

ECHA, IN COOPERATION WITH THE DANISH EPA, PROPOSES RESTRICTION ON DEHP, DBP, DIBP, AND BBP IN ARTICLES

SUMMARY

The European Chemicals Agency (ECHA), in cooperation with the Danish Environmental Protection Agency (EPA), is proposing a restriction on articles which contain the four phthalates¹ in concentrations equal to or greater than 0.1% by weight. The work was initiated under Article 69 (2) of REACH.²

The public consultation on this proposed restriction will start on 15 June 2016 and end on 15 December 2016. However, the rapporteurs of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) would welcome early comments by 1 September 2016 to assist them in their opinion development.

SUGGESTED RESTRICTION

Scope

The proposal is to restrict the placing on the market of the following articles containing the four phthalates¹ in a concentration, individually or in combination, in excess of 0.1% w/w of the plasticised material:

- a) any (indoor or outdoor) articles whose phthalate containing material may be mouthed or is in prolonged contact with human skin or any contact with mucous membranes, and
- b) any phthalate containing articles that are used (including stored) in an indoor environment where people are present under normal and reasonably foreseeable conditions and potentially exposed via inhalation. This does not apply to articles that are used only in industrial or agricultural workplaces by workers.

The proposed restriction derogates:

- articles placed on the EU market prior to the application of the restriction (envisaged three years after entry into force, i.e., probably 2020);
- articles covered by existing legislation on: food contact materials,³ immediate packaging of medicinal products,⁴ medical devices;⁵
- toys and childcare articles containing DEHP, DBP and BBP as they are already covered under restriction entry 51 of Annex XVII of REACH but not those articles containing DIBP;⁶
- measuring devices for laboratory use.

¹ Bis(2-ethylhexyl) phthalate (DEHP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP) and Benzyl butyl phthalate (BBP)

² <http://echa.europa.eu/addressing-chemicals-of-concern/restriction/echas-activities-on-restrictions/more-information/echas-work-with-annex-xiv-substances>

³ Covered by Regulation (EC) No 1935/2004 and Regulation (EU) No 10/2011

⁴ Covered by Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC

⁵ Covered by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC

⁶ Covered by existing restriction entry 51 in Annex XVII of REACH.

The articles in scope of the restriction include mainly:

- flooring,
- coated fabrics and paper,
- recreational gear and equipment,
- mattresses,
- footwear,
- office supplies and equipment, and
- other articles moulded from or coated with plastic.

The scope of the proposed restriction made by ECHA and Denmark includes wires & cables as these articles can cause dermal exposure or release phthalates to indoor air and thus, contribute to cumulative exposure and risk of the four phthalates. However, the relevant Commission services (DG GROW and DG ENV) have requested that the ECHA's Committees (RAC and SEAC), when adopting their opinions, exclude electric and electronic equipment (EEE), as defined in Article 3(1) of RoHS, from the scope of the proposal to restrict these four phthalates under REACH. This is to avoid any possible future overlaps or inconsistencies with restrictions laid down in EU sector-specific legislation.

If data related to EEE as well as other sources such as food and food contact materials are submitted in the public consultation on the proposed restriction, RAC will take this information into account for the analysis of the cumulative risks. Stakeholders are also welcome to provide information on alternatives to the four phthalates in EEE as well as in food and food contact materials or other sources not identified in the proposed restriction.

Reasons for action

The four phthalates are considered as a group of substances; they are all classified as toxic to reproduction in category 1B and have a similar anti-androgenic mode of action. They all were recently confirmed as endocrine disruptors related to human health, and DEHP also for the environment, by ECHA's Member State Committee.

All four phthalates show effects on reproductive organs and fertility in experimental animals exposed prenatally. These effects are observed in and are relevant for male humans.

Based on the 95th percentile of combined exposure to the four phthalates, a risk is identified⁷ in all but one Member State for which sufficient biomonitoring data is available. The conclusion of the Dossier Submitter's examination of the risk from the four phthalates is that their use in articles is not adequately controlled and needs to be addressed on a Union-wide basis. The risks are for the general population exposed during the service life of the articles containing the four phthalates and male children are considered the most sensitive population. It is estimated that in 2014 about 5% of new born boys in the EU28 were at risk through exposure during pregnancy and about 15.5% (or 400 000 boys) were at risk from exposure during infancy and early childhood.

⁷ Risk Characterisation Ratios (RCRs) are greater than 1.

Consequences of the action

The proposed restriction is capable of significantly reducing the risks to human health of combined exposure within a reasonable period of time, starting from 2020, although with some delay caused by the service life of articles in use.

The annual benefits of the restriction can be measured in terms of avoided cases of male infertility, estimated at €9.8 million.⁸ Potential benefits related to avoided cryptorchidism and hypospadias cases in the EU as a result of the restriction have been estimated to be over €23 million annually. The restriction may also lead to other human health and environmental benefits but these have not been quantified.

The proposed restriction is a cost-effective measure to reduce risks of the four phthalates in articles. It is also anticipated to be affordable for the majority of stakeholders as technically feasible alternatives with lower risk are available at similar prices and substitution is already taking place on many markets.

SPECIFIC INFORMATION REQUESTED

In addition to support or criticism of the information in the Annex XV restriction report, questions on specific elements of the proposal that would benefit from additional information have been identified:

- Question 1: Do you think that the scope of the proposed restriction would exclude some articles, which may pose a risk to human health? If yes, please provide the necessary information to adapt the current cumulative risk assessment.
- Question 2: Do you have any information about the presence of DIBP in toys and childcare articles, such as content, exposure, and costs of replacing DIBP with a substitute?
- Question 3: Will suppliers, manufactures and retailers be able to sufficiently reduce their inventories of articles containing the four phthalates within 3 years of entry into force of the restriction (i.e., by 2020, assuming the proposed restriction enters into force by end of 2017)? Please provide specific information supporting your answer.
- Question 4: Could you provide information on the effects of the four phthalates on the immune function, in particular on in vivo (animal) studies and dose-response relationship? Although the restriction proposal is targeted at reproductive toxicity, further information on this endpoint could support the evaluation of the proposal.
- Question 5: Could you provide relevant information regarding human health and environmental impacts of the four phthalates? Although the restriction proposal is targeted at the socio-economic impacts from human reproductive toxicity, information on other impacts (i.e., significance and

⁸ Estimated using 4% discount rate or €19.6 million, using 2% discount rate.

magnitude of the environmental impacts on long term sustainability of aquatic ecosystems) could support the evaluation of the proposal.

In addition, please provide in the general remarks section any additional information concerning possible socio-economic impacts (costs and benefits) of the proposed restriction. Such information might include, for example, value of economic activity (in particular on the import in EU) related to the four phthalates, description of the concerned supply chains, impact on employment and SME, identification of possible safer alternatives (substances, processes or technologies) including the expected costs or economic benefits associated with such alternatives.

Comments preferably by 1 September 2016

The opinion making process of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 15 June 2016. Interested parties can comment on the proposed restriction report using the ECHA website. Although the public consultation concludes on 15 December 2016, RAC and SEAC would appreciate receiving comments by 1 September 2016 to assist them in the early opinion development process.

The final opinions of both Committees are scheduled to be available by 10 June 2017. ECHA will send these two opinions to the European Commission, which will take the decision whether to include the proposed restriction in Annex XVII of the REACH Regulation.

Further information on the purpose, objectives, and process of the public consultation on restriction proposals is available in the Public Consultation Guidance http://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf.