COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, XX.Y.2008
XXX

Draft

**COMMISSION REGULATION (EC) No …/..**

**of**

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

Draft

**COMMISSION REGULATION (EC) No …/..**

**of**

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, Annex IX and Annex X to Regulation (EC) No 1907/2006.

(3) 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, Annex IX and Annex X to Regulation (EC) No 1907/2006.

(4) 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 waving have been identified. The first criterion requires that it is

[1] OJ L 396, 30.12.2006, p. 1. Regulation as corrected by OJ L 136, 29.5.2007, p.3. and amended by Regulation (EC) No 1354/2007 (OJ L 304, 22.11.2007, p. 1).

demonstrated that exposure in all scenarios is well below an appropriate DNEL or PNEC derived under specific conditions. The second criterion requires that it is demonstrated that manufacture, import, use, disposal or recycling take place under defined strictly controlled conditions. The third criterion requires that the substance is incorporated in an article in such a way that no exposure can take place and the substance is handled under strictly controlled conditions in all other stages of its life-cycle. Consequently, these criteria for justification for the omission of testing should be incorporated in Regulation (EC) No 1907/2006.

(5) Regulation (EC) No 1907/2006 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*

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 that of its publication in the *Official Journal of the European Union.*

Done at Brussels,

*For the Commission*
*Stavros DIMAS*
*Member of the Commission*

*Günter Verheugen*
*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, 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 an 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 that all of the following conditions are fulfilled:

(i) a DNEL or a PNEC can be derived from results of available test data 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;

(ii) the results of the exposure assessment covering all relevant exposures throughout the life-cycle of the substance demonstrate very low exposure in all scenarios;

(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) the manufacturer or importer demonstrates that manufacture, import, use, disposal or recycling takes place under the strictly controlled conditions set out in Article 18(4)(a) to (f).

(c) where the substance is incorporated in an article and it is permanently embedded in a matrix or otherwise rigorously contained by technical means, so that it is unlikely that workers or the general public are exposed to the substance under normal or reasonably foreseeable conditions of use, and it can be documented that the substance is not released during its entire life-cycle, provided that the substance is handled according to the conditions set out in Article 18(4)(a) to (f) during all manufacturing and production stages as well as during waste management.

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