Council of the European Union

Brussels, 13 January 2015
(OR. en)

5183/15

SAN 7

"I/A" ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
No. Cion doc.:	16988/14 + ADD1
Subject:	COMMISSION DIRECTIVE ../…/EU of XXX amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells *– Decision not to oppose adoption*

1. Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council set up measures concerning traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

   According to article 28 (4) of the Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, the procedures ensuring traceability at Community level i.a. coding of tissues and cells, shall be established by the Commission in accordance with the regulatory procedure with scrutiny.

2. The regulatory procedure with scrutiny was 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 Commission[1].

[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 powers[2], 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/EC[3], the Commission consulted the Tissues and Cells Committee on 31 October 2014, which voted unanimously in favour of the above draft Directive.

5. Consequently, the Commission submitted the above draft Directive to the Council on 12 December 2014, 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 17 December 2014 to indicate until 12 January 2015 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 the procedure under Article 5a(3)(d) of Council Decision 1999/468/EC.

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[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).