



**COUNCIL OF
THE EUROPEAN UNION**

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**COMPET 31
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COVER NOTE

from: European Commission
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to: General Secretariat of the Council

No Cion doc.: D018298/01

Subject: Draft Commission Regulation (EU) No ... amending, for the purpose of its adaptation to technical progress, 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)

Delegations will find attached Commission document D018298/01.

Encl.: D018298/01



EUROPEAN COMMISSION

Brussels, XXX
D018298/01
[...] (2011) XXX draft

COMMISSION REGULATION (EU) No .../..

of XXX

amending, for the purpose of its adaptation to technical progress, 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)

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

of XXX

amending, for the purpose of its adaptation to technical progress, 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)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of 18 December 2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Article 13(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 440/2008² contains the test methods for the purposes of the determination of the physico-chemical properties, toxicity and eco-toxicity of substances to be applied for the purposes of Regulation (EC) No 1907/2006.
- (2) It is necessary to update Regulation (EC) No 440/2008 to include with priority new and updated alternative test methods recently adopted by the OECD, in order to obtain a reduction of the number of animals to be used for experimental purposes, in accordance with Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes³ and Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes⁴. Stakeholders have been consulted on this draft.
- (3) Regulation (EC) No 440/2008 should therefore be amended accordingly.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

¹ OJ L 396, 30.12.2006, p. 1.

² OJ L 142, 31.5.2008, p. 1.

³ OJ L 276, 20.10.2010, p. 33.

⁴ OJ L 358, 18.12.1986, p. 1.

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 440/2008 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, [...]

For the Commission
The President
José Manuel BARROSO

Annex