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:


\((b)\) by substituting for the definition of “the Directives” the following:


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:

\(^2\)OJ No. L 327, 27.11.2012, p. 24
\(^3\)OJ No. L 102, 7.4.2004, p. 48.

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 20th 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.”,

(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.”.

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.)


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