



Council of the
European Union

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(OR. en)

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"I/A" ITEM NOTE

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

No. Cion doc.: 12820/14 SAN 331 PHARM 66 MI 621 COMPET 494

Subject: COMMISSION DIRECTIVE ../.../EU of XXX amending Directive
2004/33/EC as regards temporary deferral criteria for donors of allogeneic
blood donations
- Decision not to oppose adoption

1. According to Article 29 of the 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, the adaptation of the technical requirements set out in Annexes I to IV to technical and scientific progress shall be decided with the regulatory procedure with scrutiny.
2. According to the second subparagraph of Article 12 of Regulation (EU) No 182/2011 of the European Parliament and of the Council¹, the effects of Article 5a of Council Decision 1999/468/EC² are maintained for the purposes of existing basic acts making reference thereto.

¹ 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 powers (OJ L 55, 28.2.2011, p. 13).

² 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).

3. Before adopting the draft Directive referred to in the subject and in accordance with Article 5a(2) of Council Decision 1999/468/EC, the Commission consulted the Regulatory Committee on the Quality and Safety of Blood, which voted on 14 July 2014 in favour of the draft Directive (282 votes in favour and 70 votes against).
4. Consequently, the Commission submitted the draft Directive referred to in the subject to the Council on 3 September 2014, in accordance with Article 5a(3)(a) of Council Decision 1999/468/EC.
5. Under the regulatory procedure with scrutiny, the Council, acting by qualified majority, may oppose within 3 months the Commission's adoption of the draft Directive on the grounds that the draft measures proposed 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.
6. The delegations were asked on 5 September 2014 to indicate until 15 September 2014 their possible opposition to the draft Directive. The delegations did not raise any of the above-mentioned grounds for opposition.
7. **The Permanent Representatives Committee is therefore invited to recommend to the Council to confirm, as "A" item of its agenda, that it is not opposed to the draft Directive in document 12820/14.** Unless the European Parliament opposes the draft Directive within 3 months from its submission, the Commission may adopt it in accordance with the procedure under Article 5a(3)(d) of Council Decision 1999/468/EC.
