
STATUTORY INSTRUMENTS

2007 No. 1523

HUMAN TISSUE

**The Human Tissue (Quality and Safety
for Human Application) Regulations 2007**

Made - - - - - *24th May 2007*

Coming into force

*for the purposes of
regulation 1(3)*

25th May 2007

for all other purposes

5th July 2007

**THE HUMAN TISSUE (QUALITY AND SAFETY
FOR HUMAN APPLICATION) REGULATIONS 2007**

PART 1

CITATION, COMMENCEMENT, EXTENT AND INTERPRETATION

1. Citation and commencement
2. Extent and application
3. Designation of the competent authority
4. References to Directives
- 4A Modifications to the first, second, third and fourth Directives: general
- 4B Modifications to the first Directive
- 4C Modifications to the second Directive
- 4D Modifications to the third Directive
- 4E Modifications to the fourth Directive
5. Interpretation of other terms
6. References to third party agreements etc

PART 2

LICENSING OF ACTIVITIES RELATING TO THE
USE OF TISSUE FOR HUMAN APPLICATION

7. Licensing requirement
- 7A Import into Northern Ireland from the EEA
8. Application of the 2004 Act in relation to licences under Schedule 1
9. Extension of other provisions of the 2004 Act to Scotland

Changes to legislation: There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Human Tissue (Quality and Safety for Human Application) Regulations 2007. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

10. Breach of requirement to hold a licence or to act under a third party agreement
11. Preconditions to grant of licence
12. Duty of designated individual
13. Information and confidentiality
14. Breach of confidentiality requirement

PART 3

REGULATION OF LICENSED ACTIVITIES

15. Import and export of tissue and cells
16. Directions: Great Britain
- 16A. Directions: compliance with first, second, third and fourth Directives as they apply in relation to Northern Ireland

PART 4

OBLIGATIONS OF THE AUTHORITY

17. Requirement for the Authority to provide information
18. Register of licences
19. Register of serious adverse events and serious adverse reactions
20. Duties of the Authority in relation to serious adverse events and serious adverse reactions
- 20A. Duties of the Authority in relation to application of the Single European Code in relation to Northern Ireland
- 20B. Inspection of third country premises etc , Northern Ireland
- 20C. Third country premises and third country suppliers: report of inspections etc , Northern Ireland

PART 5

INSPECTION, ENTRY, SEARCH AND SEIZURE

21. Inspection of documents
- 21A. Inspection of documents to be held by an importing licence holder , Northern Ireland
22. Entry and inspection of premises
- 22A. Importing licence holders: requests for inspections , Northern Ireland
23. Entry and search in connection with suspected offence
24. Execution of warrants
25. Seizure in the course of inspection or search
26. Powers: supplementary
27. Requirements when exercising power of inspection or search
28. Enforcement
29. Meaning of duly authorised person

PART 6

AMENDMENTS TO THE 2004 ACT

30. Remit of the Authority
31. Exclusion from licensing requirement of section 16
32. Interpretation of Part 2 of the 2004 Act
33. Applications under Schedule 3 to the 2004 Act

PART 7
GENERAL

- 34ZA Powers to make regulations in relation to standards of quality and safety, Great Britain
- 34ZB Scope and nature of powers
- 34ZC Scrutiny of regulations
 - 34. Offences by bodies corporate
 - 35. Transitional arrangements: storage licences
- Signature

SCHEDULE 1 — Licences for the purposes of regulation 7
— *Power to grant licence*

- 1. The Authority may on application grant a licence for the...
 - Characteristics of licences
- 2. A licence under this Schedule may authorise the carrying-on of...
- 3. A licence— (a) shall designate an individual as the designated...
- 4. A licence — (a) shall specify the premises (other than...
- 5. It shall be a condition of a licence under this...
- 5A Where the Authority grants a licence under this Schedule authorising...
 - *Fees*
- 6. In determining the amounts of any fees to be charged...

SCHEDULE 2 — Directions for securing compliance with the first, second, third and fourth Directives
— Traceability and coding system

- 1. In relation to Great Britain, directions shall require that licence...
- 1ZA In relation to Northern Ireland, directions shall require that licence...
- 1A In relation to Northern Ireland, directions must require information that...
 - 2. Directions given for the purposes of paragraph 1(a) must include...
 - Reporting obligations
 - 3. Directions under paragraph 2(4)(c) to (e) of Schedule 3 to...
 - Serious adverse events and serious adverse reactions
- 4. In relation to Great Britain, directions shall require licence holders...
- 4ZA In relation to Northern Ireland, directions shall require licence holders...
- 4A Directions must require that importing licence holders are required to—...
 - Third party agreements and termination of licensed activities
- 5. For the purpose of securing compliance with the requirements of...
 - Procurement and use of tissue or cells
- 6. Directions shall specify the requirements to be met by all...
- 7. In relation to Great Britain, directions shall be given—
- 7A In relation to Northern Ireland, directions shall be given—
- 8. In giving directions for the purposes of paragraph 7, the...
 - Selection criteria and laboratory tests required for donors of tissues and cells
- 9. In relation to donors of tissues or cells who are...
- 10. In relation to donors of tissues or cells who are...
- 11. Directions shall, in respect of all donors of tissues or...
 - Donation and procurement procedures and reception at the tissue establishment

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12. In respect of— (a) donation and procurement procedures, and
— Requirements for holding a licence under Schedule 1
13. Directions shall be given for the purpose of securing compliance...
— Requirements for holding a licence under Schedule 1 for tissue and cell preparation processes
14. In respect of tissue and cell preparation processes, directions shall...
15. Updated information
16. Written agreements

SCHEDULE 3 — Appropriate statements

An appropriate statement for the purposes of regulation 24 must...

Explanatory Note

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Changes and effects yet to be applied to :

- Sch. 1 para. 5A words substituted by [S.I. 2019/481 reg. 3\(20\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(20) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 24)
- Sch. 2 para. 1A omitted by [S.I. 2019/481 reg. 3\(21\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(21)(b) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 25(c))
- Sch. 2 para. 4 words substituted by [S.I. 2019/481 reg. 3\(21\)\(c\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(21)(c) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 25(d))
- Sch. 2 para. 7(b) words substituted by [S.I. 2019/481 reg. 3\(21\)\(d\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(21)(d) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 25(f))
- Regulations applied by S.I. 2002/618, reg. 68(15) (as inserted) by [S.I. 2019/791 reg. 10](#) (This amendment not applied to legislation.gov.uk. Reg. 10 omitted immediately before IP completion day by virtue of S.I. 2020/1478, regs. 1(3), Sch. 2 para. 54)
- reg. 2(3)(d) word omitted by [S.I. 2024/221 reg. 21\(a\)](#)
- reg. 3 omitted by [S.I. 2019/481 reg. 3\(2\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(2) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 4)
- reg. 4 words substituted by [S.I. 2019/481 reg. 3\(3\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(3) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 5)
- reg. 5(4)(b) words substituted by [S.I. 2019/481 reg. 3\(5\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(5)(b) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 7(d))
- reg. 7(4) words omitted by [S.I. 2019/481 reg. 3\(6\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(6) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 9)
- reg. 7A omitted by [S.I. 2019/481 reg. 3\(7\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(7) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 10)
- reg. 10(2A) omitted by [S.I. 2019/481 reg. 3\(8\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(8) omitted immediately before IP completion day by virtue of S.I. 2020/1306, regs. 1, 11)
- reg. 10(3) words substituted by [S.I. 2019/481 reg. 3\(8\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(8) omitted immediately before IP completion day by virtue of S.I. 2020/1306, regs. 1, 11)
- reg. 11(4B)(c) substituted by [S.I. 2019/481 reg. 3\(9\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(9) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 12)
- reg. 16 heading words omitted by [S.I. 2019/481 reg. 3\(10\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(10)(a) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 13(a))
- reg. 20(1)(c) omitted by [S.I. 2019/481 reg. 3\(11\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(11)(a) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 15(a))
- reg. 20(1)(d) omitted by [S.I. 2019/481 reg. 3\(11\)\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(11)(a) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 15(a))

- reg. 20(3) omitted by [S.I. 2019/481 reg. 3\(11\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(11)(b) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 15(b))
- reg. 20A omitted by [S.I. 2019/481 reg. 3\(12\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(12) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 16)
- reg. 20B omitted by [S.I. 2019/481 reg. 3\(13\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(13) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 17)
- reg. 20C omitted by [S.I. 2019/481 reg. 3\(14\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(14) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 18)
- reg. 21A omitted by [S.I. 2019/481 reg. 3\(15\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(15) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 19)
- reg. 22A omitted by [S.I. 2019/481 reg. 3\(16\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(16) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 20)
- reg. 27(4) omitted by [S.I. 2019/481 reg. 3\(17\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(17) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 21)
- reg. 27(5) omitted by [S.I. 2019/481 reg. 3\(17\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(17) substituted immediately before IP completion day by S.I. 2020/1306, regs. 1, 21)
- reg. 28(1)(a) word omitted by [S.I. 2019/481 reg. 3\(18\)](#) (This amendment not applied to legislation.gov.uk. Reg. 3(18) omitted immediately before IP completion day by virtue of S.I. 2020/1306, regs. 1, 22)

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- reg. 2(3)(f) and word inserted by [S.I. 2024/221 reg. 21\(b\)](#)