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STATUTORY INSTRUMENTS

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**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>(1)</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(2),

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

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(2) 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)

- (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.

**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

19th February 2006

*Rosie Winterton*  
Minister of State,  
Department of Health

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

## 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            |

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## 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 SI2005/2792](#).

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>           |
|--|-----------------------------|---------------------------|
| All provisions in the Act, so far as not brought into force by the Act or an earlier order (for the purpose only of conferring | 20 October 2005             | <a href="#">2005/2792</a> |

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

| <i>Provision</i>                      | <i>Date of Commencement</i> | <i>S.I. No.</i> |
|---------------------------------------|-----------------------------|-----------------|
| power to make orders and regulations) |                             |                 |
| Section 13                            | 1 April 2005                | 2005/919        |
| Section 14                            | 1 April 2005                | 2005/919        |
| Section 15                            | 1 April 2005                | 2005/919        |
| 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 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 47                            | 3 October 2005              | 2005/2632       |
| Section 51 (partially)                | 20 October 2005             | 2005/2792       |
| Section 52 (partially)                | 1 April 2005                | 2005/919        |
| 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 (partially)                | 20 October 2005             | 2005/2792       |
| Section 55                            | 1 April 2005                | 2005/919        |
| Section 56 (partially)                | 20 October 2005             | 2005/2792       |
| Section 57 (partially)                | 20 October 2005             | 2005/2792       |
| Schedule 1                            | 1 April 2005                | 2005/919        |
| Schedule 2                            | 1 April 2005                | 2005/919        |
| Schedule 6 (partially)                | 1 April 2005                | 2005/919        |
| Schedule 6 (partially)                | 20 October 2005             | 2005/2792       |
| Schedule 7 (partially)                | 20 October 2005             | 2005/2792       |