



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 4 October 2012

14583/12

SAN 218

“I/A” ITEM NOTE

from : General Secretariat
to : Permanent Representatives Committee (Part I)/Council

No. Cion prop.: 13079/11 SAN 184

Subject: Draft COMMISSION DIRECTIVE ../.../EU of XXX amending Directive
2006/17/EC as regards certain technical requirements for the testing of human
tissues and cells
– *Decision not to oppose adoption*

1. Article 28, point (e) of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells¹ stipulates that if implementing measures are necessary for the adaptation to scientific and technical progress of the technical requirements for laboratory tests required for donors, they should be adopted in accordance with the regulatory procedure with scrutiny.

¹ OJ L 102, 7.4.2004, p. 48.

2. The second sub-paragraph of Article 12 of Regulation (EU) No 182/2011² determines that: "The effects of Article 5a of Decision 1999/468/EC³ shall be maintained for the purposes of existing basic acts making reference thereto."
3. Therefore, before adopting the above mentioned measures and in accordance with Article 5a(2) of Council Decision 1999/468/EC, the Commission consulted the Tissues and Cells Committee on 7 June 2012, which adopted its opinion with 338 votes in favour of the above draft Directive (out of a total of 345, one Member State not being present).
4. Consequently, the Commission submitted the above draft Directive to the Council on 26 July 2012, 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 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.
6. Delegations were asked on 7 August 2012 to indicate until 7 September 2012 their possible opposition to the draft Directive. They did not raise any of the above-mentioned grounds for opposition. The Commission has been informed of the linguistic comments made by the Hungarian delegation during the written consultation, in order for it to make the necessary modifications to the HU version of the text before the final adoption of the Commission Directive.

² Regulation (EU) No 182/2011 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).

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).

7. **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 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.
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