STATUTORY INSTRUMENTS.

S.I. No. 494 of 2015

EUROPEAN COMMUNITIES (QUALITY AND SAFETY OF HUMAN BLOOD AND BLOOD COMPONENTS) (AMENDMENT) REGULATIONS 2015

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EUROPEAN COMMUNITIES (QUALITY AND SAFETY OF HUMAN BLOOD AND BLOOD COMPONENTS) (AMENDMENT) REGULATIONS 2015

I, LEO VARADKAR, 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 effect to Commission Directive 2014/110/EU of 17 December 2014[1], hereby make the following regulations:

1. (1) These Regulations may be cited as the European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2015.

(2) The Principal Regulations, the European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2008 (S.I. No. 179 of 2008), the European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2009 (S.I. No. 507 of 2009), the Regulations of 2011 and these Regulations may be cited together as the European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005 to 2015 and shall be construed together as one.

2. In these Regulations—

"Principal Regulations" means the European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005 (S.I. No. 360 of 2005);

"Regulations of 2011" means the European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2011 (S.I. No. 329 of 2011).

3. Regulation 2(1) (as amended by Regulation 4 of the Regulations of 2011) of the Principal Regulations is amended—

(*a*) by substituting for the definition of "Commission Directive 2004/33/EC" the following:

> "'Commission Directive 2004/33/EC' means Commission Directive 2004/33/EC of 22 March 2004[2], as amended by Commission Implementing Directive 2011/38/EU of 11 April 2011[3]

[1]OJ No. L 366, 20.12.2014, p. 81.
[2]OJ No. L 91, 30.3.2004, p. 25.
[3]OJ No. L 97, 12.4.2011, p. 28.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 10*th November*, 2015.

and Commission Directive 2014/110/EU of 17 December 2014[1];", and

(*b*) by deleting the definition of "Commission Implementing Directive 2011/38/EU".

4. Regulation 6(4)(*b*)(ii) (as amended by Regulation 5 of the Regulations of 2011) of the Principal Regulations is amended by deleting "as amended by Commission Implementing Directive 2011/38/EU".

5. Regulation 9(3)(*c*) (as amended by Regulation 6 of the Regulations of 2011) of the Principal Regulations is amended by deleting "as amended by Commission Implementing Directive 2011/38/EU".

6. Regulation 23 (as amended by Regulation 7 of the Regulations of 2011) of the Principal Regulations is amended by deleting "as amended by Commission Implementing Directive 2011/38/EU".

L.S.

GIVEN under my Official Seal,
5 November 2015.

LEO VARADKAR,
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 effect to Commission Directive 2014/110/EU of 17 December 2014 amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations.

These Regulations amend the European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005.

These Regulations may be cited as the European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2015.

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