

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 (Text with EEA relevance)

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2002/98/EC of the European Parliament and 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<sup>(1)</sup>, and in particular point (f) of the second paragraph of Article 29 thereof,

Whereas:

- (1) Point 2.4 of Annex V to Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components<sup>(2)</sup> sets minimum (6,4) and maximum (7,4) pH levels for units of platelets at the end of the shelf life. Therefore, platelet units that do not meet these minimum or maximum values have to be discarded.
- (2) 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, contrary to pH levels below 6,4 that systematically result in damaging the platelets, and that a maximum pH value for platelet concentrates is thus not necessary.
- (3) Discarding platelets that exceed the maximum pH value as set out in Annex V to Directive 2004/33/EC leads to considerable losses. These losses may increase in the future due to new collection methods and storage bags, which both generate higher pH values at the end of the shelf life.
- (4) Therefore the maximum (7,4) pH value for all platelet concentrates listed in Annex V to Directive 2004/33/EC should be removed.
- (5) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Article 28 of Directive 2002/98/EC,

HAS ADOPTED THIS DIRECTIVE:

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- (1) OJ L 33, 8.2.2003, p. 30.
- (2) OJ L 91, 30.3.2004, p. 25.