

**2006 No. 404 (C. 12)**

**HUMAN TISSUE, ENGLAND AND WALES**

**HUMAN TISSUE, NORTHERN IRELAND**

**The Human Tissue Act 2004 (Commencement No. 4 and  
Transitional Provisions) Order 2006**

*Made* - - - -

19th February 2006

The Secretary of State for Health makes the following Order in exercise of the powers conferred upon her by sections 58(3) and 60(2) of the Human Tissue Act 2004<sup>(a)</sup>. In accordance with sections 58(5) and (6) and 60(3) and (4) of that Act she has consulted the National Assembly for Wales and the relevant Northern Ireland Department before exercising these powers.

**Citation and interpretation**

1.—(1) This Order may be cited as the Human Tissue Act 2004 (Commencement No. 4 and Transitional Provisions) Order 2006.

(2) In this Order—

“the Act” means the Human Tissue Act 2004.

**Appointed Day**

2.—(1) This article is subject to article 4.

(2) Section 16(1) and (2)(e)(ii) of the Act, so far as they apply for the purposes set out in paragraph (4), shall come into force on 1st March 2006 for those purposes.

(3) The provisions of the Act listed in the Schedule to this Order, so far as they apply for the purposes set out in paragraph (4), shall come into force on 1st March 2006 for those purposes.

(4) The purposes mentioned in paragraphs (2) and (3) are—

- (a) to enable the Authority to grant or refuse licences;
- (b) to require that applications for licences are accompanied by such fee as the Authority shall determine in accordance with paragraph 13(2) of Schedule 3 to the Act;
- (c) to enable the Authority to impose conditions on licences;
- (d) to enable the Authority to vary, revoke or suspend licences;
- (e) to enable the Authority to give directions under sections 23 and 24 of the Act and under paragraph 2(4) of Schedule 3 to the Act;
- (f) to require the Authority to give notice of its decisions in accordance with paragraphs 10 and 11 of Schedule 3 to the Act;

- (g) to enable a person to whom notice is given in accordance with paragraph 10 of Schedule 3 to the Act to require the Authority to give him an opportunity to make representations in accordance with that paragraph;
- (h) to enable applicants to require the Authority to reconsider decisions to revoke or vary licences;
- (i) to enable the Authority to reconsider decisions to revoke or vary licences;
- (j) to enable persons aggrieved by a decision on reconsideration to appeal on a point of law to the High Court.

3.—(1) This article is subject to article 4.

(2) Section 16(1) and (2)(e)(ii) (licence requirement) shall come into force, so far as not already in force, on 7th April 2006.

(3) The provisions listed in the Schedule:

- (a) so far as not already in force, and
- (b) so far as relevant to section 16 as brought into force by this Order or to provisions of the Act brought into force by previous Orders<sup>(a)</sup>,

shall come into force on 7th April 2006.

#### **Partial commencement of section 16(1) and (2)(e)(ii)**

4.—(1) Articles 2 and 3 do not bring into force section 16(1) and (2)(e)(ii) to the extent that those provisions require the authority of a licence for:

- (a) storage of relevant material for 48 hours or less,
- (b) storage of relevant material for scheduled purposes other than transplantation,
- (c) storage of relevant material for the purpose of organ transplantation.

(2) In this article—

“organ” means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with an important level of autonomy; and

“organ transplantation” means transplantation of:

- (a) a whole organ to function as such in the recipient, or
- (b) a part of an organ if it is to function for the same purpose as the whole organ in the recipient.

#### **Transitional arrangements: deemed licences**

5.—(1) Where under provisions brought into force by this Order:

- (a) a licence is required for storage of relevant material,
- (b) an application for such a licence is received by the Authority by 31st March 2006, and
- (c) the application is accompanied by the appropriate fee as determined under paragraph 13(2) of Schedule 3 to the Act,

a licence shall be deemed to have been granted in relation to that application.

(2) A licence deemed to have been granted under paragraph (1) shall have effect from 7th April 2006 and shall continue to have effect until either a licence is granted on the application or the application is refused.

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(a) SI 2005/919 Human Tissue Act 2004 (Commencement No.1) 2005 (c.40), SI 2005/2632 Human Tissue Act 2004 (Commencement No. 2) Order 2005 (c.108), SI 2005/2792 Human Tissue Act 2004 (Commencement No. 3 and Transitional Provisions) Order 2005 (c.115)

6.—(1) Subject to paragraphs (2) and (3) the provisions of the Act in force or brought into force by this Order apply to a licence deemed to have been granted under article 5(1) of this Order to the same extent as they would apply to a licence granted under the Act.

(2) Paragraphs 2(2), 4 and 6 of Schedule 3 to the Act shall not apply in relation to a licence deemed to have been granted under article 5(1) of this Order.

(3) For the purpose of licences deemed to have been granted under article 5(1) of this Order references in Schedule 3 to:

- (a) the premises specified in the licence shall mean the premises specified in the application form to which the licence relates;
- (b) the individual designated in the licence shall mean the person specified in the application form to which the licence relates as the proposed designated individual.

Signed by authority of the Secretary of State for Health

*Rosie Winterton*  
Minister of State,  
Department of Health

19th February 2006

## SCHEDULE

Articles 2(3) and 3(3)

**Table 1**

Provisions of the Act coming into force on 1st March 2006 for the purposes of article 2 of this Order and on 7th April 2006 for the purposes of article 3 of this Order

<i>Provision of the Act</i>	<i>Subject matter</i>
Section 17	Persons to whom licence applies
Section 18	Duty of the designated individual
Section 19	Right to reconsideration of licensing decision
Section 20	Appeals committee
Section 21	Procedure on reconsideration
Section 22	Appeal on a point of law
Section 23	Conduct of licensed activities
Section 24	Changes of licence circumstances
Section 25	Breach of licence requirement
Section 37	Directions
Section 39	Criminal justice purposes
Section 41	Interpretation of Part 2
Section 44	Surplus tissue
Section 48	Powers of inspection, entry, search and seizure
Section 49	Offences by bodies corporate
Section 50	Prosecutions
Section 51	Offences: Northern Ireland
Section 52	Orders and regulations
Section 53	Relevant material
Section 54	General interpretation
Section 56	Consequential amendments

Section 58(1) and (2)	Transition
Schedule 3	Licences for the purpose of section 16
Schedule 5	Powers of inspection, entry, search and seizure
Schedule 6, paragraph 5	Criminal Justice and Police Act 2001

## EXPLANATORY NOTE

*(This note is not part of the Order)*

This Order provides for the coming into force of provisions of the Human Tissue Act 2004 c.30 (“the Act”).

Article 2 provides for the coming into force on 1st March 2006 of section 16(1) and (2)(e)(ii) and the provisions listed in the Schedule to the extent necessary to enable the Human Tissue Authority (“the Authority”) to deal with applications for licences which will be required under section 16(1) and (2)(e)(ii) of the Act from 7th April 2006.

Article 3 provides for the coming into force on 7th April 2006 of section 16(1) and (2)(e)(ii). Under these provisions a licence is required for the storage of human tissue for the purposes specified in Schedule 1 to the Act.

Article 3 also provides for the coming into force on that date of the provisions listed in the Schedule, to the extent that they are relevant to section 16 as brought into force by this Order or to other provisions of the Act which are already in force. In particular, section 48 and paragraphs 3 to 9 of Schedule 5 to the Act (powers of inspection, entry, search and seizure), section 50 (prosecutions), section 51 (offences: Northern Ireland) and section 58(1) and (2) (transition) are relevant to section 32 (prohibition of commercial dealings in human material for transplantation) of the Act which was brought into force by Human Tissue Act 2004 (Commencement No. 3 and Transitional Provisions) Order 2005 SI 2005/2792.

Article 4 of the Order has the effect that storage for 48 hours or less, for purposes other than transplantation, or for the purpose of organ transplantation will not be subject to licensing from 7th April 2006. The definition of the term organ is taken from Directive 2002/98/EC Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.

Articles 5 and 6 make transitional arrangements.

Article 5 provides that where an application for a licence under section 16, as brought into force by this Order, is made by 31st March 2006 then a licence will be deemed to have been granted on that application until the Authority grants or refuses a licence on the application.

Article 6 provides that the provisions of the Act will apply to licences deemed to have been granted, under article 5, to the same extent as they apply to licences granted under the Act.

Schedule 1 lists the provisions which are brought into force on 1<sup>st</sup> March 2006 and 7th April 2006, by articles 2 and 3 of the Order respectively.

## NOTE AS TO EARLIER COMMENCEMENT ORDERS

*(This note is not part of the Order)*

<i>Provision</i>	<i>Date of Commencement</i>	<i>S.I. No.</i>
Section 1(9) (partially)	20 October 2005	2005/2792
Section 1(11) (partially)	20 October 2005	2005/2792
Section 4(10) (partially)	20 October 2005	2005/2792
Section 4(10) (partially)	20 October 2005	2005/2792
Section 6 (partially)	20 October 2005	2005/2792
Section 7(4)	20 October 2005	2005/2792

Section 10(9)	20 October 2005	2005/2792
Section 13	1 April 2005	2005/919
Section 14	1 April 2005	2005/919
Section 15	1 April 2005	2005/919
Section 16(3) and (5)	20 October 2005	2005/2792
Section 16(6) (partially)	20 October 2005	2005/2792
Section 21(5)	20 October 2005	2005/2792
Section 26	1 April 2005	2005/919
Section 27	1 April 2005	2005/919
Section 28	1 April 2005	2005/919
Section 29	1 April 2005	2005/919
Section 32	20 October 2005	2005/2792
Section 33(3) and (4)	20 October 2005	2005/2792
Section 34(1)	20 October 2005	2005/2792
Section 35	1 April 2005	2005/919
Section 36	1 April 2005	2005/919
Section 38	1 April 2005	2005/919
Section 39 (partially)	1 April 2005	2005/919
Section 40 (partially)	1 April 2005	2005/919
Section 41 (partially)	1 April 2005	2005/919
Section 42	1 April 2005	2005/919
Section 45 (partially)	20 October 2005	2005/2792
Section 46	20 October 2005	2005/2792
Section 47	3 October 2005	2005/2632
Section 48 (partially)	20 October 2005	2005/2792
Section 51 (partially)	20 October 2005	2005/2792
Section 52 (partially)	20 October 2005	2005/2792
Section 53 (partially)	1 April 2005	2005/919
Section 54 (partially)	1 April 2005	2005/919
Section 54(10)	20 October 2005	2005/2792
Section 54 (partially)	20 October 2005	2005/2792
Section 55	1 April 2005	2005/919
Section 57 (partially)	20 October 2005	2005/2792
Schedule 1 to the Act	1 April 2005	2005/919
Schedule 2 to the Act	1 April 2005	2005/919
Schedule 3 to the Act, paragraph 10(5)	20 October 2005	2005/2792
Schedule 3 to the Act, paragraph 13(1)	20 October 2005	2005/2792
Schedule 4 to the Act, paragraph 6(2)	20 October 2005	2005/2792
Schedule 4 to the Act, paragraph 10(b)	20 October 2005	2005/2792
Schedule 4 to the Act, paragraph 12(2)	20 October 2005	2005/2792
Schedule 4 to the Act, paragraph 13	20 October 2005	2005/2792
Schedule 5 to the Act, paragraph 4(5)	20 October 2005	2005/2792
Schedule 6 to the Act, paragraph 6	1 April 2005	2005/919
Schedule 7 to the Act, paragraph 1 (partially)	20 October 2005	2005/2792

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STATUTORY INSTRUMENTS

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