



Brussels, 21 March 2019
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COMPET 262
ENV 311
CHIMIE 52
MI 268
ENT 78
SAN 156
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EMPL 182
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'I/A' ITEM NOTE

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

No. Cion doc.: 6800/19 + ADD 1, ADD 2

Subject: COMMISSION REGULATION (EU) .../... of XXX amending, for the purpose of its adaptation to technical progress, the Annex to Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Decision not to oppose adoption

1. Regulation (EC) No 440/2008 lays down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

2. The Organisation for Economic Co-operation and Development (OECD) develops harmonised and internationally agreed test guidelines for the testing of chemicals for regulatory purposes. The OECD regularly issues new and revised test guidelines, taking account of scientific progress in this area.
3. In order to take into account technical progress and, whenever possible, to reduce the number of animals used for experimental purposes in accordance with Article 13(2) of Regulation (EC) No 1907/2006, following the adoption of relevant OECD test guidelines, two new test methods for the assessment of ecotoxicity and nine new test methods for the determination of toxicity to human health should be laid down and seven test methods should be updated.
4. Therefore, in accordance with Article 5a(2) of Council Decision 1999/468/EC¹, the Committee established under Regulation (EC) No 1907/2006 was consulted on 15 February 2019. It voted in favour of the above draft Regulation.
6. The delegations were asked on 25 February 2019 to indicate their possible opposition to the draft Regulation before 18 March 2019. No delegation raised any opposition.
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 Regulation in subject.

¹ 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).