STATUTORY INSTRUMENTS.

S.I. No. 329 of 2011

EUROPEAN COMMUNITIES (QUALITY AND SAFETY OF HUMAN BLOOD AND BLOOD COMPONENTS) (AMENDMENT) REGULATIONS 2011

(Prn. A11/1155)

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EUROPEAN COMMUNITIES (QUALITY AND SAFETY OF HUMAN BLOOD AND BLOOD COMPONENTS) (AMENDMENT) REGULATIONS 2011

I, JAMES REILLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act l972 (No. 27 of l972) and for the purpose of giving effect to Commission Implementing Directive 2011/38/EU of 11 April 2011[1] amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life and for the purpose of giving further effect to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003[2] 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, hereby make the following Regulations:

1. These Regulations may be cited as the European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2011.

2. These Regulations come into operation on 30 June 2011.

3. 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).

4. Regulation 2(1) of the Principal Regulations is amended by inserting the following after the definition of "Commission Directive 2004/33/EC":

> "Commission Implementing Directive 2011/38/EU" means Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life;".

5. Regulation 6(4)(*b*)(ii) of the Principal Regulations is amended by inserting "as amended by Commission Implementing Directive 2011/38/EU" after "Commission Directive 2004/33/EC".

6. Regulation 9 of the Principal Regulations is amended—

(*a*) in paragraph (2)—

(i) in subparagraph (*e*), by deleting "the evaluations, and" and substituting "the evaluations,",

[1]OJ No. L 97, 12.4.2011, p.28
[2]OJ No. L 33, 08.3.2003, p.30

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 1*st July*, 2011.

(ii) in subparagraph (*f*)(iii), by deleting "donate." and substituting "donate, and", and

(iii) by inserting the following after paragraph (*f*):

"(*g*) encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are, in so far as possible, provided from such donations, in particular—

(i) disseminating information about blood donation, and

(ii) advertising for blood donors.",

and

(*b*) in paragraph (3)(*c*), by inserting "as amended by Commission Implementing Directive 2011/38/EU" after "Commission Directive 2004/33/EC".

7. Regulation 23 of the Principal Regulations is amended by inserting "as amended by Commission Implementing Directive 2011/38/EU" after "Commission Directive 2004/33/EC".

Signed,
29 June 2011.

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 effect to Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life. Recent scientific evidence and field practice experience has demonstrated that values higher than pH 7.4 do not affect the quality and safety of stored platelets and that a maximum pH value for platelet concentrates is thus not necessary.

The Regulations also give further effect to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 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 to provide that blood establishments should encourage the voluntary unpaid donation of blood and blood components.

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