplantation.

With the exception of regulation 25(2), (3), (4) and (7) and regulation 29, these regulations extend to the whole of the United Kingdom. Regulation 25(2), (3), (4) and (7) extends to England and Wales and Northern Ireland only and regulation 29 extends to Scotland only.

Regulation 4 appoints the Human Tissue Authority ("the Authority") as the competent authority for the purposes of the Directive.

Regulation 5 requires procurement activities and transplantation activities to be carried out under the authority of a licence granted under Schedule 1. Procurement activities include donor characterisation, organ characterisation, preservation of an organ, making arrangements to transport an organ, and retrieval of an organ. Transplantation activities include donor characterisation, organ characterisation, preservation of an organ, making arrangements to transport an organ and implantation of an organ. Regulation 8 makes it an offence to carry out a procurement activity or a transplantation activity without a licence and provides for maximum penalties. Schedule 1 provides for the grant of a licence and regulation 6 applies a number of provisions of the Human Tissue Act 2004 ("the 2004 Act") to such licences, including the procedures to be followed in respect of an application for a licence and the variation, suspension or revocation of a licence and powers to impose fees.

Regulation 9 imposes preconditions to the grant of a licence, which includes the Authority being satisfied that the applicant meets the relevant licensing conditions set out in Schedule 1.

Regulation 10 imposes a duty on the licence holder to ensure that only suitable persons participate in carrying on the activities, that suitable practices are used in doing so, and that the conditions of the licence and requirements imposed by directions are complied with. Regulation 11 imposes an obligation on the Authority to give directions in accordance with Schedule 2 to ensure consistent compliance by licence holders with the licensing conditions. Regulation 12 imposes an obligation on the Authority to give guidance to licence holders.

Regulation 13 imposes an obligation on the Authority to establish and maintain a Framework which covers all stages of the chain from donation to transplantation and includes information about licensing. It also imposes an obligation on the Authority to ensure that licence holders are controlled for the purposes of ensuring compliance with the Directive. Regulations 14 to 18 impose further obligations on the Authority, including requirements to keep records and publish reports, make arrangements to endeavour to follow up living donors in particular cases, obligations in respect of serious adverse events and reactions, requirements to establish and maintain a traceability system, keep traceability data in particular cases and obligations in respect of organs sent to another country. Regulation 19 requires the Authority to participate in the EU network of competent authorities, and regulation 20 provides that the Authority must provide information to the Secretary of State or the Scottish Ministers if requested to do so by the Secretary of State or the Scottish Ministers.

Regulation 21 permits the Authority to make arrangements which permit another body to assist the Authority with its functions. Regulation 22 provides that an officer or member of a body corporate, or a partner in Scottish partnership, commits an offence when it is proved that such body or partnership committed an offence under these Regulations with the consent or connivance of that officer or partner, or it was attributable to neglect on the part of that officer, member or partner.

Regulation 23 makes transitional provisions in respect of a procurement activity or a transplantation activity that is commenced before the 27thAugust 2012.
Regulation 24 requires the Secretary of State to review the operation and effect of these Regulations and publish a report within five years after they come fully into force and within every five years after that. Following a review, it will fall to the Secretary of State to consider whether these Regulations should remain as they are, or be revoked or be amended. A further instrument would be needed to revoke these regulations or to amend them.
Regulation 25 makes consequential amendments to the 2004 Act, including an amendment to section 32 of that Act. Section 32 prohibits specified commercial dealings in human material for transplantation, but subsection (3) permits persons to engage in those specified activities if the Authority designates that person lawfully to engage in that activity. Regulation 25 restricts section 32(3) by removing the Authority's power to designate an individual lawfully to carry out those specified activities when they relate to an organ intended to be used for the purposes of transplantation. Regulation 25 also makes an amendment to Schedule 2 to the 2004 Act to permit Scottish Ministers to nominate a member of the Authority to make representations about the carrying out of the Authority's functions in Scotland. Regulation 26 makes amendments to the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 to align the definition of an organ to the definition of an organ in the Directive and these Regulations, and to impose further obligations on a medical practitioner who has referred the matter of removing an organ to the Authority for approval.
Regulation 27 makes an amendment to the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 to align the definition of an organ to the definition of an organ in the Directive and these Regulations, and regulation 28 makes an amendment to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 to extend section 14 of the 2004 Act to Scotland so far as it relates to activities within section 14(1)(h) of the 2004 Act. Regulation 29 makes amendments to the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006.
An Impact Assessment and a Transposition Note have been prepared for these Regulations. Copies of the Impact Assessment and the Transposition Note can be obtained from the Organ and Tissue Transplantation Team, Department of Health, Area 6.21, 6th floor South, Wellington House, 133-135 Waterloo Road, London SE1 8UG and are published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk.

Changes to legislation:
There are currently no known outstanding effects for the The Quality and Safety of Organs Intended for Transplantation Regulations 2012.