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ENVIRONMENT DIRECTORATE-GENERAL
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ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Resources Based, Manufacturing and Consumer Goods Industries
REACH
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Phthalates entry 52

Commission conclusions on the review clause and next steps

The Commission presented the paper (doc. CA/44/2013) for discussion and comments during the CARACAL meeting of 26-28 November 2013. This document was endorsed by the CARACAL and stakeholders after a consultation period of one month.

Foreword:

This paper focuses on the substances targeted by entry 52 of Annex XVII to REACH, i.e. DINP, DIDP and DNOP

1) Background

Entry 52 of Annex XVII to REACH restricts the use of DINP, DIDP and DNOP in toys and childcare articles which can be placed in the mouth by children. This entry contains a review clause, calling upon the Commission to *"re-evaluate, by 16 January 2010, the measures provided for in relation to this entry in the light of new scientific information on such substances and (...) if justified, these measures shall be modified accordingly"*.

In accordance with this provision, the Commission requested ECHA on 4 September 2009 *"to review the available new scientific information for DINP, DIDP and DNOP and to evaluate whether there is evidence that would justify a re-examination of the existing restrictions in accordance with Article 69(5) or if applicable Article 68(2) of REACH"*. In its request, the European Commission also suggested that highest priority should be given to *"an evaluation of whether the use of these phthalates in articles intended to be used by children (other than toys and childcare articles) (...) poses a risk to children that is not adequately controlled"*.

ECHA published its reports containing the results of its work on its website in July 2010¹. Earlier draft reports had been updated on the basis of comments received from CARACAL members and observers in June 2010.

In these reports, ECHA collected information on the uses of the three phthalates and their hazards to human health. ECHA also assessed the exposure to the phthalates and possible risks to the general population and to children from the use of toys and childcare articles, the use in school supplies as well as from other sources. ECHA concluded that the available new information with regard to the uses of and exposure to these phthalates did not indicate the need for an urgent re-examination of the existing restrictions. In addition it was recommended by ECHA to await the first registration deadline of the REACH Regulation before deciding on any further steps in this re-evaluation process. The Commission announced its intention to follow this recommendation during the CARACAL meeting held on 15-17 June 2010.

On 14 December 2010, the 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 under REACH"*.

A draft review was produced by ECHA and was assessed by the ECHA Risk Assessment Committee (RAC) upon request of ECHA's Executive Director². To support the opinion-forming process, a 12-week public consultation was conducted and the RAC opinion was delivered on 8 March 2013³, taking into account the comments of all interested parties

¹ http://echa.europa.eu/documents/10162/13641/dinp_echa_review_report_2010_6_en.pdf;
http://echa.europa.eu/documents/10162/13641/didp_echa_review_report_2010_6_en.pdf;
http://echa.europa.eu/documents/10162/13641/dnop_echa_review_report_2010_6_en.pdf

² <http://echa.europa.eu/documents/10162/2f5ebd3b-7ddb-4822-9800-247e8f5346e2>

³ <http://echa.europa.eu/documents/10162/31ec5ce2-ec0f-4dcc-b572-b81f4d6fa7f2>

provided during the public consultation. The final ECHA report was updated considering the opinion of the RAC and the comments provided during the public consultation.

In summer 2013, ECHA published the final report on its website⁴ with the conclusion of this second phase of the review.

2) Main ECHA conclusions

ECHA report focussed on DINP and DIDP. No REACH registration dossier have been submitted to ECHA for DNOP thereby supporting the conclusions of the ECHA 2010 review report that on one hand there seems to be confusion around the substance identity of DNOP and on the other hand that there seems DNOP is not used anymore in EU. ECHA therefore considered that there is no new information that would justify the re-examination of the current restriction on DNOP.

a) Risk for children

- from toys and childcare articles

ECHA noted that risk characterization ratios (RCRs) ranging from 1.3 to 2.0 could be derived for reasonable worst case scenarios of exposure if the existing restriction on DINP and DIDP in toys was not in place, indicating that "*a risk from the mouthing of toys and childcare articles with DINP and DIDP cannot be excluded if the existing restriction were lifted (i.e. in the scenario where DINP or DIDP would be present in toys and childcare articles that can be placed in the mouth)*".

- from school materials

Amongst school materials, the literature identified especially erasers as a possible source of exposure to DINP and DIDP. According to ECHA's assessment, it is not anticipated that mouthing of erasers containing DINP or DIDP would lead to a considerable risk.

- from indoor environment and food

ECHA noted that no risk is expected from combined exposure⁵ to DINP and DIDP for children exposed via food and the indoor environment (indoor air and house dust), as the sum of the RCRs calculated for combined exposure to DINP and DIDP are below 1.

b) Risk for adults

- from articles which cause dermal exposure

ECHA concluded that dermal exposure (from articles which are in direct contact with the skin such as garments, plastic bags, shower curtains etc.) to DINP and DIDP are not expected to result in a risk for adults or the developing foetus in pregnant women.

- from sex toys

ECHA calculated a RCR of 0.4 in a reasonable worst case scenario of use of sex toys containing DINP or DIDP and concluded that their use would not result in a risk.

- from indoor environment and food

⁴ <http://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715>

⁵ "Combined exposure" includes all routes, pathways, and sources of exposure to multiple chemicals (SCHER/SCENIHR/SCCS 2011).

ECHA concluded that *“exposure from food and the indoor environment are not very significant in the adult population, which is confirmed by the available biomonitoring data”*.

c) Overall ECHA conclusions

Overall, ECHA concluded that a risk from the mouthing of toys and childcare articles containing DINP or DIDP cannot be excluded if the existing restriction were lifted, on the basis of the calculated RCRs.

No further risks were identified for other sources of exposure, taking into account the combined exposure to DINP and DIDP (assuming dose addition for liver toxicity, i.e. assuming that DINP and DIDP act in the same way). Therefore, based on this assessment, ECHA concluded that no additional risk management measures are needed to reduce the exposure of children and adults to DINP and DIDP, provided that the existing measures, and in particular the restriction in toys and childcare articles which can be placed in the mouth by children, are maintained.

Based on the above, ECHA concluded that there is no evidence that would justify a re-examination of the existing restriction on DINP and DIDP in toys and childcare articles which can be placed in the mouth by children (restriction entry 52 in Annex XVII to REACH).

These conclusions were supported by ECHA’s Committee for Risk Assessment in its opinion of 8 March 2013 on the draft report.

3) Commission conclusions

On the basis of the ECHA report and its conclusions as well as the RAC opinion, the Commission considers that:

- the existing restriction should be maintained as its withdrawal could lead to a situation where children would be at risk which is currently avoided due to the existing ban of the presence of these substances in these articles;
- on the basis of the available information, no unacceptable risk has been characterised for the uses of DINP and DIDP in articles other than toys and childcare articles which can be placed in the mouth.

In the light of the absence of any further risks from the uses of DINP and DIDP, the evaluation of potential substitutes has been less pertinent. However, it should be noted that, in accordance with Article 69 of REACH, the restriction process can be initiated at any moment, if a Member State or the Commission considers that the manufacture, placing on the market or use of a substance poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, and it is demonstrated that action on a Union-wide basis is necessary.

4) Next steps

The Commission services consider that the tasks called for by the review clause are satisfied and fully completed.