Note for the attention of Tim Bowmer, the Chairman of the Committee for Risk Assessment

Subject: Request to the Committee for Risk Assessment for an opinion on the draft review report of ECHA "Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to Regulation (EC) No 1907/2006 (REACH)" – extended deadline

The Committee for Risk Assessment (RAC) was requested to draw up an opinion according to the attached mandate (Annex 1).

RAC is requested to assess ECHA's draft review report as well as the comments received during public consultation and to adopt an opinion as soon as possible and not later than 31 March 2013[1].

(signed)

Geert Dancet
Executive Director

Annex 1 Request to the Committee for Risk Assessment for an opinion on the draft review report of ECHA "Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to Regulation (EC) No 1907/2006(REACH)"

[1] The original deadline was December 2012

Note for the attention of Pilar Rodríguez Iglesias, acting Chair of the Committee for Risk Assessment

Subject: Request to the Committee for Risk Assessment for an opinion on the draft review report of ECHA "Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to Regulation (EC) No 1907/2006 (REACH)"

The Committee for Risk Assessment (RAC) is requested to draw up an opinion according to the following mandate.

1. Background

Entries 51 and 52 of Annex XVII to REACH include the restrictions on the placing on the market and use of the phthalates DEHP, DBP, BBP, DINP, DIDP and DNOP in toys and childcare articles, as initially introduced by Directive 2005/84/EC of the European Parliament and of the Council of 14 December 2005.

The restriction in entry 52 covers the placing on the market and use in toys and childcare articles which can be placed *in the mouth by children*. In addition, and as explicitly mentioned in entries 51 and 52 of Annex XVII, the Commission had to re-evaluate the restrictions concerning these phthalates and their substitutes in the light of new scientific information by 16 January 2010, and if justified, modify these restrictions accordingly.

In a first phase, ECHA has completed review reports for all six phthalates covered by the two restriction entries (published in July 2010[1]). In a second phase, the European Commission requested ECHA *"to review and analyse new scientific information, if any, coming from the registration dossiers with a view to completing the assessment of information already included in the existing review reports and, as appropriate, revise the ECHA conclusions, including the need or not for further actions on these three non-classified phthalates [DINP, DIDP and DNOP] under REACH."*[2] (14 December 2010). The need to update the first phase assessments and conclusions was limited to the reports concerning DINP and DIDP.[3] The scope of this mandate is thus limited to the second phase draft review

[1] http://echa.europa.eu/web/guest/regulations/reach/restrictions/echas-activities-on-restrictions

[2] Note for the attention of J. De Bruijn, Director of Risk Management - ECHA
Subject: REACH Annex XVII, entries 51 and 52 on phthalates - Request to ECHA to review and analyse the information coming from the registration dossiers in order to complete the review reports. Ref. Ares (2010)945804-14/12/2010.

[3] As indicated, ECHA has also published review reports for the other substances covered by entries 51 and 52 in the first phase. There was no need completing the assessment in the existing review reports for these other phthalates. Indeed, DEHP, DBP and BBP are included in Annex XIV to REACH, and a restriction proposal on DEHP, DBP, BBP and DIBP has been submitted by Denmark on 14 April 2011. Therefore, the scope was limited to further review of the information on entry 52 phthalates, i.e. DINP,

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report concerning DINP and DIDP.

ECHA has prepared a draft review report on the new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to REACH. This draft report contains a hazard assessment (including proposals for the derived no effect levels (DNELs)). The hazard assessment is based on information from the EU Risk Assessments of the two substances[4] and on additional scientific information made available after their publication, including those from the registration dossiers. ECHA's draft review report contains a thorough exposure assessment for consumers (exposure from direct contact with articles, the indoor environment and food, as well as exposure estimates from biomonitoring data), a risk characterization, and conclusions on whether or not there is a need for modifying the current restrictions for DINP and DIDP.

ECHA's draft review report will be submitted for public consultation for 12 weeks. The comments from public consultation will be made available to RAC. After receiving the opinion of RAC on the draft review report, ECHA intends to finalise the report and send it to the Commission.

2. Terms of Reference

Against the above background RAC is requested, pursuant to Article 77(3)(c) of REACH, to:

Adopt an opinion on ECHA's draft report "Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to Regulation (EC) No 1907/2006 (REACH)". Comments from the public consultation should be taken into account by RAC.

A) RAC should assess in its opinion the overall scientific quality of the report, its completeness, potential weaknesses, as well as the scientific validity of the conclusions drawn. If RAC disagrees with the conclusions, it is invited to elaborate on its reasons.

B) The opinion should in particular respond, based on the available evidence presented in the draft review report, to the following questions:

1) Is the selection of no observed adverse effect levels (NOAELs) and assessment factors (AF) to derive the derived no effect levels (DNELs) appropriate and sufficiently justified?

2) Does RAC support the assumptions and conclusions of the exposure assessment?

3) Does RAC agree to the conclusions of the draft review report that exposure to DINP and DIDP from mouthing of toys and childcare articles would present a risk, if the existing restriction was lifted?

4) Does RAC agree to the conclusions of the draft review report regarding consumer

DIDP and DNOP. As far as DNOP is concerned, no REACH registration dossier has been submitted so far to ECHA. This supports the information in the ECHA review report on DNOP from July 2010 that on the one hand there seems to be confusion around the substance identity of DNOP, and on the other hand there seems to be no commercial market in the EU for DNOP. Therefore, ECHA did not conduct any further evaluation of DNOP. ECHA considers that the conclusions drawn in the published review report are still valid, i.e. that there is no new information available that would justify the re-examination of the current restriction on DNOP.

[4] EC (2003a). 1,2-benzenedicarboxylic acid, di-C9-11- branched alkyl esters, C10-rich and di-"isodecyl" phthalate (DIDP). European Union Risk Assessment Report. Volume 36. European Chemicals Bureau. Office for Official Publications of the European Communities, Luxembourg; EC (2003b). 1,2-benzenedicarboxylic acid, di-C8-10- branched alkyl esters, C9-rich and di-"isononyl" phthalate (DINP). European Union Risk Assessment Report. Volume 35. European Chemicals Bureau. Office for Official Publications of the European Communities, Luxembourg.

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risk from the presence of DINP and DIDP in articles other than toys and childcare articles?

5) Does RAC agree to the conclusions of the draft review report regarding the risk from combined exposure[5] to DINP and DIDP?

3. Timescale for the RAC opinion

RAC is requested to assess ECHA's draft review report as well as the comments received during public consultation and to adopt an opinion as soon as possible and not later than December 2012.

4. Remuneration

The task for RAC following from this request is not covered by the Management Board decision on the Financial Arrangements for Transfer of a Proportion of Fees to the Member States, and therefore no remuneration can be paid by the Agency.

Geert Dancet
Executive Director

[5] 'Combined exposure' includes all routes, pathways, and sources of exposure to multiple chemicals (as defined in the joint opinion of SCHER, SCENIHR and SCCS "Toxicity and Assessment of Chemical Mixtures" from 2011).