



Council of the
European Union

Brussels, 21 April 2016
(OR. en)

8103/16

SAN 141

'I/A' ITEM NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

No. prev. doc.: 7566/16 SAN 113

Subject: COMMISSION DIRECTIVE (EU) .../... of XXX amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments
– *Decision not to oppose adoption*

1. Commission Directive 2005/62/EC as regards quality system standards and specifications for blood establishments is a Directive implementing Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. According to Recital 30 of the Directive 2002/98/EC, the measures necessary for the implementation of this Directive should be adopted in accordance with the regulatory procedure with scrutiny.
2. The regulatory procedure with scrutiny is regulated by Article 5a of the Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission¹.

¹ OJ L 184, 17.7.1999, p. 23.

3. According to the second subparagraph of Article 12 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers², the effects of Article 5a of Decision 1999/468/EC are maintained for the purposes of existing basic acts making reference thereto.
4. Before adopting the above mentioned measures and in accordance with Article 5a(3) of Council Decision 1999/468/EC³, the Commission consulted the regulatory Committee on the quality and safety of blood, which on 18 March 2016 voted by unanimity in favour of the above draft Directive.
5. Consequently, the Commission submitted the above draft Directive to the Council on 4 April 2016, in accordance with Article 5a(3)(a) of Council Decision 1999/468/EC.
6. Under the regulatory procedure with scrutiny, the Council, acting by qualified majority, may oppose the Commission's adoption of the draft Commission Directive on the grounds that the draft measures presented by the Commission:
 - exceed the implementing powers provided for in the basic instrument, or
 - are not compatible with the aim or the content of the basic instrument, or
 - do not respect the principles of subsidiarity or proportionality.
7. The delegations were asked on 5 April 2016 to indicate until 20 April 2016 their possible opposition to the draft Directive. The delegations did not raise any of the above-mentioned grounds for opposition.
8. **The Permanent Representatives Committee is therefore invited to recommend to the Council to confirm, as an "A" item of its agenda, that it is not opposed to the draft Directive in subject.** Unless the European Parliament opposes the Regulation within 3 months from its submission, the Commission may adopt it in accordance with Article 5a(3)(d) of Council Decision 1999/468/EC.

² OJ L 55, 28.2.2011, p. 13.

³ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23), as amended by Decision 2006/512/EC (JO L 200, 22.7.2006, p. 11).