



Council of the
European Union

Brussels, 19 January 2017
(OR. en)

5459/17

COMPET 36
ENV 37
CHIMIE 8
MI 55
ENT 17
SAN 32
CONSOM 22

'I/A' ITEM NOTE

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

No. Cion doc.: 15193/16 COMPET 647 ENV 768 CHIMIE 76 MI 779 ENT 225 SAN 421
CONSOM 305 + ADD 1

Subject: COMMISSION REGULATION (EU) .../... of XXX amending Annex VII to
Regulation (EC) No 1907/2006 of the European Parliament and of the
Council on the Registration, Evaluation, Authorisation and Restriction of
Chemicals (REACH) as regards skin sensitisation and repealing
Commission Regulation (EU) 2016/1688
– Decision not to oppose adoption

1. Article 13(2) of Regulation (EC) No 1907/2006¹ provides that test methods used to generate information on intrinsic properties of substances required by that Regulation are to be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved. When appropriate validated test methods become available, the Commission Regulation (EC) No 440/2008 and the Annexes to Regulation (EC) No 1907/2006 should, if relevant, be amended in accordance with the regulatory procedure with scrutiny.

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin corrosion/irritation, serious eye damage/eye irritation and acute toxicity (OJ L 396, 30.12.2006, p. 1).

2. Therefore, in accordance with Article 5a(2) of Council Decision 1999/468/EC², the Committee established under Regulation (EC) No 1907/2006 was consulted on 20 April 2016. It voted in favour of the above draft Regulation (one Member State abstaining).
3. Consequently, the Commission submitted the above draft Regulation to the Council on 30 November 2016, in accordance with Article 5a(3)(a) of Council Decision 1999/468/EC.
4. Under the regulatory procedure with scrutiny, the Council, acting by qualified majority, may oppose the Commission's adoption of the draft Commission Regulations 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.
5. The delegations were asked on 5 December 2016 to indicate their possible opposition to the draft Regulation before 13 January 2017. No delegation raised any of the above-mentioned grounds for opposition.
6. 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 Regulation in subject.

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), as amended by Decision 2006/512/EC (JO L 200, 22.7.2006, p. 11).