



**COUNCIL OF
THE EUROPEAN UNION**

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Subject: 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)

Delegations will find attached document D032186/01.

Encl.: D032186/01



Brussels, **XXX**
D032186/01
[...](2013) **XXX** draft

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

of **XXX**

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

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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 the European Parliament and of the Council of 18 December 2006 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(2) 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 chemicals 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 test methods recently adopted by the OECD in order to take into account technical progress, and to ensure the 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 Council³. Stakeholders have been consulted on this draft.
- (3) This adaptation to technical progress contains six new test methods for the determination of toxicity and other health effects including a developmental neurotoxicity study, an extended one-generation reproductive toxicity study, an transgenic rodent *in vivo* gene mutation assay, an *in vitro* test to assess effects on the synthesis of steroid hormones, as well as two *in vivo* methods to assess oestrogenic and (anti)androgenic effects.

¹ OJ L 396, 30.12.2006, p. 1.

² Commission Regulation (EC) No 440/2008 of 30 May 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) (OJ L 142, 31.5.2008, p. 1).

³ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

- (4) Regulation (EC) No 440/2008 should therefore be amended accordingly.
- (5) 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,

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