



**EUROPEAN COMMISSION**  
ENVIRONMENT DIRECTORATE-GENERAL  
**Green Economy**  
**Chemicals**

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL  
Resources Based, Manufacturing and Consumer Goods Industries  
**REACH**  
**Chemicals Industry**

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**15th Meeting of Competent Authorities for REACH and CLP (CARACAL)**  
**8-9 July 2014**  
**Charlemagne Building, Brussels, Belgium**

**Concerns:** **Phthalates in entry 51 (DEHP, DBP, BBP) of Annex XVII to REACH - the Commission services' conclusions on the review and follow-up actions**

**Agenda Point:** **Info Point 7**

**Action Requested:** **The CARACAL and stakeholders are invited to take note of this document.**

## 1) Background

Entry 51 of Annex XVII to REACH restricts the use of DEHP, DBP, BBP in toys and childcare articles and placing on the market of toys and childcare articles containing them in a concentration greater than 0,1% by weight of the plasticized material. The entry contains a review clause in its paragraph 3, 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 their substitutes, 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 DEHP, DBP, BBP and to evaluate whether there is evidence that would justify a re-examination of the existing restriction. In its request, the 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.

In March 2010, ECHA provided the Commission with the review reports for each of those phthalates in which it stated that the available new information with regard to uses of and the exposure to these phthalates does not indicate the need for an urgent re-examination of the existing restrictions and suggested to wait until the first registration deadline will have passed in order to enable the Commission to confirm or contest the conclusion of ECHA and before deciding on any further action on this group of substances.

Following the ECHA review reports, on 14 December 2010, the Commission, noting that the first registration deadline had passed and that the substances DEHP, DBP and BBP were included in the draft Commission Regulation to be listed in Annex XIV to REACH, requested ECHA to complete the review reports and "*to assess whether there is at that stage a need for further actions on these three phthalates under REACH on the basis of the registration dossiers*".

Following the submission of Denmark in April 2011 of an Annex XV dossier for restriction regarding the risks from the presence of DEHP, DBP, BBP and DIBP in certain articles and the opinion of RAC, ECHA considered that a review of information coming from the registration dossiers has been performed within that restrictions process. The data available in the registration dossiers in the spring of 2011 were taken into account during the preparation of the Annex XV dossier by the dossier submitter and during the opinion-making process on the suggested restriction in that dossier. Following the opinion of RAC that "*the data available do not indicate that currently (2012) there is a risk from combined exposure to the four phthalates*" that restriction process has been terminated by the Commission by not amending Annex XVII to REACH and a Communication will be published reflecting this situation.

Furthermore, by means of Commission Regulation (EU) No 143/2011<sup>1</sup> and Regulation (EU) No 125/2012, the Commission included the four phthalates into Annex XIV to REACH. The applicants for authorisation need to provide in their applications exposure scenarios for the

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<sup>1</sup>Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 044, 18.2.2011, p.2).

use applied for and the subsequent life-cycle steps, which will allow an assessment of whether risks to human health are adequately controlled, including from the presence of the substances in articles as required by Article 69(2) of REACH.

Having taken all these developments into account, ECHA concluded in November 2013 that there is no need for further action under the specific review clause in entry 51, considering altogether the registration dossiers, the obligations under Annex XIV, and the ECHA obligation under Article 69 (2).

## **2) The Commission services' conclusions**

The Commission services agree with the abovementioned ECHA's conclusion. On this basis, the Commission services consider that the re-evaluation of entry 51 is completed and the existing restriction in entry 51 of Annex XVII 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.

Moreover, pursuant to Article 69(2) of REACH, ECHA has the obligation to consider after the "sunset date" (21 February 2015) whether the use of those phthalates in articles poses a risk to human health or the environment that is not adequately controlled. In fact, in anticipation of Article 69(2), the Commission has already asked ECHA to prepare by 1 April 2015 an analysis which conforms with the requirements of an Annex XV dossier for restriction, with the aim of assessing if the continued use of DEHP, DBP, BBP and DIBP in articles poses a risk, either individually or in combination, that is not adequately controlled and needs to be addressed.

## **3) Next steps**

The Commission services consider that the task called for by the review clause is fulfilled and therefore propose adoption of a technical amendment of Annex XVII to REACH, on the basis of Article 131 of REACH, inter alia, to repeal paragraph 3 of entry 51. The English version of the draft Regulation has been already distributed to the REACH Committee members on 20 May 2014.

This paper will also be available on DG Enterprise and Industry's website.