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 (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*.

[1] OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3.

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

ANNEX

Section 3 of Annex XI to Regulation (EC) No 1907/2006 is replaced by the following:

'3. SUBSTANCE-TAILORED EXPOSURE-DRIVEN TESTING

3.1. Testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report.

3.2. In all cases, adequate justification and documentation shall be provided. The justification shall be based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I and shall meet any one of the following criteria:

(a) the manufacturer or importer demonstrates and documents that all of the following conditions are fulfilled:

(i) the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5;

(ii) a DNEL or a PNEC can be derived from results of available test data for the substance concerned taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes (*);

(iii) the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC;

(b) where the substance is not incorporated in an article the manufacturer or importer demonstrates and documents for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f) apply;

(c) where the substance is incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously contained by technical means, it is demonstrated and documented that all of the following conditions are fulfilled:

(i) the substance is not released during its life cycle;

(ii) the likelihood that workers or the general public or the environment are exposed to the substance under normal or reasonably foreseeable conditions of use is negligible; and

(iii) the substance is handled according to the conditions set out in Article 18(4)(a) to (f) during all manufacturing and production stages including the waste management of the substance during these stages.

3.3. The specific conditions of use must be communicated through the supply chain in accordance with Article 31 or 32, as the case may be.

(*) For the purpose of subparagraph 3.2(a)(ii), without prejudice to column 2 of Section 8.7 of Annexes IX and X, a DNEL derived from a screening test for reproductive/developmental toxicity shall not be considered appropriate to omit a prenatal developmental toxicity study or a two-generation reproductive toxicity study. For the purpose of subparagraph 3.2(a)(ii), without prejudice to column 2 of section 8.6 of Annexes IX and X, a DNEL derived from a 28-day repeated dose toxicity study shall not be considered appropriate to omit a 90-day repeated dose toxicity study.'