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(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

COMMUNICATION FROM THE COMMISSION

on the finalisation of the restriction process on the four phthalates (DEHP, DBP, BBP and DIBP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Text with EEA relevance)

(2014/C 260/01)

1. INTRODUCTION

On 14 April 2011, in accordance with Article 69(4) of Regulation (EC) No 1907/2006 [1] (REACH), Denmark submitted to the European Chemicals Agency (ECHA) an Annex XV dossier for a restriction proposal. The proposal was to restrict at EU level the placing on the market of articles intended for use indoors and articles that may come into direct contact with the skin or mucous membranes, which contain one or more of four phthalates in a concentration greater than 0,1 % by weight of any plasticised material. The four phthalates are the following: DEHP (bis (2-ethylhexyl) phthalate; CAS No 117-81-7; EC No 204-211-0); DBP (dibutyl phthalate; CAS No 84-74-2; EC No 201-557-4); BBP (benzyl butyl phthalate; CAS 85-68-7; EC No 201-622-7); DIBP (diisobutyl phthalate; CAS 84-69-5; EC 201-553-2). Denmark considered that due to the reproductive toxicity and endocrine-disrupting properties of those phthalates, their presence in articles and their combined exposure pose a risk to human health that is not adequately controlled and needs to be addressed at the EU level.

On 15 June 2012, in accordance with Article 70 of REACH, the ECHA Committee for Risk Assessment (RAC) adopted its opinion, by consensus, on the proposed restriction. In its opinion, RAC considered that the proposed restriction is not justified because the available data do not indicate that in 2012 there is a risk from combined exposure to the four phthalates. According to RAC, the existing regulatory requirements and consequent reduction in use are further reducing the exposure, as will the authorisation requirements imposed on these phthalates in the next few years.

On 5 December 2012, in accordance with Article 71 of REACH, the ECHA Committee for Socioeconomic Analysis (SEAC) adopted its opinion, by consensus, on the suggested restriction in which it concluded that it had no basis to support the proposed restriction. This conclusion is based on the RAC opinion described above.

On 19 December 2012, in accordance with Article 72 of REACH, ECHA submitted to the Commission the RAC and SEAC opinions.

Pursuant to Article 73(1) of REACH, if the conditions laid down in Article 68 are fulfilled, the Commission shall prepare a draft amendment to Annex XVII, within three months of receipt of the SEAC opinion.

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 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 (OJ L 396, 30.12.2006, p. 1).

The four phthalates are classified as reproductive toxicants category 1B under Annex VI to the CLP Regulation ([1]). Like other reproductive toxicants category 1B and in accordance with entry 30 of Annex XVII to REACH, the four phthalates cannot be placed on the market or used, as such, as constituents of other substances or in mixtures to be supplied to the general public when the concentration of one of these phthalates is greater to or equal to 0,3 %.

The use of three of these phthalates (DEHP, DBP and BBP) in toys and childcare articles is restricted by entry 51 of Annex XVII to REACH. In the frame of the review clause included in this entry, ECHA at the request of the Commission assessed in 2010 whether the entry should be modified, in the light of new scientific information. It was concluded ([2]) that the available new information on uses and exposure to those three phthalates did not bring a new perspective to the assessments already performed and used as a basis for those restrictions. It was also concluded that this new information did not indicate the need for an urgent re-examination of the existing restriction.

2. MAIN ELEMENTS CONSIDERED BY THE COMMISSION IN ITS EVALUATION

When concluding on whether the conditions laid down in Article 68 of REACH are fulfilled and a restriction justified, the Commission considered, in particular, the following elements of the restriction dossier and of the Committees' opinions.

First, it was difficult for RAC to conclude on the contribution of the four phthalates to the infertility problems and increases in hormone dependent cancers observed in humans. In fact, available epidemiology studies in human do not allow a conclusion to be drawn on a direct causal relationship between the effects investigated (mainly anti-androgenic) and the exposure to the four phthalates. On the other hand, RAC agreed that, based on animal data, several effects seemed to be linked to an anti-androgenic mode of action. The committee hence considered all those effects as relevant endpoints and selected the most sensitive of these effects for deriving the level of exposure to a substance above which humans should not be exposed (Derived No Effect Levels, DNELs). However, RAC considered that the derived DNELs were overestimated for certain reasons detailed in the opinion such as the use of conservative initial dose levels ([3]).

Second, in the exposure assessment, RAC evaluated the scenarios proposed in the restriction dossier where exposure to the phthalates contained in articles may result from direct contact with the articles and with dust and indoor air containing the four phthalates. Exposure from food intake was also included in the evaluation.

RAC considered the exposure estimates based on modelling provided in the restriction dossier as being very worst case and not reliable for several reasons detailed in its opinion. Therefore, the calculated Risk Characterisation Ratios (RCRs) from exposure to articles, from the indoor environment, and from food intake, were considered to be overestimated.

With the aim of getting a better representation of the total/combined levels of the four phthalates the population is exposed to, RAC considered the human biomonitoring studies made available in the Annex XV dossier for restriction and during the restriction process to derive exposure estimates. The exposure estimates calculated using those biomonitoring data resulted in combined RCRs for the four phthalates of 1,59 and 1,23 for child and adult respectively (reasonable worst case), which indicate a risk as being above 1. It was recognised by RAC that the biomonitoring data could lead to some underestimations of exposure, as the data were only available for a relatively small number of people, not covering all age groups and probably not reflecting the situation in the whole of Europe (as the data were available only from Germany and Denmark). However, RAC considered that, since the available biomonitoring studies were relating to samples taken before 2007, the exposure estimates were not reflecting the current situation and were overestimated in

([1]) Regulation (EC) No 1272/2008of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([2]) http://echa.europa.eu/documents/10162/13641/dehp_echa_review_report_2010_6_en.pdf; http://echa.europa.eu/documents/10162/13641/bbp_echa_review_report_2010_6_en.pdf; http://echa.europa.eu/documents/10162/13641/dbp_echa_review_report_2010_6_en.pdf.

([3]) NOAEL (No Observed Adverse Effect Level) or LOAEL (Lowest Observed Adverse Effect Level).

view of the implementation of the EU legislation on phthalates in food contact materials ([1]), in cosmetics ([2]) and in childcare articles and toys ([3]), that were expected to have decreased the exposure.

As indicated in the RAC opinion, between 2007 and 2010, there was a decrease of 40 % of the presence of the four phthalates in the EU produced articles, a decrease of 13 % of the presence of the four phthalates in imported articles into the EU, and a decrease of 35 % of the amount of the four phthalates in articles marketed in the EU. It was also noted that the calculated RCRs represent the result of exposure to all articles containing phthalates, including those that are not intended to be restricted by the proposal. RAC therefore concluded that the calculated RCRs above 1 were overall overestimations of the current situation.

Furthermore, RAC and SEAC noted that for many applications, the phasing out of the four phthalates and/or phthalates in general has already taken place, or is underway. In addition, based on a number of different scenarios, SEAC projected the amounts of the four phthalates in articles marketed in the EU for 2015 and 2020. Those projections indicated continued considerable decrease of the presence of the four phthalates in articles in the EU. On this basis, RAC concluded that the decrease in volume taking place will further reduce the exposure to a level which is of no concern to human health. SEAC was also of the opinion that the main drivers of substitution being the EU legislation – such as on the classification of the four phthalates as reproductive toxicants, the EU legislation restricting their use in toys and childcare articles as well as the EU legislation on plastic food contact materials – the substitution of the four phthalates with other plasticisers is expected to continue due to the inclusion of these phthalates in the candidate list of Substances of Very High Concern in accordance with Article 59 of REACH, and Annex XIV to REACH and the fact that a substitution plan must be provided when applying for an authorisation if there are suitable alternatives. Other market factors, such as trend of using non-phthalates plasticisers and uncertainties of long-term price and availability of phthalates feedstocks, support this trend of substitution.

In its opinion, SEAC noted that it could not carry out a proportionality assessment of the proposed restriction given the absence of relevant information in the Annex XV dossier for restriction and collected during the restriction process. There was neither a demonstration nor an assessment of the benefits of the proposed restriction related to possible reduced health impacts. The information available to SEAC did not allow for any assessment of potential environmental benefits of the proposed restriction. With regard to substitution costs to industry, SEAC found that prices of alternatives (including both phthalate and non-phthalate plasticisers) are generally in the range of 0 %-30 % higher. Limited information was available to SEAC with regard to reformulation and other relevant costs of substitution, given the wide variety of applications. Overall, SEAC estimated that alternatives are technically available at an affordable cost for the majority of applications. However, the proposed restriction may have an adverse economic impact on the PVC recycling sector or require more time and resources for substitution in certain sectors (e.g. aerospace industry). SEAC also noted that given the very wide scope of the proposal, it has not been demonstrated that the proposed restriction would actually be the most appropriate measure.

On 9 April and 12 July 2013, Denmark provided references to further information to the Commission, requesting that this information is considered by the Commission before taking a decision. The information referred to mainly focused on data from biomonitoring studies and on the presence of the four phthalates in imported articles. The Commission asked the ECHA Secretariat to conduct a preliminary evaluation of whether these data would be of a nature to challenge the RAC and SEAC opinions.

In its preliminary evaluation, the ECHA Secretariat concluded that on the basis of newly available biomonitoring data for the Danish population, the exposure in that Member State in 2011 was about half that of the values from 2007, therefore confirming the assumptions of a declining trend and the conclusions of RAC and SEAC. The biomonitoring data for the population from other EU Member States was, however, not publicly available. It was considered by ECHA as too preliminary (as not peer-reviewed) to be able to conduct a proper analysis and draw any firm conclusion, and to challenge the opinions of RAC and SEAC.

([1]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4) and Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

([2]) Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.9.1976, p. 169).

([3]) Directive 2005/84/EC of the European Parliament and of the Council of 14 December 2005 (OJ L 344, 27.12.2005, p. 40), currently under entry 51 of Annex XVII to REACH.

Furthermore, the ECHA Secretariat considered that the data and the additional considerations provided by Denmark on the presence of phthalates in imported articles do not allow drawing any different conclusion than those of RAC and SEAC. Although it might have been less steep than assumed by SEAC, the data do not contradict the assumption of RAC of a declining trend of the volume of phthalates in articles on the EU market, which seems to be confirmed by the preliminary evaluation made by ECHA on the biomonitoring data.

On the basis of the preliminary evaluation conducted by the ECHA Secretariat of the information referred to by Denmark in its correspondence of 9 April and 12 July 2013, the Commission considers that, given its limited availability and preliminary nature, these data do not constitute at this stage a sufficient basis to challenge the RAC and SEAC opinions.

3. **CONCLUSIONS**

Pursuant to Article 73(1) of REACH, the Commission considers that the conditions laid down in Article 68 are not fulfilled and did therefore not prepare a draft amendment to Annex XVII and did not seek for a final decision according to the procedure laid down in Article 73(2) of REACH.

REACH harmonises the conditions for or prohibition of the manufacture, use or placing on the market of chemical substances that went through the REACH Restriction process (Articles 69 to 73 of REACH). Therefore, once the restriction process is finalised, Member States should not maintain or introduce national restrictions different from those adopted at EU level addressing the risks assessed in the Annex XV restriction dossier.

In the present case of the four phthalates this means that, since the Commission decided not to adopt the proposed restriction at EU level, Member States should not maintain or introduce national restrictions that address the risks which were already evaluated during the EU restriction process.

The Commission recalls ECHA's obligation to consider, after the sunset date (21 February 2015) for the four phthalates listed in Annex XIV, whether the use of those phthalates in articles poses a risk to human health or the environment that is not adequately controlled, in accordance with Article 69(2) of REACH. This procedure would also accommodate the recommendation of RAC in its opinion to monitor the market trends, use patterns, body burden based on biomonitoring, content in and migration from articles.

The Commission considers that any newly available data, including new biomonitoring data, as referred to by Denmark in its submissions of 9 April and 12 July 2013, will be evaluated by ECHA under this procedure. The Commission will request ECHA to initiate this procedure already before the sunset date for these substances.

In case concerns arise whether other phthalates that are classified as reproductive toxicant 1A/B should be of concern or in case new scientific evidence indicates an unacceptable risk from the exposure to those four phthalates, the risk to human health arising from the total combined exposure to all classified phthalates could be assessed and could lead to a new restriction process according to Article 69 of REACH.