

DIRECTIVES

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⁽¹⁾, 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⁽²⁾ 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:

Article 1

Annex V to Directive 2004/33/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 2011 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 11 April 2011.

For the Commission

The President

José Manuel BARROSO

⁽¹⁾ OJ L 33, 8.2.2003, p. 30.

⁽²⁾ OJ L 91, 30.3.2004, p. 25.

ANNEX

In point 2.4 of Annex V to Directive 2004/33/EC, for the entries:

- 'Platelets, apheresis',
- 'Platelets, aphaeresis, leucocyte-depleted',
- 'Platelets, recovered, pooled',
- 'Platelets, recovered, pooled, leucocyte-depleted',
- 'Platelets, recovered, single unit', and
- 'Platelets, recovered, single unit, leucocyte-depleted',

the acceptable results for quality measurements for pH are replaced by the following:

'Minimum 6,4 corrected for 22 °C, at the end of the shelf life'.
