



Council of the  
European Union

Brussels, 14 September 2016  
(OR. en)

12209/16

COMPET 482  
ENV 583  
CHIMIE 47  
MI 574  
ENT 168  
SAN 324  
CONSOM 212

#### COVER NOTE

---

From:	European Commission
date of receipt:	5 September 2016
To:	General Secretariat of the Council
No. Cion doc.:	D045907/02
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)

---

Delegations will find attached document D045907/02.

---

Encl.: D045907/02



Brussels, **XXX**  
D045907/02  
[...](2016) **XXX** draft

**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)**

(Text with EEA relevance)

# 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)**

(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/EC<sup>1</sup>, and in particular Article 13(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 440/2008<sup>2</sup> contains the test methods for the purposes of the determination of the physicochemical properties, toxicity and ecotoxicity 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 new and updated test methods recently adopted by the Organisation for Economic Co-operation and Development (OECD) in order to take into account technical progress, and to ensure the reduction in 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<sup>3</sup>. Stakeholders have been consulted on this draft.
- (3) The adaptation to technical progress contains twenty test methods: one new method for the determination of a physicochemical property, five new and one updated test methods for the assessment of ecotoxicity, two updated test methods to assess the

---

<sup>1</sup> OJ L 396, 30.12.2006, p. 1.

<sup>2</sup> 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).

<sup>3</sup> 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).

environmental fate and behaviour and four new and seven updated test methods for the determination of effects on human health.

- (4) The OECD regularly reviews its test guidelines in order to identify those which are scientifically obsolete. This adaptation to technical progress deletes six test methods for which the corresponding OECD test guidelines have been cancelled.
- (5) Regulation (EC) No 440/2008 should therefore be amended accordingly.
- (6) 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 [...]*

This Regulation shall enter into force on the twentieth 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  
Jean-Claude Juncker*