Commission Regulation (EC) No 134/2009 of 16 February 2009 amending 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 Annex XI (Text with EEA relevance)

COMMISSION REGULATION (EC) No 134/2009

of 16 February 2009

amending 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 Annex XI

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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/EC[(1)], and in particular Article 131 thereof,

Whereas:

(1) Regulation (EC) No 1907/2006 establishes registration obligations of Community manufacturers or importers of substances on their own, in preparations or articles, where, as part of the registration dossier, registrants have to provide the information required under Annexes VI to XI.

(2) Annex XI allows registrants, under certain conditions, to omit testing in accordance with sections 8.6 and 8.7 of Annex VIII and in accordance with Annex IX and Annex X to Regulation (EC) No 1907/2006.

(3) For the avoidance of doubt it should be clarified that in section 3.1 the reference to sections 8.6 and 8.7 refers to Annex VIII only.

(4) It is necessary to establish the criteria defining what constitutes adequate justification for the omission of testing under sections 8.6 and 8.7 of Annex VIII and in accordance with Annex IX and Annex X to Regulation (EC) No 1907/2006.

(5) Based on experience gained through the development of guidance for the chemicals safety assessment under Regulation (EC) No 1907/2006, three different criteria for exposure-based waiving have been identified. The first criterion requires that it is demonstrated and documented that exposure in all scenarios is well below an appropriate derived no-effect level (DNEL) or predicted no-effect concentration

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 134/2009. (See end of Document for details)*

(PNEC) derived under specific conditions. The second criterion requires that it is demonstrated and documented that strictly controlled conditions apply throughout the life cycle. The third criterion requires that where the substance is incorporated in an article, the substance is incorporated in such a way that no exposure can take place and the substance is not released during its life cycle and is handled under strictly controlled conditions during all manufacturing and production stages. Consequently, these criteria for justification for the omission of testing should be incorporated in Regulation (EC) No 1907/2006.

(6) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(7) 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

Annex XI to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third day following 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, 16 February 2009.

For the Commission

Stavros DIMAS

Member of the Commission