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 (Text with EEA relevance)

COMMISSION DIRECTIVE 2014/110/EU

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amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations

(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 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[(1)], and in particular point (d) of the second paragraph of Article 29 thereof,

Whereas:

(1) Point 2.2 of Annex III to Commission Directive 2004/33/EC[(2)] lays down temporary deferral criteria for donors with an infectious illness or donors leaving an area where an infectious illness is present.

(2) Point 2.2.1 of Annex III to Directive 2004/33/EC establishes a deferral period for prospective donors of 28 days after leaving an area with ongoing transmission of West Nile Virus (WNV) to humans.

(3) Recent scientific evidence has demonstrated that a temporary deferral of such prospective donors is not required if a Nucleic Acid Test (NAT) was carried out and the test was negative.

(4) Therefore, the Member States should be given the option to apply such a test, if they want to replace the temporary deferral criteria.

(5) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2002/98/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The deferral criterion for West Nile Virus set out in the table (second column, last row) of point 2.2.1 of Annex III to Directive 2004/33/EC is replaced by the following:

> 28 days after leaving a risk area of locally acquired West Nile Virus unless an individual Nucleic Acid Test (NAT) is negative.

Article 2

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 2015 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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 twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 17 December 2014.

For the Commission

The President

Jean-Claude JUNCKER

(**1**) OJ L 33, 8.2.2003, p. 30.

(**2**) 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 (OJ L 91, 30.3.2004, p. 25).