STATUTORY INSTRUMENTS.

S.I. No. 209 of 2014

EUROPEAN COMMUNITIES (QUALITY AND SAFETY OF HUMAN TISSUES AND CELLS) (AMENDMENT) REGULATIONS 2014

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I, JAMES REILLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Regulation (EC) No. 596/2009 of the European Parliament and of the Council of 18 June 2009[1] and giving effect to Commission Directive 2012/39/EU of 26 November 2012[2], hereby make the following regulations:

1. These Regulations may be cited as the European Communities (Quality and Safety of Human Tissues and Cells) (Amendment) Regulations 2014.

2. In these Regulations, "Principal Regulations" means the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 (S.I. No. 158 of 2006).

3. Regulation 2(1) of the Principal Regulations is amended—

(*a*) by substituting for the definition of "the Directive" the following:

> "'the Directive' means Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004[3], as amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council of 18 June 2009[1];", and

(*b*) by substituting for the definition of "the Directives" the following:

> "'the Directives' means the Directive and Commission Directive 2006/17/EC of 8 February 2006[4], as amended by Commission Directive 2012/39/EU of 26 November 2012[2];".

4. Schedule 2 to the Principal Regulations is amended by substituting for paragraph 1.2 the following:

"HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.".

5. Schedule 3 to the Principal Regulations is amended—

(*a*) by substituting for paragraph 2.4 the following:

[1]OJ No. L 188, 18.7.2009, p. 14.
[2]OJ No. L 327, 27.11.2012, p. 24
[3]OJ No. L 102, 7.4.2004, p. 48.
[4]OJ No. L 38, 9.2.2006, p. 40.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 20*th May*, 2014.

"HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.",

(*b*) by substituting for paragraph 3.3 the following:

"HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.", and

(*c*) by substituting for paragraph 4.2 the following:

"For donations other than by partners, blood samples must be obtained at the time of each donation.

For donation by partners (not for direct use), blood samples must be obtained within three months before the first donation. For further partner donations by the same donor, further blood samples must be obtained no later than 24 months from the previous sampling.".

L.S.

GIVEN under my Official Seal,
14 May 2014.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations give further effect to Regulation (EC) No. 596/2009 of the European Parliament and of the Council of 18 June 2009, which amends Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

These Regulations also give effect to Commission Directive 2012/39/EU of 26 November 2012, which amends Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.

These Regulations may be cited as the European Communities (Quality and Safety of Human Tissues and Cells) (Amendment) Regulations 2014.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2
(Teil: 01 - 6476834 nó 1890 213434; Fax: 01 - 6476843)
nó trí aon díoltóir leabhar.

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DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2.
(Tel: 01 - 6476834 or 1890 213434; Fax: 01 - 6476843)
or through any bookseller.

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ISBN 978-1-4468-1913-5

€2.54

9 781446 819135

Wt. (B30592). 285. 5/14. Clondalkin. Gr 30-15.