**Response to comments document (RCOM)**

on the Annex XV dossier

proposing restriction on

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

**Non-confidential**

**ECHA/RAC/RES-O-0000001412-86-140/F**

ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

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| Substance name | EC number | CAS number |
| Diisobutyl phthalate (DIBP),  Dibutyl phthalate (DBP),  Benzyl butyl phthalate (BBP),  Bis(2-ethylhexyl) phthalate (DEHP) | 201-553-2  201-557-4  201-622-7  204-211-0 | 84-69-5  84-74-2  85-68-7  117-81-7 |

### 16 March 2017

General Comments and answers to specific information requests

## Specific information requests:

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.
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?
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.
4. Could you provide information on the effects of the four phthalates on 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.
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 magnitude of the environmental impacts on long term sustainability of aquatic ecosystems) could support the evaluation of the proposal.

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| **Ref.** | **Date/type/Org.** | **Comments** |
| **1462** | **Date:** 2016/06/22 20:27  **Content:**  Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** Design Chain Associates, LLC  **Org. country:** United States | **Comment:**  This is purely an editorial comment. Table 1 currently says:  ii. Immediate packaging of medicinal products covered by Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC, or to medical devices covered by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC.  Packaging and medical devices should be split out into separate line items to improve clarity and readability, e.g.:  ii. Immediate packaging of medicinal products covered by Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC  iii. Medical devices covered by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC. |
| **Dossier submitter response:**  Thank you for your comment. The Dossier Submitter has addressed all comments on the wording of the proposed restriction from the Forum for Exchange of Information on Enforcement (Forum). |
| **RAC Rapporteurs comments:**  Thank you for your suggestion. It has been taken in the revised restriction wording. |
| **SEAC Rapporteurs comments:**  Thank you for the comment. We agree with the response provided by the Dossier Submitter. |
| **1468** | **Date:** 2016/08/04 14:24  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:** European Environmental Bureau (EEB)  **Org. country:** Belgium  **Attachment:** | **Comment:**  The EEB supports the restriction proposal of DEHP, BBP, DBP and DIBP in articles in order to reduce human and environmental exposure and their related adverse effects.  We consider that articles and materials for agriculture use, such as films, canvasses and irrigation and draining pipes and fittings should be included in the scope of the restriction as they may be an important source of these four phthalates to the environment and to man via the environment.  The four phthalates considered in this restriction have been identified as endocrine disrupters, and should therefore be considered non threshold substances during the risk characterisation.  We provide further information on the environmental effects of these four phthalates, showing that exposure to these substances causes long-term damage to various biological systems including endocrine and immune systems in invertebrates, fish, amphibians, mammals and birds.  Finally, we would like to express our surprise with the question regarding the ability of suppliers, manufactures and retailers to sufficiently reduce their inventories of articles containing the four phthalates within three years of entry into force of the restriction. The dossier concludes that 400,000 juvenile boys and 150,000 neonates were at risk in 2014. Should not the aim of the regulatory measure be to reduce as much as possible the risk, by avoiding the marketing of articles containing these substances as soon as possible? |
| **Answer to specific info request 1:**  We consider that articles and materials for agriculture use, such as films, canvasses and irrigation and draining pipes and fittings should be included in the scope of the restriction as they may be an important source of these four phthalates to the environment and to man via the environment. It is estimated that over 280,000 t of PVC was used in agriculture in Europe in 2004. If a low content of phthalates (15%) in these PVC articles is considered, this would represent a total use of 42,000 tonnes of phthalates in agriculture uses per year. |
| **Answer to specific info request 5:**  The proposal describes environmental effects of DEHP based on the ECHA background document (2014). Similar toxic mechanisms have been reported in the literature for other phthalates and evidence continues to accumulate as reflected in numerous recent publications. A small selection of recent publications (2015 and 2016) is presented here. Exposure to phthalates causes long-term damage to various biological systems including endocrine and immune systems in invertebrates, fish, amphibians, mammals and birds. Mathieu et al. reviewed effects of amongst others DEHP, BBP and DBP on thyroid hormone, growth hormone and reproduction in mammals, fish and amphibians (Gen. Comp. Endocrinol. 2015; Mathieu-Denoncourt et al.). Endocrine effects relating to changes in avian migration have been reported recently. Consequences of exposure to ED substances on migration success need further clarification as 40% of the migratory bird species are declining worldwide (Endocrine disruptors effects on wild life and human health (Abstract book) 2016; Morrissey). Effects of phthalates on the immune system of wild salmon in Alaska were reported in June 2016. Tissue phthalate levels, including DEHP and DBP, correlate with changes in immune gene expression in juvenile wild salmon in Alaska. The authors suggested that other marine species may be similarly affected by chronic phthalate exposure. (Arch. Environ. Contam. Toxicol. 2016; Martins et al.). The studies confirm that the phthalates induce effects to all levels of organisation in a wide range of wildlife. |
| **Dossier submitter response:**  Thank you for your comments and for your support of the restriction proposal, as well as for highlighting the need for addressing the concerns associated with exposure to the four phthalates as soon as possible, and therefore, for advocating a shorter transitional period.  During the formalisation of the restriction proposal, the Dossier submitter examined the effectiveness, practicality and monitorability of a potential restriction of articles containing the four phthalates for agricultural use together will all other articles containing the four phthalates. It was concluded that this restriction management option had lower benefit-cost ratio than the proposed restriction. Therefore, this restriction management option was not proposed.  The four phthalates indeed have endocrine disruptive properties (they are anti-androgens), as also acknowledged by the Member State Committee (MSC). However, to date they have not yet been formally identified as substances of equivalent concern on the basis of Article 57(f) for human health. The Dossier Submitter recognises that the existence of a threshold has not yet been assessed and documented for DEHP, DBP, DIBP and BBP and that this leads to uncertainties regarding the appropriateness of the derived DNELs.  The information you provided regarding environmental effects of phthalates has been incorporated in the dossier. |
| **RAC Rapporteurs comments:**  RAC agrees with the Dossier Submitter’s response and notes that the additional information you refer to has been addressed in the Background Document. RAC has no further comments. |
| **SEAC Rapporteurs comments:**  Thank you for the comment. The SEAC Rapporteurs assessed the restriction options as proposed by the Dossier Submitter. Regarding the environmental effects, SEAC recognizes the importance of the issue and has addressed it in the 3rd draft opinion. |
| **1470** | **Date:** 2016/08/30 14:41  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Other socio economic analysis (SEA) issues  **Type:** MemberState  **Country:**  Norway  **Attachment:** | **Comment:**  Comments from the Norwegian Environment Agency to ECHA/DK´s restriction proposal on DEHP, DBP, DIBP, and BBP in articles  The Norwegian CA would like to thank ECHA and the Danish CA for assessing the new information on the four phthalates and submitting the proposal for restriction. The evidence clearly demonstrates the need for restricting articles which contain the four phthalates in concentrations equal to or greater than 0.1% by weight. We note that the work was initiated under Article 69 (2) of REACH.  We fully support the restriction proposal, which we consider to be sufficiently justified. Recent biomonitoring data demonstrate a risk and we do not anticipate this risk to be reduced without restriction of imported articles. The use of the four phtalates is decreasing in EU/EEA today reflected in the data from our Product register, see table 1, the substances will still be present in imported articles. Our data show that the import of such articles have increased. We refer to the statistics we submitted to ECHA in the Call for Evidence last year, reproduced here in table 2. We do not have more recent data on this import until spring 2017.  Table 1: Net tons of DEHP, DBP, DIBP, and BBP registered in the Norwegian Product Register (NB! in chemicals, not articles). NB! Table provided in attachment.  Table 2: Import of cables, flooring, wall covering and roofing made of flexible PVC to Norway (NB! Table provided in attachment.  Page 15: 1.1.4.1.3 DIBP  The reasoning for concluding on a lower potency of DIBP than DBP is somewhat unclear, and we propose to use the same DNEL for both substances. This should be clarified further. We appreciate that the uncertainties for the DNEL-setting are thouroughly described in the report.  Page 23-27: 1.1.5.1.1 Exposure estimates based on biomonitoring data  The DS are aware of uncertainties in using biomonitoring data to estimate the total exposure to different phthalates. This has been explained clearly in this chapter.  • Uncertainty in using spot urine samples and 95th percentile for the worst case scenario (footnote 10 on page 24)  • Paragraph (1.1.5.1.3. Uncertainties in biomonitoring) discusses other uncertainties in using biomonitoring data.  Despite the uncertainties, comparing the exposure estimates from biomonitoring data (Table 7) to modelled estimates of aggregated exposure (Table 14) showed that the values are in the same range and are most likely not over estimated. We attach an updated table with results from the Norwegian Institute of Public health, see below. The table was submitted during the Call for evidence 2015, but has now been updated with the addition of two new publications; Stroemmen et al., 2016 (Environment International 89–90 (2016) 228–234), and Sabaredzovic et al. 2015 (Journal of Chromatography B, 1002 (2015) 343–352).  Table 3: Information on ongoing projects at the Norwegian Institute of Public Health (NIPH) where analyses have been accomplished and results are about to be published  (NB! Table provded in attachment) |
| **Answer to specific info request 1:**  The scope of the restriction and the specific wording of the legislative text will be scrutinised in the Forum working group where Norway participates, so we have no additional comments on this for now. |
| **Answer to specific info request 2:**  Norway participated in the PROSAFE project where toys intended for children under 3 years were checked. None of the 15 Norwegian plastic toys analysed for DIBP contained more than 0.1%. Please note that in some European countries the level of DIBP was above 0.1%, see the PROSAFE report: http://www.prosafe.org/index.php?option=com\_content&view=article&id=126&Itemid=628 |
| **Answer to specific info request 4:**  In a project on phthalates, an expert at the Norwegian Institute of Public Health recently went through the literature searching for phthalates studies with animal models relevant for asthma and allergy. This was done especially to investigate if the concentrations used in animal studies are relevant for human exposure. The following additional studies which could possibly be of interest for assessing the immune-toxicity of the phthalates were found, and the studies are described by the scientist accordingly:  "Overall, 34 animal studies were identified that included outcomes with relevance for asthma and allergy. DEHP was by far the most commonly applied phthalate (22 studies), while DnBP and BBzP were less common (10 and 4 studies, respectively). Although a range of animal studies report that phthalates exert adjuvant effects on airway and allergy related endpoints (reviewed in [1]), most studies use irrelevant exposure routes (subcutaneous or intraperitoneal injection) or doses far above human exposure levels (700 to 7000 µg/kg/day). With respect to studies assessing endpoints with relevance for atopic dermatitis, extreme exposures are also common. For instance, topical administration of a 50% phthalate and 50% FITC mixture or oral administration of 4000 to 6000 µg DEHP /kg/day have been used [2, 3, 5, 6]. In spite of their limitations, these studies do serve a function in terms of ‘proof of principle’, since they demonstrate that phthalates can induce aggravation of allergen- or hapten-induced effects in animal models.  Three studies reported effects of DEHP doses with relevance for human environmental exposure. In two studies, oral administrations from 30 µg/kg/day induced adjuvant effects, including increased IgE and histopathological changes in the airways in a dose dependent manner [7,8]. In the third study, nasal instillation of DEHP from 0.36 µg/kg/day increased IL-13 levels, but no significant adjuvant effects were detected [4]. No studies were identified reporting effects of relevant doses of phthalates in other model systems relevant for allergic or airway outcomes. Moreover, there was insufficient data to conclude with regard to the relative potency of phthalates to induce adjuvant effects, since few studies included more than one phthalate. In conclusion, there is need for more studies using relevant doses and endpoints to support the current epidemiological data, which suggests an association between phthalate exposure and asthma and allergy.  References:  [1] Bornehag CG, Nanberg E. Phthalate exposure and asthma in children. International journal of andrology 2010;33(2):333-45.  [2] Li J, Li L, Zuo H, Ke C, Yan B, Wen H, et al. T-helper type-2 contact hypersensitivity of Balb/c mice aggravated by dibutyl phthalate via long-term dermal exposure. PLoS One 2014;9(2):e87887.  [3] Sadakane K, Ichinose T, Takano H, Yanagisawa R, Koike E. Effects of oral administration of di-(2-ethylhexyl) and diisononyl phthalates on atopic dermatitis in NC/Nga mice. Immunopharmacol Immunotoxicol 2014;36(1):61-9.  [4] He M, Inoue K, Yoshida S, Tanaka M, Takano H, Sun G, et al. Effects of airway exposure to di-(2-ethylhexyl) phthalate on allergic rhinitis. Immunopharmacol Immunotoxicol 2013;35(3):390-5.  [5] Takano H, Yanagisawa R, Inoue K, Ichinose T, Sadakane K, Yoshikawa T. Di-(2-ethylhexyl) phthalate enhances atopic dermatitis-like skin lesions in mice. Environ Health Perspect 2006;114(8):1266-9.  [6] Imai Y, Kondo A, Iizuka H, Maruyama T, Kurohane K. Effects of phthalate esters on the sensitization phase of contact hypersensitivity induced by fluorescein isothiocyanate. Clin Exp Allergy 2006;36(11):1462-8.  [7] Guo J, Han B, Qin L, Li B, You H, Yang J, et al. Pulmonary toxicity and adjuvant effect of di-(2-exylhexyl) phthalate in ovalbumin-immunized BALB/c mice. PLoS One 2012;7(6):e39008. (NB! This study is already listed in the References in the restriction appendix)  [8] Han Y, Wang X, Chen G, Xu G, Liu X, Zhu W, et al. Di-(2-ethylhexyl) phthalate adjuvantly induces imbalanced humoral immunity in ovalbumin-sensitized BALB/c mice ascribing to T follicular helper cells hyperfunction. Toxicology 2014;324:88-97. doi: 10.1016/j.tox.2014.07.011. Epub;2014 Aug 2:88-97." |
| **Dossier submitter response:**  Thank you for your comments and for your support for the restriction proposal.  The Background Document acknowledges that the potency difference assumed for DIBP in comparison to DBP is uncertain. A sensitivity scenario has been included in section B.9.3 of the  Background Document to show the effect on the RCRs when it is assumed that the DNELs for all four phthalates are equal to the DNEL of DBP (6.7 µg/kg bw/day).  The information you provided on immunotoxicity, biomonitoring (Sabaredzovic et al. 2015; Strømmen et al. 2016), food (Sakhi et al. 2014), DIBP use in toys and childcare articles, and data from the Product register and on imported articles have been incorporated in the Background Document. |
| **RAC Rapporteurs comments:**  Thank you for the additional information provided, in particular on immunotoxicity. RAC shares your view that the available data on this endpoint indicate that phthalate exposure could lead to immunological disorders (allergy, asthma and eczema), possibly even at levels lower than reproductive toxicity. But like you RAC thinks there is a need for more robust data, in order to take effects on the immune system into consideration for quantitative risk assessment.  As to whether DIBP is equipotent to DBP or slightly less potent is indeed a point of uncertainty. Both options have therefore been considered in the Background Document. See also section B.1.2.4 of the opinion. |
| **SEAC Rapporteurs comments:**  Thank you for the comment. No action needed on behalf of SEAC. |
| **1471** | **Date:** 2016/08/31 07:22  **Content:** Scope or restriction option analysis;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** JEITA  **Org. country:** Japan  **Attachment:** | **Comment:**  We believe that the EEE covered by RoHS Directive should be clearly exempted from the scope of possible future restriction under REACH in the same way of current paragraph 8 (k) of entry 63, as follows:  “Paragraph 1 and 2 shall not apply to articles covered under existing legislation:  ...  iv electrical and electronic equipment within the scope of Directive 2011/65/EU.”  Justification:  1. Double-regulation should be avoided in line with the concept of “Better Regulation”  As you have very well known, the electrical and electronic equipments (hereinafter “EEE”) are already covered under RoHS Directive 2011/65/EU. The four phthalates (DEHP, BBP, DBP and DIBP) are to be strictly restricted by Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU .  We feel serious concern about possible double-regulation by REACH and RoHS recently. There is no exemption for EEE under RoHS, though RoHS will restrict 4 phthalate from 2019. Both requirements are slightly different, however, we believe that the restriction of EEE under RoHS would be reasonable from the point of view on the risk.  The reasons why RoHS is not exempted from proposed restriction seem to be, in short, as follows:  1) restriction by combination of 4 phthalates are not covered by RoHS (therefore, requirement under REACH would be tighter than RoHS) ; and  2) by restricting these substances under REACH, the exclusions (such as spare parts for existing EEE) and future possible exemptions under RoHS become impossible to apply, in spite of existing RoHS law text.  We have serious concern on its logic in itself. This seems to be opposite against “better regulation”. If the future proposals on substances restricted under RoHS are in line with this logic, any exclusions and exemptions might be made invalid by REACH restriction proposed later. If such non-sense is allowed, what is the raison d' être for RoHS?  According to the “Information note on restriction　report ” provided in this consultation, “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.”  This request should be carefully considered. We completely agree with it because these DGs view is plainly reasonable.  We believe that restriction on four phthalates under RoHS Directive is adequately set as shown below. Even if ECHA considers that these phthalates EEE should be restricted at the same wording of proposed REACH restriction, such proposal for EEE should be discussed under RoHS Directive but not REACH in order to avoid double-regulation.  2. Restriction on four phthalates under RoHS Directive is adequately set.  The Directive restricts these phthalates in all EEE covered under RoHS Directive 2011/65/EU with maximum tolerable value of 0.1% in “homogenous material”, and currently there is no application exempted from the restriction. The EEE industry has already prepared to comply with the new restriction under the RoHS Directive. These phthalates are individually restricted under the RoHS Directive, however, the denominator of RoHS is strictly defined, and we believe the restriction under RoHS would never be weaker than this proposal under REACH.  According to Article 6(2) of RoHS Directive 2011/65/EU, the dossier for proposal must contain following items:  (a) precise and clear wording of the proposed restriction;  (b) references and scientific evidence for the restriction;  (c) information on the use of the substance or the group of similar substances in EEE;  (d) information on detrimental effects and exposure in particular during waste EEE management operations;  (e) information on possible substitutes and other alternatives, their availability and reliability;  (f) justification for considering a Union-wide restriction as the most appropriate measure;  (g) socioeconomic assessment.  Especially, by the requirement for the items (b) and (f) above, dossiers for restriction proposal for four phthalates contain risk-assessment, by taking the item (d) on waste EEE management operations into consideration, which is beyond REACH.  RoHS restriction dossiers on four phthalates are as follows:  - ROHS ANNEX II DOSSIER FOR DEHP (January 2014)  http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex6\_RoHS\_AnnexII\_Dossier\_DEHP.pdf  - ROHS ANNEX II DOSSIER FOR BBP (January 2014)  http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex7\_RoHS\_AnnexII\_Dossier\_BBP.pdf  - ROHS ANNEX II DOSSIER FOR DBP (January 2014)  http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex8\_RoHS\_AnnexII\_Dossier\_DBP.pdf  - ROHS Annex II Dossier for DIBP:Proposal for restriction of a substance in electrical and electronic substances under RoHS Final Version May 2014  http://rohs.exemptions.oeko.info/fileadmin/user\_upload/reports/20140520\_DIBP\_AnnexII\_Dossier\_final.pdf  Each dossier subscribes hazard on human and environment, then, analyses the possibility of exposure. Based on these processes, for example, DEHP dossier concludes as follows:  “The proposed maximum concentration value of DEHP to be tolerated in EEE is 0.1 weight % per homogenous material. Given the level of risk identified when assuming a DEHP concentration in PVC of a few % it can be expected that a maximum concentration of 0.1 weight % will lead to significantly reduced risks.”  We believe these conclusions would be appropriate for control of the risks presented by these phthalates in EEE throughout the lifecycle and also in end-of- life phase.  3. Consideration on “Common understanding of REACH vs RoHS”  According to “Common understanding of REACH vs RoHS in CARACAL, CA/36/2014” and as described in A.1 of “REACH AND DIRECTIVE 2011/65/EU (RoHS) A COMMON UNDERSTANDING” published in July 2014,  http://ec.europa.eu/DocsRoom/documents/5804/attachments/1/translations/en/renditions/native  following issue should be considered to avoid double-regulation when proposing a restriction under REACH for a substance already in RoHS:  “The simplest way to avoid duplications and/or inconsistencies for a given substance already included in RoHS is, to exclude EEE within the scope of RoHS from the scope of a proposed REACH restriction also covering EEE. This approach was adopted for Diphenylether, octabromo derivative (entry 45 of Annex XVII to REACH). It avoids the problem described in the REACH review, relating to the use of cadmium in electrical contacts (entry 23.7.) where both instruments cover the same substance and applications but slightly differently.”  In current case, following question would be the key.  “The question therefore is whether RoHS can be considered to afford adequate control of the risks presented by the substance in EEE throughout the lifecycle of the product such that those risks do not need to be addressed under REACH.”  As mentioned above, restriction under RoHS has been set according to the proper assessment and is not weaker than proposed restriction under REACH, though there are slight differences between restriction wordings. Therefore, additional redundant restriction under REACH would never be needed for electrical and electronic equipment within the scope of Directive 2011/65/EU.  We have serious concern about the useless confusion in the worst case where such additional restriction with different MCV, exemptions or denominator from those under RoHS would appear for EEE in future in this situation.  If every insignificant difference leads to double-regulation by later-proposed REACH restriction, we are forced to doubt about the effectiveness of RoHS Directive. We afraid that such situation may demoralise the EEE industry which has faithfully taken measures to control substances in products. |
| **Answer to specific info request 1:**  We never think the scope of the proposed restriction would exclude some articles which may pose a risk to human health. However, in spite of the above question, there is no checkbox stating "we don't think so". Isn't this a kind of leading question? We feel concern about the equity of the question. Please see our general comment and the attachment. |
| **Answer to specific info request 3:**  As you have very well known, the electrical and electronic equipments (hereinafter “EEE”) are already covered under RoHS Directive 2011/65/EU. The four phthalates (DEHP, BBP, DBP and DIBP) are to be strictly restricted by Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU. EEE industry and its suppliers have faithfully started to prepare and take measures to control substances in four phthalates according to RoHS Directive, not REACH. Such preparation may include collecting evidence and analysing parts with high concern. RoHS restriction of 4 phthalates will be applied to most of EEE from July 22, 2019, but many EE manufacturers plan to finish the preparation for compliance beforehand so that management through supply-chain would have certainly taken effect at the date starting restriction. Restriction under REACH would come after or around that date, and it may force unnecessary additional cost and burden on the EE industry in addition to the compliance to RoHS. We seriously feel concern about such unacceptable situation for the industry. If every insignificant difference leads to double-regulation by later-proposed REACH restriction, we are forced to doubt about the effectiveness of RoHS Directive. We afraid that such situation may deeply demoralise the EE industry. |
| **Answer to specific info request 5:**  According to Article 6(2) of RoHS Directive 2011/65/EU, the dossier for proposal of restriction of a substance must contain following items:  (a) precise and clear wording of the proposed restriction;  (b) references and scientific evidence for the restriction;  (c) information on the use of the substance or the group of similar substances in EEE;  (d) information on detrimental effects and exposure in particular during waste EEE management operations;  (e) information on possible substitutes and other alternatives, their availability and reliability;  (f) justification for considering a Union-wide restriction as the most appropriate measure;  (g) socioeconomic assessment.  Especially, by the requirement for the items (b) and (f) above, dossiers for restriction proposal for four phthalates contain risk-assessment, by taking the item (d) on waste EEE management operations into consideration, which is beyond REACH.  RoHS restriction dossiers on four phthalates are as follows:  - ROHS ANNEX II DOSSIER FOR DEHP (January 2014)  http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex6\_RoHS\_AnnexII\_Dossier\_DEHP.pdf  - ROHS ANNEX II DOSSIER FOR BBP (January 2014)  http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex7\_RoHS\_AnnexII\_Dossier\_BBP.pdf  - ROHS ANNEX II DOSSIER FOR DBP (January 2014)  http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex8\_RoHS\_AnnexII\_Dossier\_DBP.pdf  - ROHS Annex II Dossier for DIBP:Proposal for restriction of a substance in electrical and electronic substances under RoHS Final Version May 2014  http://rohs.exemptions.oeko.info/fileadmin/user\_upload/reports/20140520\_DIBP\_AnnexII\_Dossier\_final.pdf  Each dossier subscribes hazard on human and environment, then, analyses the possibility of exposure. Based on these processes, for example, DEHP dossier concludes as follows:  “The proposed maximum concentration value of DEHP to be tolerated in EEE is 0.1 weight % per homogenous material. Given the level of risk identified when assuming a DEHP concentration in PVC of a few % it can be expected that a maximum concentration of 0.1 weight % will lead to significantly reduced risks.”  We believe these conclusions would be appropriate for control of the risks presented by these phthalates in EEE throughout the lifecycle and also in end-of- life phase. |
| **Dossier submitter response:**  Thank you for your comments. The scope of the proposed restriction has been adjusted to clearly exclude the articles covered under the RoHS Directive. |
| **RAC Rapporteurs comments:**  No further comments. |
| **SEAC Rapporteurs comments:**  Thank you for the comment. SEAC agrees for the RoHS Directive to be derogated from scope of the proposed restriction. |
| **1472** | **Date:** 2016/08/31 10:29  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Description of analytical methods;  Information on costs  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Japan Plasticizers Industry Association  **Org. country:** Japan  **Attachment:** | **Comment:**  JPIA is an industry group consisting of Japanese enterprises manufacturing and marketing plasticizers.  Concerning the four phthalate-based chemicals (DEHP, a principal plasticizer manufactured in Japan and mainly used for soft PVC molded articles, DBP, BBP and DIBP), ECHA has proposed its restrictions for articles 1st April 2016.  We, JPIA, are unable to agree with the restriction proposal for the four phthalates in the EU because of the following reasons, which are shown in this context below in detail, and JPIA requires immediate withdrawal, or scope reduction of the restriction proposal. |
| **Answer to specific info request 1:**  No. We do not think so. The scope is overly wide. Strict observation of the Restriction for Toy and Food contact material should reduce exposure level below TDI. |
| **Answer to specific info request 5:**  See 6 attached for the JPIA positions. |
| **Dossier submitter response:**  Thank you for your comments. Please see Dossier Submitter’s response to the later, nearly identical, comment number 1494 submitted jointly by Japan Plasticizers Industry Association and China Plasticizers Industry Association. |
| **RAC Rapporteurs comments:**  Please see the RAC comments to comment number 1494. |
| **SEAC Rapporteurs comments:**  Thank you for the comment. Please see the SEAC comments to comment number 1494. |
| **1473** | **Date:** 2016/08/31 13:43  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Baseline;  Information on alternatives;  Information on costs;  Information on benefits;  Other socio economic analysis (SEA) issues;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** DEZA, a.s.  **Org. country:** Czech Republic  **Attachment:** | **Comment:**  Please note that attached document contains DEZA’s initial overarching comments on key issues within the restriction report. DEZA will be submitting more detailed scientific observations in line with the 2nd deadline for comments in December 2016. |
| **Answer to specific info request 1:**  please read the attached document |
| **Answer to specific info request 2:**  information will be submitted at later stage (within deadline for public consultation) |
| **Answer to specific info request 3:**  please read the attached document |
| **Answer to specific info request 4:**  information will be submitted at later stage (within deadline for public consultation) |
| **Answer to specific info request 5:**  please read the attached document |
| **Dossier submitter response:**  Thank you for your comments.  1) The ECHA guidance on Annex XV for restrictions clarifies that the basis to ‘identify a risk’ is the current exposure and the current risk (e.g. point 5.2.3). However, in order to evaluate the risk reduction capacity, and to be able to weigh benefits against costs of a restriction, the Dossier Submitter undertook to estimate future risks on the basis of informed assumptions, including related to the declining use of the four phthalates as a result of authorisation requirements under Title VII of REACH and other regulatory and market trend (see section 2.3.1. in Background document).  In June 2016, RAC and SEAC agreed the dossier is in compliance with the requirements of the REACH Regulation.  2) An RCR at or above 1 at the 95th percentile of exposure in 2039 in 6 Member States out of 15 is considered to be an EU-wide risk (40% of Member States). In addition, it has been shown that in fact in all Member States there is a fraction of the population that may be at risk (high percentiles of exposure). Furthermore, it is stressed that uncertainties point towards higher risk levels. The assessment concluded that the proposed restriction is capable of reducing the risks to human health of combined exposure significantly (RCRs are expected to be reduced to levels equal to or below 1 at the 95th percentile) within a reasonable period of time, starting from 2020, although with some delay caused by the service-life of articles still in use.  3) Under Article 69(2) of REACH, ECHA is required to assess if use of DEHP, DBP, BBP and DIBP in articles poses a risk to human health or the environment that is not adequately controlled, and if not, to prepare a restriction proposal under REACH. The Dossier Submitter agrees that the contribution of food consumption to exposure to the four phthalates is important, especially for DEHP. The Dossier Submitter decided to exclude food contact materials from the scope of the proposed restriction on the grounds that a sector-specific legislation would lead to more efficient use of regulatory resources and would lead to improved clarity to stakeholders. Therefore, in addition to the proposed restriction, the Dossier Submitter encourages the relevant authorities in the EU to take the necessary measures to reduce the risks relating to the four phthalates from food consumption.  4) From one of the most commonly used plasticiser, today DEHP is accountable for a small portion of plasticiser use in the EU. Market information shows that there are a number of alternatives technically and economically feasible to replace DEHP use in the articles in scope. (See Annex D) Recognising that some downstream users may need time to transition to the alternatives and the proposed review period for applications for authorisation, the Dossier Submitter proposes three year transitional period for the restriction after its entry into force. The Dossier Submitter has also considered the need for (time limited) derogations when stakeholders have outlined a specific use where the transition would require additional time due to certification or other requirements. The dossier also acknowledged that there are uncertainties with respect to the hazard profile of the alternatives (i.e., table D7 identify that DPHP, DEHA, TOTM, DEGD and DGD are on CoRAP.)  5) The confidential version of the dossier made available to RAC and SEAC provide detailed market information which demonstrates that variety of alternatives are available in sufficient quantities. Publicly available information supports these conclusions: For example, two public sources indicate of the expanding capacity for DEHT for example on the EU market in addition to the information in the applications for authorisation: The Background Document refers to announcement by Zakłady Azotowe Kędzierzyn S.A. (a.k.a., ZAK, one of the applicants for authorisation) in 2012 to produce DEHT[[1]](#footnote-1) and by Oxea in 2014 to increase of its European capacity by 50,000 tonnes by end of 2015 “in order to meet strongly growing customer demand”.[[2]](#footnote-2) (See Annex D)  6) The Dossier Submitter concludes on the research & development, reformulation, plant and process modification costs on the basis of: i) substantial substitution of the four phthalates has already occurred in the EU and internationally, which indicates that industry has high degree of familiarity with the ability to transition to alternatives; ii) Drop-in alternatives to the four phthalates are available, iii) no information has been provided in consultations for previous regulatory actions that indicate that these costs are substantial for industry or that enable quantification of these costs. These conclusions also take into account information provided in the applications for authorisation.  Table D11 shows that the Dossier Submitter assumes cost differentials between DEHP and its main alternatives in the main scenario. These are varied for sensitivity purposes (see Annex E) but cost difference between the four phthalates and its alternatives is assumed also in the low cost scenario. These scenarios are consistent with recent pricing information available on alternatives. The Dossier Submitter takes the point of the aggregated nature of the plasticiser market and the aggressive pricing strategies that can be pursued by manufacturers in such markets and has incorporated it in the Background Document. We point out, however, that the market for DEHP in the EU is also highly aggregated with only two manufacturers applying for authorisation, one of which has already announced their intention to manufacture an alternative.[[3]](#footnote-3)  We thank you for pointing out inconsistency on p.63 of the submitted dossier and its Annex D. The statement has been edited.  7) The Dossier Submitter provides evidence in the Background Document in terms of historical market trends, current and projected availability of the various alternatives, and the projected tonnes of DEHP to be impacted by the restriction, that the three year transitional period for the proposed restriction will be sufficient to transition to the alternatives. The Dossier Submitter has also considered the need for (time limited) derogations when stakeholders have outlined a specific use where the transition would require additional time due to certification or other requirements. The recommended transitional period takes into account the recommended review period for the applications for authorisation[[4]](#footnote-4) on the uses of DEHP which fall in the scope of this proposal. (See sections 2.2.1 and 2.3.1) The impact of the restriction on articles outside its scope are discussed in “Impacts on articles outside the scope of the restriction” in the Background Document and Annex D, where issues such as economies of scale and mixed product lines are noted.  8) The Dossier Submitter reflected in the Background Document your point that SMEs are more likely to have limited production lines and therefore, are less likely to shift away from DEHP as a general purpose plasticiser due to its advantages in diverse applications. However, it is noted that there are other general purpose plasticisers which have been shown to be technically feasible across diverse applications (e.g., DINP, DEHT) at similar prices. Furthermore, the industry’s long-term experience with substitution, long-standing knowledge of regulatory action on the four phthalates, substantial share of DEHP use remaining outside the scope, etc. will facilitate the transition to alternatives within the proposed three-year transitional period. (See section SME impacts in Background Document and its Annex D)  9) The data provided by EuPC also includes anticipated impacts of the proposed restriction on integrated recyclers and independent article manufacturers using recycled materials.  10) The human health impact calculations take into account the possibility that the majority of DEHP tonnages are substituted by DINP. The Background Document was edited to make this clearer.  The commenter asserts that a break-even 7% infertility incidence in the population at risk appears unrealistic. Section 2.8.3 of the report states that: “To justify the restriction on a cost-benefit basis, it is necessary for the restriction to prevent about 3 655 cases of male infertility annually. This represents about 0.1% of the average annual male births projected in the EU28 or less than 7% of the population at risk due to foetal exposure or about 2% of the population at risk due to infant and early childhood exposure.” and “Taking into account other health impacts that are associated with exposure to phthalates, to justify the restriction on a cost-benefit basis, it is necessary for the restriction to prevent about 2 110 cases of male infertility (mid-point estimate for male infertility) and 250 cases of cryptorchidism or 420 cases of hypospadias. This is less than 5% of the population at risk due to foetal exposure or less than 1.5% of the population at risk due to infancy and early childhood exposure”. Table D25 shows the combination of cases of the three health outcomes the proposed restriction needs to avoid for the monetised benefits of the restriction to exceed the costs. They represent 5% or less from the population at risk due to foetal exposure or 1.5% of less of the population at risk due to foetal and early childhood exposure or less than 0.1% of all annual male births in the EU. However, it is important to differentiate between the population at risk and the entire population of male children born in the EU. The population at risk was estimated based on the number of live births in each EU28 country and the geometric mean and 95th percentile RCR values projected for 2030. The number of boys at risk due to foetal exposure is estimated to be 1.1 million boys over a time span of 20 years (2.1% of all new born boys). Although the foetus is thought to be more sensitive to the effects of the four phthalates, children are among the sensitive population because of their developing reproductive system. Using the exposure values from children, 3.5 million boys over a time span of 20 years (6.8% of new born boys) are estimated to be at risk. As mentioned above, in fact in all Member States there is a fraction of the population that may be at risk and uncertainties point towards higher risk levels which means that the percentage may be underestimated rather than overestimated. See section 2.6.1 for further information on population at risk.  11) Thank you for your recommendations. We address them in the points above. We noted your support for a restriction on DBP, DIBP and BBP. |
| **RAC Rapporteurs comments:**  RAC supports the responses given by the Dossier Submitter. Some additional comments include:  1) RAC does not consider the basis of the restriction proposal outdated as the basis for the risk assessment is the most recently available, large scale biomonitoring study (i.e., the DEMOCOPHES data from 2011-2012) **plus** informed assumptions (including related to the declining use of the four phthalates as a result of authorisation requirements) translating the 2011-2012 data in present day risks (i.e. 2014/2015, when drafting the Annex XV dossier).  2) There is no reason to assume that the situation in the Member States that did not participate in the DEMOCOPHES project would be very different from the Member States that partipated. Therefore, it is to be expected that without a restriction in place, the number of Member States with an RCR ≥1 in 2039 will certainly be higher than “only” 6.  3) Although RAC notes the important contribution of food consumption to exposure to the four phthalates, addressing the risks solely through the existing FCM legislation is not considered the best option. One reason is that it is not clear what the contribution of FCMs is to the exposure via food, relative to other sources. Another reason is that the FCM regulation does not consider the overall phthalate burden from repeated contact with FCMs or combined effects from other sources of exposure. But RAC certainly encourages the relevant authorities in the EU to take the necessary measures to reduce the risks relating to the four phthalates from food consumption, however as an additional measure to the proposed restriction. |
| **SEAC Rapporteurs comments:**  Thank you for your information. The SEAC Rapporteurs agree with the responses by the Dossier Submitter, and make further comments:   * Your comments on availability and cost of alternatives have been taken into account, and SEAC carried out a sensitivity analysis to calculate the materials substitution costs in case more stakeholderes would need to use more expensive alternatives. * Regarding the quantification of human health damage costs/benefits SEAC agrees that comparison of break-even percentages with percentage of the population at risk is difficult. However, also comparing the percentage of break-even cases to the prevalence of infertility attributed to phthalates in a recent publication, SEAC found that the break-even analysis is supporting the conclusion that the proposed restriction is proportionate. |
| **1474** | **Date:** 2016/08/31 15:58  **Content:** Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. name:** Danish Working Environment Authority  **Org. country:** Denmark  **Attachment:** | **Comment:**  Please read the attached file |
| **Dossier submitter response:**  Thank you for your comment. The Dossier Submitter has addressed all comments on the wording of the proposed restriction from the Forum for Exchange of Information on Enforcement (Forum), including your comment on the definition of “agricultural workplaces”. Professional uses of the substances are not derogated per se and if the articles meet the requirements in paragraphs 1 to 4 of the revised wording, these would be in the scope of the restriction. |
| **RAC Rapporteurs comments:**  No further comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. SEAC concurs with the new wording that clarifies the definition of ''agricultural workplaces''. |
| **1475** | **Date:** 2016/08/31 18:21  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Description of analytical methods  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** ECPI (European Council for Plasticisers and Intermediates  **Org. country:** Belgium  **Attachment:** | **Comment:**  CPI comments on the Annex XV Restriction Report – Proposal for a Restriction – Substance names: Four phthalates (DEHP, BBP, DBP, DIBP)  Summary of comments  The screening level risk assessment approach employed in the Annex XV proposal for a Restriction of four phthalates (DEHP, BBP, DBP, DIBP), which relied upon worst-case input parameters for hazard and exposure, does not reasonably demonstrate a risk from combined exposure to DEHP, BBP, DBP, DIBP. Taking into account the failure to demonstrate a risk from combined exposure, coupled with the observation of reduced exposure over time to these phthalates and an anticipated continuous reduction in exposure due to existing and pending regulatory requirements ECPI concludes there is no risk assessment basis which supports that a restriction is necessary.  With respect to DEHP, RAC and SEAC have recommended Authorisation in flexible PVC compounding and article manufacture (the recycling of PVC made with DEHP has also been recommended for Authorisation by RAC and SEAC with adoption by the European Commission and Member States “REACH Committee” in 2016). In the RAC opinion on Authorisation it was stated that the use of flexible PVC articles made with DEHP pose no risks to the general population. From a regulatory perspective ECPI understands the logic that restrictions should now be proposed for non-Authorised uses. This creates a level playing field for EU manufacturers of articles made with DEHP compared to non-EU manufacturers of articles made with DEHP (where non-EU producers and users of DEHP are not subject to Authorisation). ECPI therefore agrees with restrictions under REACH for uses of DEHP which have not been subject to the Authorisation recommendation – it should be clear though that any restrictions should be limited to such non-Authorised uses only. |
| **Answer to specific info request 4:**  Kimber I et al, Toxicol 2010,271,38-82 |
| **Answer to specific info request 5:**  please refer to attached document |
| **Dossier submitter response:**  Thank you for your comments. We noted your support for a restriction on DEHP for non-Authorised uses in order to create a level playing field for EU manufacturers of articles vis-à-vis non-EU manufacturers.  The DEMOCOPHES biomonitoring data that is one of the key new elements in the restriction proposal was not available in 2011. The adjustment of the baseline is based on new information and balanced assumptions as well as more concrete knowledge regarding the impact of applications for authorisation.  1. Based on Meek et al. (2011), the risk assessment can be considered to be a Tier 2 or Tier 3 assessment (the highest tier possible) rather than a screening assessment as asserted by the commenter: to estimate exposure recent large scale biomonitoring data was used with additional (partly probabilistic) modelling in support; DNEL setting builds on an in-depth assessment of a large number of studies in several EU risk assessments, subsequent risk assessments as well as opinions of scientific bodies, and includes refined information on mode of action, potency and species differences; and the population at risk is estimated using the exposure distribution in the population (from biomonitoring). It is a misinterpretation that the tiered system would be designed to continue iterations and use of resources until the point that there is not anymore a concern.  The commenter refers to Meek et al. (2011) to support the statement that the hazard index approach would be unsophisticated. Meek et al. (2011) summarise the WHO/IPCS framework for risk assessment of combined exposure to multiple chemicals and state “In this framework, dose additivity is the default assumption for estimating risk in **all** tiers” (emphasis added). Thus, regardless of the Tier level of assessment, dose addition is an appropriate assumption under the WHO/IPCS framework. Meek et al. (2011) acknowledge that *for chemicals* *in general* dose addition may be a conservative assumption since chemicals may act by different modes of action, but in the case of the four phthalates the evidence that they are anti-androgenic as a result of inhibition of fetal testosterone production in the rat is overwhelming, i.e., all four phthalates follow the same mode of action. Moreover, in the case of phthalates there is actual substance specific experimental data that provides strong evidence that dose-addition accurately predicts effects from combined exposure (Hannas et al. 2011; Howdeshell et al. 2008; Howdeshell et al. 2015). Lastly, dose addition is the accepted approach by other regulatory scientists (e.g. CHAP 2014; Health Canada 2015). Therefore, the Dossier Submitter rejects the statement that the hazard index approach would be unsophisticated.  The commenter refers to Table 18 of the original submission to support that the *modelling* would be worst-case but fails to acknowledge that in fact, the table clearly shows that 95th percentile biomonitoring data in several countries is higher than the modelled estimates which are therefore demonstrated not to be conservative. Importantly, the risk assessment is especially based on recent biomonitoring data (DEMOCOPHES). The main function of exposure modelling in the assessment is to provide further understanding of the relevant contribution of exposure sources. Secondary, modelling also provides additional support to the biomonitoring estimates.  Furthermore, for the reasons explained in details in the Background Document, the 95th percentile of exposure from biomonitoring for the individual phthalate is not conservative (on the contrary), see section B.8.3.2.2 of the Background Document. However, the Background Document acknowledged that, addition of RCRs based on 95th percentiles of several phthalates may lead to some overestimation of the RCRs, although consistent evidence indicates that individuals exposed to high levels of one of the four phthalates often are exposed at high levels to other phthalates as well. The data in Figure 2 of the study by ExxonMobil (Qian et al. 2015) confirmed this, and importantly demonstrates that the addition of RCRs based on the 95th percentile is in fact reasonable in the current risk assessment since 2% of the participants were exposed above the 95th percentile for three or more phthalates simultaneously (see also section B.8.3.2.6 Background Document).  The contribution of each of the individual phthalate to the risk is transparently reported in each table of section B9.  2. As described in the Background Document, the DNELs derived for DEHP, DBP and BBP are established values in risk assessment (see e.g. EU Risk Assessment Reports and opinions from RAC and EFSA). The Background Document clearly identifies the reasons why the effects seen at the respective NOAELs can all be attributed to anti-androgenicity. The detailed reasons for performing read-across from DBP to DIBP are outlined in the Background Document. Briefly, DIBP is data poor (no two-generation studies are available for DIBP and it has only been studied at doses >100 mg/kg bw/day), whereas many studies with DBP are available. Since DIBP is a branched isomer of DBP having the same molecular weight and physicochemical properties and the new mechanistic evidence supports a similar anti-androgenic potency of the two isomers, it was considered important and valid to perform read-across, thus making the best use of the strong database for DBP.  Presumably the commenter meant to refer to the cumulative risk assessment by CHAP (2014) as references in the Background Document (instead of CPSC of 2015, reference not provided). Unlike the impression given by the commenter, CHAP (2014) did only use a POD of 125 mg/kg/day as one of the 3 scenarios for its cumulative risk assessment. One of the other two scenarios used a single POD of 5 mg/kg/day for all 4 phthalates (based on the NOAEL of DEHP) considering that DIBP, DBP, DEHP, and BBP are approximately equipotent in terms of testosterone modulated effects and that the other three phthalates could then be assumed to have a POD equal to DEHP as well. On request by RAC, the Dossier Submitter made a similar sensitivity assessment assuming all four phthalates are equipotent with as a reference DBP which would double the RCRs.  Unlike the commenter asserts, uncertainties in the exposure estimates based on biomonitoring have been identified transparently, amongst others in section B.8.2 of the Background Document.  Regarding other repeated comments, see point 1 above.  3. Uncertainties were assessed thoroughly and summarised in Table 19 of the proposal (Table 21 and Table B72 in the Background Document). In addition to arrows, some quantitative information is given where possible to suggest to magnitude of the impact. The commenter asserts that the Dossier Submitter fails to consider the larger database for BBP. The Dossier Submitter would like to highlight that in fact the DNEL for BBP was maintained, bearing this fact in mind. The Dossier Submitter does not consider it is obvious that the shape of the dose-response is clearly different for BBP compared with DBP/DEHP in Howdeshell et al. (2008). The shape of a dose-response is also determined by the dose levels and individual results and thus it should be considered that no data was available for BBP at 33 and 50 mg/kg/d in contrast with DBP and that the result at 100 mg/kg/d was somewhat aberrant (higher than control) for BBP. Importantly, Howdeshell et al. (2008) concluded that BBP, DBP, DEHP, and DiBP were equipotent (ED50 of 440 ± 16 mg/kg/day). Thus, considering the evidence for equipotency and the fact that spermatocyte development and male mammary gland changes (vacuolar degeneration and alveolar atrophy) to our knowledge are not assessed in studies with BBP, the Dossier Submitter considers this is a relevant uncertainty. Similarly, the Dossier Submitter considered the larger database for DEHP and did not propose to change the DNEL. However, the Dossier Submitter considers the findings of cryptorchidism in Andrade et al. (2006) with a LOAEL of 5 mg/kg bw/day relevant to consider in uncertainty assessment. Similarly, the Dossier Submitter considers the findings of mild dysgenesis in Christiansen et al. (2010) with a LOAEL of 3 mg/kg bw/day relevant to consider in uncertainty assessment. The findings in Christiansen et al. (2010) at LOAEL of 3 mg/kg bw/day should be interpreted together with the observed reduced anogenital distance and increased nipple retention at 10 mg/kg bw/day (with NOAEL of 3 mg/kg bw/day). In this context it is noted that Christensen et al. (2014) used the LOAEL of 3 mg/kg bw/day as a basis for deriving an alternate reference dose of 3 µg/kg bw/day for use in cumulative risk assessment.  Regarding the immune system, the Dossier Submitter has provided a more thorough assessment in the Background Document that essentially confirms the conclusions from the submitted restriction proposal. *All* studies with direct oral exposure to DEHP, the only oral study with DBP, and two inhalation studies with DEHP and its monoester metabolite, MEHP, displayed adjuvant effects in rodents. All studies with DBP confirm an adjuvant effect via the dermal route of application, however studies with DEHP, BBP and DINP are generally not suggestive of adjuvant effects following dermal application. Further supportive evidence for adjuvant properties of phthalates is provided by studies using the intraperitoneal or subcutaneous route and from epidemiological studies. It can be concluded that there are indications that phthalate exposure could lead to immunological disorders in humans (allergy, asthma and eczema), possibly at levels lower than reproductive toxicity. However, in order to take effects on the immune system into consideration for quantitative risk assessment, there is a need for further robust data. Similarly, there is evidence for other effects such as on the metabolic system and neurological development that, although the Background Document does not characterise these effects to the extent of immune effects, should also not be ignored in uncertainty assessment.  The Dossier Submitter has motivated transparently in section B.4.5.3 the basis for the statement that the existence of a threshold has not yet been assessed and documented for DEHP, DBP, DIBP and BBP and that this leads to uncertainties regarding the appropriateness of the derived DNELs. Amongst others it might be difficult to estimate with any confidence the biological thresholds of adversity based on currently available standard tests.  The context for the observation for higher concentrations in morning urine samples in Federiksen et al. (2011) is explained by the authors: morning urine is less diluted. The reference made to Preau et al. by Frederiksen et al. (2011) to support the statement that concentrations of MEHHP (5OH-MEHP) would be 42% higher in morning urine than in spot urine samples refers to uncorrected urinary concentrations. When the creatinine corrected values in Table 1 and 3 in Preau et al. (2010) are considered, it is obvious that the first morning void estimates are significantly lower than the spot samples or 24-h collection (for the latter one can multiply the morning urine creatinine corrected value with a factor of 1.2 to compare with the 24h value, i.e., assuming 1.2 g/day creatinine excretion). Preau et al. (2010) state *“for MEHHP, the GM concentration of samples collected in the evening (33.2 µg/L) was significantly higher (p < 0.01) than in samples collected in the morning (18.7 µg/L) or in the afternoon (18.1 µg/L).”*. However, Frederiksen et al. (2011) also report that in their study of children 40-48% of the metabolites were excreted in the first morning void and that this percentage decreased with increasing age. This is in contrast with Preau et al. (2010), although the age difference may be an explaining factor for this difference. In sum, it is not fully clear if the statement that morning spot samples may lead to systematic underestimation of exposure is fully justified and the Dossier Submitter therefore amended the conclusion and the uncertainty description in Table 21 and Table B72 in the Background Document.  Regarding the possible species differences, the Dossier Submitter reviewed the studies by Habert et al. (2014) and Spade et al. (2014) and amended the Background Document. The Dossier Submitter considers the conclusion in the original proposal is still valid: *“It can be concluded that there are indications of species differences in metabolism and possibly in effects on fetal steroidogenesis, but the evidence is insufficient to deviate from the default assumption that humans are more sensitive than the test species (rat) (ECHA guidance Chapter R.8). The default assumption in DNEL derivation is that there is an interspecies differences of a factor 10 (4 for allometric scaling and 2.5 for remaining differences). There are indications that the neonatal period may be a sensitive window of exposure for humans.”.* This conclusion is in line with the recent opinion by SCENIHR (2016) and with the previous conclusions by RAC (ECHA 2012a). Table 19 of the proposal (Table 21 and Table B72 in the Background Document) already specified that considerations regarding possible species differences suggest an uncertainty to the RCRs and that this consideration in isolation indicates RCRs may be lower and thus may be overestimated (downwards arrow).  4. The Dossier Submitter undertook to estimate future exposure to the four phthalates on the basis of informed assumptions, including related to the declining use of the four phthalates as a result of authorisation requirements under Title VII of REACH and other regulatory and market trends.  5. The Dossier Submitter excluded food contact materials from the scope of the proposed restriction on the grounds that a sector-specific legislation would lead to more efficient use of regulatory resources and would lead to improved clarity to stakeholders. In addition to the proposed restriction, the Dossier Submitter encourages the relevant authorities in the EU to take the necessary measures to reduce the risks relating to the four phthalates from food consumption.  The comments have been considered in the Background Document. |
| **RAC Rapporteurs comments:**  RAC supports the response given by the Dossier Submitter, and notes that the additional information provided has been addressed in the Background Document.  In view of the intention of the restriction proposal, i.e., to limit the overall risk from combined exposure (i.e., from the sum of the four phthalates in the sum of individual articles) RAC further considers that:   * it is not appropriate to focus only on individual phthalates/individual articles; * dose addition is a suitable method for combined risk assessment, noting that this method has been recently also used or recommended for phthalates by other regulatory bodies (e.g., CHAP 2014 (the Chronic Hazard Advisory Panel on Phthalates and Phthalates alternatives, U.S. Consumer Product Safety Commission); Health Canada, 2015); * the use of biomonitoring data on the exposure side is not first tier, nor conservative; * the DNELs used on the hazard side are not overly conservative, given indications for other effects that are possibily more sensitive; * lowering of the DNEL for DIBP is justified because the previously used/agreed DNEL does not adequately reflect its anti-androgenic potency; * use of the 95th percentile as an estimate of the reasonable worst case exposure is common practice in consumer risk assessment; * use of the 95th percentile in this particular case is justified, covering for the fact that highly exposed individuals or subpopulations may not have been well represented in the relatively small sample size per country in the DEMOCOPHES study, and the fact that very small children as sub-population are not included in this study; * addition of RCRs based on the 95th percentile intakes is a reasonable and not too worst case approach, given that coexposure to high levels of multiple phthalates is not uncommon (see also the Qian et al., 2015 paper you refer to); * the declining trend in phthalate exposure over time has been taken into account in the Background Document when estimating future exposures, as are other informed assumptions.   Please also see section B.1 of the opinion, where most of the points raised have been considered. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. The SEAC Rapporteurs agree with the responses by the Dossier Submitter. Your suggestions on restricting DEHP for non-authorised uses, on declining rates of exposure over time, and the appropriateness of the proposed restriction in the EU have been noted. |
| **1476** | **Date:** 2016/08/31 19:12  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Baseline;  Description of analytical methods;  Information on alternatives;  Information on costs;  Information on benefits;  Other socio economic analysis (SEA) issues;  Transit  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** EKOTREND Ludky s.r.o.  **Org. country:** Czech Republic  **Attachment:** | **Comment:** |
| **Answer to specific info request 1:**  please read attached document |
| **Answer to specific info request 2:**  please read attached document |
| **Answer to specific info request 3:**  please read attached document |
| **Answer to specific info request 4:**  please read attached document |
| **Answer to specific info request 5:**  please read attached document |
| **Dossier submitter response:**  Thank you for your comments. For response to points 1-6 and 8-11, please see Dossier Submitter’s response to the nearly identical comment number 1473 submitted by DEZA a.s.  7. The Dossier Submitter has noted that some compounders or article manufacturers producing multiple products on a limited number of production lines may require one plasticiser to accommodate all product requirements. However, it is noted that there are other general purpose plasticisers which have been shown to be technically feasible across diverse applications (e.g., DINP, DEHT) at similar prices as DEHP. Furthermore, the industry’s long-term experience with substitution, long-standing knowledge of regulatory action on the four phthalates, substantial share of DEHP use remaining outside the scope, etc. will facilitate the transition to alternatives within the proposed three-year transitional period. The Dossier Submitter has also considered the need for (time limited) derogations when stakeholders have outlined a specific use where the transition would require additional time due to certification or other requirements. |
| **RAC Rapporteurs comments:**  Please see the RAC comments to comment number 1473. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. SEAC's reply is identical to that in comment number 1473. |
| **1477** | **Date:** 2016/09/01 10:14  **Content:** Scope or restriction option analysis;  Information on alternatives;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** DIGITALEUROPE  **Org. country:** Belgium  **Attachment:** | **Comment:** |
| **Dossier submitter response:**  Thank you for your comments. The scope of the proposed restriction has been adjusted to clearly exclude the articles covered under the RoHS Directive. Regarding the request that the restriction limit would apply to the phthalates individually as opposed to the four phthalates combined, for consistency with the current entries 51 and 52 of Annex XVII of REACH, the Dossier Submitter maintains that the restriction should apply to the phthalates in combination. The experience with the current entries 51 and 52 has shown this limit is implementable and enforceable. |
| **RAC Rapporteurs comments:**  No further comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. SEAC concurs with the derogation of articles under RoHS from the scope of the proposed restriction. |
| **1478** | **Date:** 2016/09/01 10:25  **Content:** Transitional period;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** ACEA  **Org. country:** Belgium  **Attachment:** | **Comment:**  Input to ACEA advocacy regarding restriction report from ECHA on the following 4 phthalates: DIBP, DBP, BBP, DEHP  Introduction:  ACEA welcomes the opportunity to provide input into the restriction proposal for the 4 phthalates.  The points that we would like to address are:  1. Continued exemption for service parts and remanufactured parts (see Appendix A).  2. Concerns for the automotive industry with the current phrase of “Placed on the EU market prior to the application of the restriction” with respect to new vehicle development (see Appendix B).  3. For interior air and exposure by inhalation, if this is required then a threshold limit should be established (see Appendix C).  Summary:  To address the concerns highlighted above, ACEA would like to propose that the restriction is amended accordingly (suggested changes are highlighted in bold). Please note that the ACEA proposals are subjected to the products of the Automobile Industry. However, the same issue would most probably also be relevant for other complex articles produced by other sectors:  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. To reduce the risk related to potentially exposure by inhalation, the concentration of the four phthalates in air, individually or in combination, shall not exceed 120 µg/m3. 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 for the first time prior to the application of the restriction (envisaged three years after entry into force, i.e., probably 2020);  • all vehicles placed on the EU market for the first time up to 3 years after entry into force of the restriction (i.e., probably 2020);  • spare parts and remanufactured parts for vehicles that are not subject to this restriction (i.e. for vehicles produced up until 3 years after entry into force, i.e., probably 2020) are also exempt.  o articles covered by existing legislation on: food contact materials,3 immediate packaging of medicinal products,4 medical devices;5  o 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  o measuring devices for laboratory use.  \*\*\*  For supplementing information please refer to the uploaded document including  Appendix A, B and C |
| **Dossier submitter response:**  Thank you for your proposal. Following the comments in Appendices A and B, ECHA requested from ACEA additional information to assess the need for the requested derogations and amendments to the proposed wording of the restriction. The answers provided by ACEA can be found in comment number 1506\_2. Please see comment number 1506\_2 for the Dossier Submitter response to the comments in Appendices A and B.  Appendix C: The restriction proposal considers all sources and all exposure routes. For example, in addition to the exposure via inhalation, the dermal route is a relevant aspect of the basis for the proposed restriction when considering specifically the automotive industry. When the restriction is introduced it will be sufficient to ensure compliance with the concentration limit for the four phthalates in each plasticised material. However, the Dossier Submitter welcomes any additional controls the automotive industry may wish to implement to limit exposure to the four phthalates. |
| **RAC Rapporteurs comments:**  Appendix C: no further comments.  For comments in Appendices A and B: please see RAC Rapporteurs comments to comment number 1506\_2. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. SEAC will assess (any) new information to be received and (any) amendments of the wording of the proposed restriction regarding your comment on the automotive industry. |
| **1480** | **Date:** 2016/09/01 16:33  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Transitional period  **Type:** MemberState  **Country:**  Sweden | **Comment:**  The Swedish Chemicals Agency would like to thank ECHA and DK for this restriction proposal. We agree on the importance of regulating imported articles, especially since this is a large and growing share of the market. |
| **Answer to specific info request 1:**  The Swedish Chemicals Agency would like to include vehicle interiors in the scope. This particular use was identified in KemI-report 4/15 (http://www.kemi.se/global/rapporter/2015/report-4-15-phatalates.pdf). Vehicle interiors emits phthalates into the indoor environment of the vehicle causing exposure via inhalation. In some uses – such as seat covers – there is also a dermal exposure. This exposure may cause a risk particularly to those undertaking long and frequent car, bus and truck trips; for instance bus and truck drivers.  The report identified the occurrence of the following phthalates in trucks/buses (section 4.3.2, p.45-46):  • Seats, seat coverings: DINP, DEHP, DPHP  • Components in braking system, starter motor: DEHP  • Fifth wheel, oil cooler, power transmission: DEHP  • Lamps, Loudspeaker: DEHP  • Wires, Wiring harness: DEHP  • Engine unit, fuel tank, main switch: DBP  • Starter motor: DEHP, DBP  • Doors, cab roof: DIBP |
| **Answer to specific info request 2:**  In enforcement projects conducted in year 2013-2016, the Swedish Chemicals Agency analysed toys for phataltes content. The following DIBP concentrations were found:  Year 2013:  •Bath toy made of soft plastics - 23-29 %  •Hop ball made of green plastics - 40-42 %  •Doll made of soft plastics - 0.35-0.36 %  •Plastic chicken with a screeming noise (not electrical) - 34-36 %  Year 2015 No DIBP  Year 2016 No DIBP  Notably there was no DIBP found in the analysed toys in 2015 and 2016. This may implicate that retailers and wholesalers have become aware of the risk related to DIBP in toys, and removed them from their assortment.  In 2014, the Swedish Chemicals Agency conducted an inventory of the presence of phthalates in articles. The results are presented in a report, which is available in Swedish at http://www.kemi.se/global/pm/2014/pm-2-14-ftalater.pdf). In Annex 6 to the report (p 85-86) it is stated that the Environmental Office of Gothenburg (Miljöförvaltningen i Göteborg) found DIBP in a doll’s head (1200 mg/kg in), in a plastic toy dolphin (250 000 mg/kg), and in a plastic ball (200 mg/kg). The Environmental Office of Luleå (Miljökontotet i Luleå) found DIBP in a bath toy (650 mg/kg). Also Environmental Office of Örebro (Miljökontoret i Örebro) found in an enforcement project DIBP in toys, at concentrations up to 110 mg/kg. |
| **Answer to specific info request 3:**  The Swedish Chemicals Agency thinks that the suggested implementation period is more than enough for the flooring sector, and that a shorter implementation period should be considered. SE manufacturers of flooring have already substituted to alternative plasticisers. There is also a similar trend in the rest of the EU. See section 3.3.1 in KemI report 4/16 (http://www.kemi.se/global/rapporter/2016/report-4-16-hazardous-chemicals-in-construction-products.pdf).  Furthermore, the results from the enforcement project conducted by the Swedish Chemicals Agency in 2013-2016 indicate that toys containing DIBP has been removed from the market (see answer to question 2), which would suggest that a shorter implementation period is possible. |
| **Dossier submitter response:**  Thank you for your comments. The information you provided on DIBP in toys, the ability of industry to comply with the proposed restriction within a shorter than three years transitional period, and support for including vehicle interiors in the scope have been incorporated in the Background Document. |
| **RAC Rapporteurs comments:**  Thank you for the additional information, which RAC notes has been addressed in the Background Document. RAC further notes that vehicle interiors are indoor-like environments and therefore, within the scope. |
| **SEAC Rapporteurs comments:**  Thank you for your comment for the inclusion of vehicle interiors within the scope of the proposed restriction. SEAC agrees with the inclusion, which has been incorporated in the Background Document, as referred to by the Dossier Submitter above. |
| **1481** | **Date:** 2016/09/01 23:26  **Content:** Scope or restriction option analysis;  Hazard or exposure  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:** ClientEarth  **Org. country:** United Kingdom | **Comment:**  Scope or restriction option analysis  The rational for not proposing the remaining restriction options is presented in Annex D, Section D.1.2 (p230). The derogation for Food Contact Materials is justified on the basis that sector-specific legislation would lead to a more efficient use of resources and improved clarity for stakeholders. However, this proposal highlights the need to take measures to reduce the risks of the four phthalates from food consumption but it is unclear that there are any incentives for sector-specific legislation to propose such measures.  Table D2 p239 of Annexes – The rationale for discarding the restriction option for all products placed on the market and production of articles containing the four phthalates appears to be driven only by the costs to the recycling sector.  Hazard or exposure  1.1.5.1. Human exposure (p23).  - “The population is divided into three age groups: (male) infants at the age of 6-12 months, (male) children at the age of 6-11 years and women. Infants at the age of 6-12 months are expected to mouth many articles and are being weaned onto “normal” food.”. Whilst the mouthing behaviour of infants is considered, the fact that infants (and toddlers) are also likely to spend considerable amount of time in direct contact (dermal exposure) with flooring is not mentioned. Toddlers (children younger than 6 years old) may also have higher exposures but this age group is not considered.  P 26. “Fromme et al. (2013b) reported that the floor covering in 63 daycare centres from Bavaria, Berlin and North Rhine-Westfalia did not significantly correlate with excretion of phthalate metabolites. The authors however observed a significant correlation between phthalate concentrations in dust samples and urinary levels of DBP, BBP and to a lesser extent also DEHP metabolites.” But table B24 in Annexes (p131) shows that higher concentrations of phthalates were found in indoor air and dust of daycare centres than in homes (for studies that measured both), yet this specific environment is not considered in the exposure scenarios.  Another environment that is not given consideration is the car. Infants, toddlers, children may also be in direct contact with car seats and it is unclear to what extent this would be covered by assumptions for daily dermal contact for children below.  P32. Daily dermal contact for children and infants is assumed to be 30mins under the typical scenario or 1 ½ hour under reasonable worst case scenario. The surface area in contact with articles containing one or more of the four phthalates is assumed to be 10% and 25% of the total body surface area respectively in the typical case and reasonable worst case scenario. It is unclear to what extent these assumptions would apply to crawling behaviour (potentially larger surface area for longer periods of time?).  ClientEarth may submit further comments before the final deadline. |
| **Dossier submitter response:**  Thank you for your comments.  Scope: Your comments on FCMs have been reflected in the Background Document. Regarding the rationale for discarding the *Restriction on the production as well as placing on the market of all articles*, we point to the first bullet under *disadvantages*, where we explain that the additional articles to be included in the scope (primarily outdoor articles with no dermal or low inhalation exposure) have lower contribution to risk and therefore, their inclusion in the scope of the restriction would lead to small increase in its benefits. Therefore, taking into account other factors, such as the costs of this restriction option, it was concluded that overall this restriction option is less effective than the proposed restriction.  Human exposure: The Dossier Submitter considers that three age groups are sufficient to demonstrate the need for a restriction based on a risk in infants, children and pregnant women. The intake estimates of phthalates in house dust are based on the weighted averages from several studies and thus take into account the measurements from day care centres. Exposure from car interiors is assumed to be covered by the estimates for exposure from indoor air and dermal contact. In selecting the reasonable worst case parameters for dermal exposure, the Dossier Submitter considered both short term and long term exposure (crawling behaviour was considered). Please also note that the main source of exposure data is considered to be biomonitoring data. |
| **RAC Rapporteurs comments:**  RAC agrees with the Dossier Submitter’s response and has no further comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comments, which have been noted. SEAC considers that there will be more clarity if FCMs are dealt with by the relevant legislation and that including all articles under scope would not be proportionate. |
| **1483** | **Date:** 2016/09/02 09:18  **Content:** Other socio economic analysis (SEA) issues  **Type:** MemberState  **Country:**  Finland | **Comment:**  First, we would like to thank the dossier authors for preparing this restriction report. Overall we think that the dossier is carefully done. Below you can find a couple of SEA-focused issues we’d like to comment on.  The discount factors (4 % and 2%) used in the restriction proposal are pretty good as such. Nevertheless, in order to better follow the recommendations of SEA Guidance it could’ve been reasonable to conduct a sensitivity analysis of benefits calculation also with a declining discount rate (since the benefits are assumed to be realized from 2050 onwards and are very sensitive to the choice of the discount rate). In addition to SEA Guidance recommendations, the use of a declining discount rate is supported by many actors. There has also been discussion about whether the impacts on health and environment should be discounted at all. In the light of the abovementioned considerations, we suggest that the benefits in the dossier may have been undervalued (also keeping in mind that not all the positive impacts have been monetized).  The expression “baseline” is to our perception inconsistently used. “Baseline” should only be used to indicate the state-of-play without the proposed restriction. In the dossier and its annexes the terms “proposed restriction scenario” and “baseline (main)” seemed to have been used for same purposes. This might have confused some readers since the “baseline (main)” and “baseline” sound quite the same. In addition, there was a little mistake in table 21 representing the baseline assumptions. In the column of “tonnages in imported articles” it should read “—1 % annual growth since 2020 --“ rather than “—since 2014 ―”. And therefore, what happens between 2014 and 2020 seems to be missing. There also appears to be a mismatch between tables 22 and C1 (in annexes) concerning the year 2014.  On page 66 one should use present value (PV) instead of net present value (NPV) since this section discusses only the calculation of costs. We also noticed that there might be inconsistency between what is introduced and actually calculated. The text reads: “The NPV of these future costs over the next 20 years—“, the table reads “Net costs from 2020 onward” and the calculation seems to be from 2014 onward (since it is the base year for discounting). In any case, if all the calculations behind the figures had been presented, it would have enhanced the transparency of the dossier.  Lastly, we’d like to raise a question about the argument that even in the worst case scenario the benefits would outweigh the costs. In the dossier this is formulated as follows (p. 355): “This [benefits would exceed the costs] is also demonstrated in the unlikely worse case situation when the highest costs scenario (High testing costs, High material costs & Baseline scenario for Low tonnages in Table E14) is compared to the lowest benefits valuation scenario (Low estimate in Table E15).“ The costs according to the worst-case scenario are approx. 23M€ while the benefits in the lowest estimate are only approx. 7M€. More clarification is needed if the argument is really valid and that understandability would be guaranteed. |
| **Dossier submitter response:**  Thank you for your comments. We have clarified the points you bring to our attention in the Background Document. The need for “declining discount rate” and “underestimation of benefits” was discussed with the rapporteurs and SEAC and addressed in their opinion. |
| **RAC Rapporteurs comments:**  No comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comments, which have been taken into account in the drafting of the opinion. |
| **1484** | **Date:** 2016/09/02 15:33  **Content:** Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Orgalime  **Org. country:** Belgium  **Country:**  Belgium | **Comment:**  Orgalime thanks ECHA for the consultation on the proposal for a REACH restriction on articles containing the four phthalates (DEHP, DBP, BBP and DIBP) in concentrations equal to or greater than 0.1% by weight.  Orgalime as the voice of European manufacturers of electrical and electronic equipment, mechanical engineering and metal articles would like to comment on the proposal from the perspective of these affected product groups, and expected legislative overlaps with existing sector specific chemicals legislation in particular. Other Possible applications beyond these sectors are not the subject of our response, since they are not included in our membership.  Against this setting, we would like to particularly raise our concern that the proposal, if it is finally adopted, would create double and conflicting legislation for the use of these substances in electrical and electronic equipment (“EEE”) for the following reasons:  • The scope of the present REACH restriction proposal includes “any phthalate containing articles that are used (including stored) in an indoor environment where people are present under normal and foreseeable conditions and potentially exposed via inhalation. This does not apply to articles that are used only in industrial and agricultural workplaces by workers”. This definition would include a wide variety of EEE in its scope.  • At the same time, sector specific legislation exists, namely Directive 2011/65/EU (“RoHS Directive”), which lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) and which restricts the use of certain hazardous substances in EEE placed on the Union market.  Commission Delegated Directive (EU) 2015/863 of 31 March 2015 has amended the list of RoHS restricted substances given in Annex II to Directive 2011/65/EU and restricts the use of DEHP, DBP, BBP and DIBP in EEE with a maximum 0.1% concentration values tolerated by weight in homogeneous materials.  This amendment provides for the specific conditions of these restrictions following scientific analysis and stakeholder consultations, including provisions regarding the appropriate scope, concentration levels or compliance deadlines.  Also, under the RoHS Directive manufacturers can, under certain conditions, request an exemption for a specific application of a restricted substance when alternatives are not available. Such a mechanism is not foreseen in the current ECHA proposal, but is essential to ensure that critical EEE applications, including in the industrial sector, can continue to operate in the absence of an alternative.  The current ECHA proposal thus overlaps and conflicts with this just adopted RoHS requirement for EEE in several areas, and especially for medical devices, cables, wires and spare parts.  • The suggested REACH restriction proposal includes a list of suggested derogations, which however does not include a derogation for EEE as falling in the scope of Directive 2011/65/EU. This contradicts the “Common Understanding on the interface of REACH and RoHS” agreed in CARACAL, which states that in the case of an existing RoHS restriction “The simplest way to avoid duplication and/or inconsistencies for a given substance already included in RoHS is, to exclude EEE within the scope of RoHS from the scope from a proposed REACH restriction also covering EEE”.  Therefore, Orgalime asks ECHA to add the following derogation to its REACH restriction proposal:  “The proposed restriction does not apply to electrical and electronic equipment within the scope of Directive 2011/65/EU.”  ORGALIME, the European Engineering Industries Association, speaks for 41 trade federations representing companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 24 European countries. The industry employs some 10.9 million people in the EU and in 2015 accounted for more than €1,900 billion of annual output. The industry accounts for over a quarter of manufacturing output and a third of the manufactured exports of the European Union. More information is available on our website: www.orgalime.org. |
| **Dossier submitter response:**  Thank you for your comments. The scope of the proposed restriction has been adjusted to clearly exclude the articles covered under the RoHS Directive. |
| **RAC Rapporteurs comments:**  No further comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. SEAC agrees with the exemption of articles under RoHS from the scope of the proposed restriction. |
| **1487** | **Date:** 2016/09/14 12:09  **Content:** Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** AmChgam EU, CECED, EPTA, ESIA, JBCE, KEA, SEMI, TIE  **Org. country:** Belgium  **Attachment:** | **Comment:** |
| **Dossier submitter response:**  Thank you for your comments. The scope of the proposed restriction has been adjusted to clearly exclude the articles covered under the RoHS Directive. |
| **RAC Rapporteurs comments:**  No further comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. SEAC agrees with the exemption of articles under RoHS from the scope of the proposed restriction. |
| **1489** | **Date:** 2016/10/24 11:55  **Type:** MemberState  **Country:**  United Kingdom  **Attachment:** | **Comment:** |
| **Dossier submitter response:**  Thank you for your comments and for your support of the restriction proposal from an environmental protection point of view. We have incorporated the points you bring to our attention in the Background Document. |
| **RAC Rapporteurs comments:**  Thank you for the additional information, which RAC notes has been addressed in the Background Document. RAC agrees that any associated risks for the environment from the articles in scope (e.g. due to emissions to wastewater and possibly drinking water) would also be reduced as a result of the proposed restriction. |
| **SEAC Rapporteurs comments:**  Thank you for your comments, which have been noted. The SEAC Rapporteurs took into account environmental impacts of DEHP and its status under the Water Framework Directive in its opinion. |
| **1491** | **Date:** 2016/10/27 09:02  **Content:** Scope or restriction option analysis  **Type:** Individual  **Country:**  Poland  **Attachment:** | **Comment:** |
| **Answer to specific info request 1:**  Please refer to the uploaded document. |
| **Answer to specific info request 2:**  Please refer to the uploaded document. |
| **Answer to specific info request 3:**  Please refer to the uploaded document. |
| **Answer to specific info request 4:**  Please refer to the uploaded document. |
| **Answer to specific info request 5:**  Please refer to the uploaded document. |
| **Dossier submitter response:**  Thank you for your comments. Please see Dossier Submitter’s response to the nearly identical comment number 1473 submitted by DEZA a.s. |
| **RAC Rapporteurs comments:**  Please see RAC Rapporteurs comments to comment number 1473. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. Please see our answer to comment number 1473 submitted by DEZA a.s. |
| **1493** | **Date:** 2016/11/14 20:37  **Content:** Information on alternatives  Information on costs  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** ECPI  **Org. country:** Belgium  **Attachment:** | **Comment:** |
| **Dossier submitter response:**  Thank you for your comments. Your comments in support for the Dossier Submitter’s selection of the main alternatives that will likely replace DEHP (DINP, DIDP, and DEHT/DHPP), access to precursors for plasticiser manufacturers as well as the statement on p. 57 in the submitted dossier have been included in the Background Document. We note, however, that the restriction costs are only those incremental costs that will be incurred by industry (and society) as a result of its entry into force. These would exclude any costs arisen as a result of past regulatory or market forces. |
| **RAC Rapporteurs comments:**  No comment. |
| **SEAC Rapporteurs comments:**  Thank you for your comments, which have been noted. We agree with Dossier Submitter’s response. |
| **1494** | **Date:** 2016/11/29 10:40  **Content:** Scope or restriction option analysis  Hazard or exposure  Description of analytical methods  Information on alternatives  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** China Plasticizer Industry Association and Japan Industry Association  **Org. country:** Japan  **Attachment:** | **Comment:** |
| **Answer to specific info request 1:**  See attached file |
| **Answer to specific info request 5:**  See attached file |
| **Dossier submitter response:**  Thank you for your comments. Please see also the earlier and nearly identical comment number 1472 submitted by Japan Plasticizers Industry Association.  1. The preparation of this restriction dossier on the four phthalates in articles was initiated on the basis of Article 69(2) of the REACH Regulation. The current restriction proposal builds on the previous proposal submitted by Denmark in 2011 and takes into account new information on hazard and exposure (especially DEMOCOPHES biomonitoring data), additional data on costs and trends in substitution, and a review of new information on benefits. Furthermore, the scope of the new proposal has taken into account comments made on better targeting of the proposal and the baseline has been adjusted to take account of the information available since the previous discussions. This additional information has been presented to RAC and SEAC to review and formulate an opinion.  2. In 2014, 12 out of 15 Member States RCRs for combined 95th percentile exposure to DEHP, DBP, BBP and DIBP are at or above 1 for children. In Member States with a combined RCR at or below 1 at the 95th percentile exposure level there was still a risk for individuals with the highest exposure levels in the study population. It can be concluded that there was a risk in all Member States.  3. In case of a restriction on DBP alone the projections show there still would be a risk because of the significant contribution from DEHP and DIBP as well as the remaining exposure to DBP from other sources that do not fall within the scope of a restriction on DBP only. Moreover, the other 3 phthalates are also included in Annex XIV and thus are aimed to be progressively replaced with suitable alternatives. Lastly, and as outlined in the Background Document, there are uncertainties to the RCRs that suggest the RCRs may be underestimated and that establishing a threshold may not be appropriate.  4. Table 18 of the original submission clearly shows that 95th percentile biomonitoring data in several countries is higher than the modelled estimates which are therefore demonstrated not to be “erroneous”. Importantly, the risk assessment is based on recent biomonitoring data (DEMOCOPHES), not on modelling. All information from the consultation during the preparation of the proposal was considered.  5. The Dossier Submitter considers the approach to combined risk assessment for the 4 phthalates appropriate. The commenter does not point to specific problems or alternatives to the approach.  6. Regarding the possible species differences, the Dossier Submitter notes that Kurata et al. (1998) and Tomonari et al. (2006) were already included in the submitted restriction proposal. The second Kurata et al. (2012) reference provided (point 4 in your list) refers to the species differences in conjugation of metabolites. The Background Document acknowledged that metabolism is rapid in both humans and animals with the first step in the metabolism of DEHP is the formation of the short-lived monoester MEHP. The major share of the simple monoester is further metabolised to produce a number of oxidative metabolites. The results in Kurata et al. (2012) suggest that most of the metabolites were excreted as glucuronides in humans, whereas in rodents most of these metabolites were excreted as free forms. This observation is relevant as glucuronides are not biologically active and thus may lead to some species-differences in potency of DEHP toxicity. It is noted that SCENIHR (2016) assessed this study and discussed its potential role in species differences but did not adjust the default assessment factors for interspecies differences. The first Kurata et al. (2012) reference provided (point 3 in your list) was already considered in the assessment by RAC of the toxicokinetics of DEHP when reviewing the data for DINP and DIDP[[5]](#footnote-5) and the reference DNEL of RAC from 2013 for DEHP already takes this information into account[[6]](#footnote-6). It is noted that recovery of 8% in urine of marmosets (Study II) is not a credible result, and is not consistent with the results in Study I (in case it would be accepted, this would indicate that the marmoset would not be an appropriate model to study absorption of DEHP in humans). Indeed, based on results with human volunteers, RAC considered that humans orally absorb about 100%.  The Dossier Submitter considers the conclusion in the original proposal is still valid: *“It can be concluded that there are indications of species differences in metabolism and possibly in effects on fetal steroidogenesis, but the evidence is insufficient to deviate from the default assumption that humans are more sensitive than the test species (rat) (ECHA guidance Chapter R.8). The default assumption in DNEL derivation is that there is an interspecies differences of a factor 10 (4 for allometric scaling and 2.5 for remaining differences). There are indications that the neonatal period may be a sensitive window of exposure for humans.”.* This conclusion is in line with the recent opinion by SCENIHR (2016) and with the previous conclusions by RAC (ECHA 2012a). However, Table 19 of the proposal (Table 21 and Table B72 in the Background Document) specifies that considerations regarding possible species differences suggest an uncertainty to the RCRs and that this consideration in isolation indicates RCRs may be lower and thus may be overestimated (downwards arrow).  With regard to the study by Adachi et al. (2015), the Dossier Submitter notes that the investigation is not so much directed at species differences, but presents a way to estimate the human intake of phthalates based on urinary concentration of phthalate metabolites in a chimeric mouse model in combination with a PBPK model. Generally accepted practices and methods in calculating the intake levels for the four phthalates from human biomonitoring studies.  7. The Dossier Submitter recognises that the proposed restriction will have an impact on the recycling sector. It is monetised in section 2.4.3 of the Background Document. The transitional period of the proposed restriction also considers the review periods of the granted or pending decisions on authorisations in scope; therefore, the proposed restriction is to take effect after their end.  8. The Dossier Submitter has considered the latest available market intelligence and information from the applications for authorisation in the estimation of the cost difference between the four phthalates and their alternatives. The Dossier Submitter has also considered all concrete requests for derogations where the transitioning to the alternatives has been demonstrated challenging.  9. Articles falling in the scope of RoHS have been derogated in the proposed restriction. For consistency with the current entries 51 and 52 of Annex XVII of REACH, the Dossier Submitter maintains that the restriction should apply to the phthalates in combination. The experience with the current entries 51 and 52 has shown this limit is implementable and enforceable. |
| **RAC Rapporteurs comments:**  RAC supports the response given by the Dossier Submitter. Some additional comments:  2/3. RAC is of the opinion that the DEMOCOPHES project, which is the most recent available biomonitoring study of this scale, can be seen as representative for EU28. There is no reason to assume that the situation in the Member States that did not participate in this project would be very different from the Member States that partipated. RAC further notes that looking at the exposure from individual phthalates (as suggested) is not in line with the intention of the restriction proposal, i.e., to limit the overall risk from combined exposure (i.e., from the sum of the four phthalates in the sum of individual articles).  4. Given that the results of the exposure modelling correspond reasonably well with the biomonitoring data, RAC does not consider the exposure modelling to be incredible/overestimated.  5. RAC notes that dose addition, the method used for the combined risk assessment of the four phthalates, has been recently also used or recommended by other regulatory bodies (e.g. CHAP, 2014; Health Canada, 2015).  6. RAC notes the available information on possible species differences in sensitivity for the effects of phthalates has been given due consideration in the Background Document. RAC supports the conclusion by the Dossier Submitter that the evidence is still insufficient to deviate from the default interspecies assessment factor 10 (= 4 (allometric scaling) \* 2.5 (remaining differences), and notes that it is in line with recent risk assessments on phthalates by other regulatory bodies (e.g., CHAP, 2014; SCENIHR, 2016), who addressed the issue of possible interspecies differences in sensitivity, but judged it too early to deviate from the default assessment factor of 10 for interspecies differences. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. SEAC agrees with the Dossier Submitter’s response and took note of your points on the comparison with the previous proposal, the consistency between the proposed restriction and authorisation for recycled PVC. SEAC agrees with the exemption of articles under RoHS from the scope of the proposed restriction. |
| **1499** | **Date:** 2016/12/14 11:49  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Information on alternatives;  Information on costs;  Information on benefits  **Type:** BehalfOfAnOrganisation  **Org. type:** National Authority  **Org. country:** France  **Country:**  France  **Attachments:**    <confidential attachment removed> | **Comment:**  Please, find attached in section IV an Excel file with all the comments for Anses. |
| **Dossier submitter response:**  Thank you for your detailed comments. All 75 comments have been considered in the process of amending the Background Document. Responses to selected comments are as follows:   * Row 7: A sensitivity scenario has been added to the Background Document to show the effect on the RCRs when it is assumed that the DNELs for all four phthalates are equal to the DNEL of DBP (6.7 µg/kg bw/day). RCRs change linear with exposure and thus, it was not considered necessary to build a separate scenario for when, e.g., exposure would be doubled. * Row 8: The section “Justification for the selected scope of the proposed restriction” clarifies the choice of 0.1% w/w as follows: “This restriction proposal argues that in the majority of article types in the scope of this proposal, a combined concentration of DEHP, DBP, DIBP, and BBP of less than or equal to 0.1% is required in order to adequately manage the risk to human health. This concentration limit is seen to effectively discourage any intentional use in articles within scope.”. * Row 18: The Dossier Submitter agrees that a slight increase of the exposure level within the 'critical windows of exposure' may be sufficient to cause adverse effects to the fœtus and that as a consequence, even acute and/or short term exposure (e.g., used in blood transfusion) should be accounted for. This is reflected in Table 21 and Table B72 in the Background Document. * Row 35 and 37: The Dossier Submitter believes the potential adverse effect of a possible substitution with DINP is sufficiently reflected in the Background Document, e.g., in section B.9.1, Table B72 (other anti-androgenic substances may contribute significantly to the total risk) and section D.3.5.4. * Row 38: When there is indeed an underestimation of the risks, the risk reduction capacity would be higher. The assessment would indeed support further measures and the Dossier Submitter sees it as supporting the advice to the relevant authorities in the EU to take the necessary measures to reduce the risks relating to the four phthalates from food consumption in addition to the current restriction proposal under REACH. * Row 42: As the first wave of spermatocyte development is supported by androgens (Picut et al. 2015), it is considered likely that interference with testosterone production may be related to timing of testicular development (note that indeed the effect was observed at PND 21 in Lee et al. (2004) which coincides with the juvenile period in Picut et al. (2015) and thus well within the period of androgen-dependence). Regarding effects on the male mammary gland, Lee et al. (2004) refer to flutamide: *“We have previously described atrophy of mammary gland alveoli after repeated oral doses of FA in young adult male rats (Toyoda et al., 2000), and both in vivo and in vitro studies have suggested a direct antiandrogenic action of this compound on the growth of mammary alveolar cells (Di Monaco et al., 1993; Sourla et al., 1998).”*. It is unclear which publication “Dekant 2012” refers to. The Dossier Submitter considers it reasonable to regard the observed reduction of testicular spermatocyte development and male mammary gland effects as anti-androgenic. See also the reply to comment 1504. |
| **RAC Rapporteurs comments:**  Thank you for the additional data provided on biomonitoring, indoor environment and food in France. RAC notes that these data, as well as your detailed comments on the Background Document, have been considered, where possible and necessary. |
| **SEAC Rapporteurs comments:**  Thank you for your comments and for the information you provided. The SEAC Rapporteurs had several similar comments on the estimation of the benefits (e.g., derivation of attributable fractions) and these were taken into account in the preparation of the SEAC opinion. |
| **1500** | **Date:** 2016/12/15 12:46  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Description of analytical methods  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** Japan Plasticizer Industry Association  **Org. country:** Japan  **Attachment:** | **Comment:**  See attached faile |
| **Answer to specific info request 5:**  See attached file |
| **Dossier submitter response:**  Thank you for your comments. The Dossier Submitter took into account comments from the recycling industry regarding the potential impacts of the restriction on the sector.  The Koch 2016 paper (in German) describes the changes in the phthalate market over the last decades and shows that substitution of the four phthalates takes place. Your inference that this decline in tonnes of phthalates used (in particular DEHP) impacts the biomonitoring data has in fact been addressed in the Background Document in the projections for 2020. See section D.3.5.3 of the Background Document.  The Dossier Submitter believes the exposure assessment is well supported with literature data in the Background Document. The commenter does not present specific arguments to support the contrary.  SCENIHR (2016) has been has been given due consideration in the Background Document and the derivation of the DNEL for DEHP are consistent with SCENIHR (2016). The focus of SCENIHR (2016) was the risks of DEHP in medical devices (and not evaluate combined exposure to the four phthalates from all exposure routes by means of DEMOCOPHES biomonitoring). Importantly, SCENIHR (2016) concluded: *“Adult haemodialysis patients have the highest exposure to DEHP because the TDI is exceeded during their long and intense treatments. Neonates and infants (especially those in Neonatal Intensive Care Units) also have high exposure due to multiple treatments they require, and they are at greatest risk because of their relative low body weight and developmental stage. Bear in mind, that many interventions that result in phthalate exposure also save lives, so they should not be avoided, although exposure to phthalates should be reduced as much as possible.”*.  The relationship between cause and effect and the limitations of epidemiological studies in this respect are discussed in e.g. section D.3.5.1 of the Background Document. The results from ECPI sponsored audit by Swaen et al. (2016) are not yet published (the article provided as a reference is a “Rapid report” and does not actually report any results).  Regarding species differences, see the reply to your comment number 1494. |
| **RAC Rapporteurs comments:**  RAC supports the response given by the Dossier Submitter. Please also see the RAC Rapporteurs comments on comment number 1494. |
| **SEAC Rapporteurs comments:**  Thank you for your comment which was noted. The SEAC Rapporteurs agree with response by the Dossier Submitter. |
| **1501** | **Date:** 2016/12/15 13:11  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** International NGO  **Org. name:** ChemSec  **Org. country:** Sweden | **Comment:**  ChemSec welcomes the proposed restriction of the four phthalates. Restriction is the logical follow up procedure of the authorisation process, limiting also imported articles. We are, however, critical towards that the uses that should not be covered include industrial or agricultural workplaces as we do not see why these categories should be less worthy of protection. Workers protection regulation is a good complement to REACH, not a substitute. We are also doubting how it can be ensured that the products covered by this restriction can only be used, and stored, outdoors. Consumers may purchase a product with the intention of using it in a different way, and seasonal changes will lead to indoor storage despite instructions that often are lost after packaging is removed. Especially in colder regions of the EU, storage of outdoor equipment during winter is often necessary to be placed indoors. |
| **Dossier submitter response:**  Thank you for your support for the proposed restriction. The Dossier Submitter evaluated the effectiveness, practicality and monitorability of several other restriction options, including a restriction option banning the use of the four phthalates for all articles types. It was found that these restriction options were less effective than the proposed restriction, for example because industrial, agricultural and outdoor articles (without potential for dermal exposure) have less contribution to risk to human health of the general population, in vulnerable groups in particular. Please see section D.1.2 of the Background Document. |
| **RAC Rapporteurs comments:**  RAC agrees with the Dossier Submitter’s response and has no further comments. |
| **SEAC Rapporteurs comments:**  Thank you for your comment. The SEAC Rapporteurs concur with the evaluation by the Dossier Submitter that the proposed restriction of the four phthalates from all articles would not be proportionate. |
| **1502** | **Date:** 2016/12/15 15:32  **Content:** Scope or restriction option analysis;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** MedTech Europe  **Org. country:** Belgium  **Attachment:** | **Comment:**  Please consult the uploaded document for comments. |
| **Dossier submitter response:**  Thank you for your comments. The scope of the proposed restriction has been adjusted to clearly exclude the articles covered under the RoHS Directive. As explained in section D.1.2 of the Background Document, the concentration limit was selected to effectively eliminate any intentional use of the four phthalates in the articles in scope and is achievable on the basis of information about the limits of detection for prevailing testing methods. The Dossier Submitter also proposed an amendment of the proposed restriction wording to ensure imported components of exempted medical devices are also exempted. This intent was also specified in the aforementioned section D.1.2 in the Background Document. Finally, the Dossier Submitter has addressed all comments on the wording of the proposed restriction from the Forum. |
| **RAC Rapporteurs comments:**  No further comments. The additional derogation proposed (for components of derogated medical devices) is supported by RAC. |
| **SEAC Rapporteurs comments:**  Thank you for your comment, which was noted. The SEAC Rapporteurs find that some of your concerns are addressed in the new version of the wording of the restriction as proposed by SEAC (components of medical devices). |
| **1503** | **Date:** 2016/12/15 15:51  **Content:** Scope or restriction option analysis;  Baseline;  Information on costs;  Other socio economic analysis (SEA) issues;  Request for exemption  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** European Plastics Converters  **Org. country:** Belgium  **Attachments:**    <confidential attachment removed>  **Privacy comment:** protection of commercial interests | **Comment:**  See Position Paper |
| **Answer to specific info request 3:**  See Position Paper |
| **Dossier submitter response:**  Thank you for your comments and for your assistance in the information gathering for the preparation of this dossier that helped us establish that the DEHP containing recyclate is used mainly in industrial and agricultural applications (outside scope of the restriction proposal) and very few tonnages in boots and wellingtons manufacturing. The information you provided assisted us with the justification of the derogations on industrial and agricultural applications. As very few tonnes of recyclate is likely to be affected, it is foreseeable to assume that this recyclate can be used for other applications outside the scope of the restriction, therefore, the total tonnes of recycled material would likely be unaffected. As manufacturing is not restricted, it is also possible that boots and wellingtons containing DEHP to be exported to international markets where such restriction is not in place at least in a short term if the transitional period of three years is insufficient to transition to DEHP-free source. We also calculated that if the boots and wellingtons are produced from a virgin material, the increase in their raw material costs will be about 1-2% of their sales price. The Dossier Submitter also evaluated the possibility for a derogation on boots and wellingtons manufactured using recycled material. It was concluded that the derogation will be difficult to enforce (as it will be difficult to differentiate between those produced from virgin and recycled material) and that the proposed restriction (excluding a derogation on boots and wellingtons) is effective, practical and monitorable.  In addition, we confirm that the declining exposure trend evident in biomonitoring results and substitution of the four phthalates internationally have been taken into account in the projected future use and exposure to the four phthalates. Please see section D.3.5.3. and section 1.3 (summary of Annex C) and the response to comment 1504. Your comments on use of the four phthalates in flooring and coated products have been taken into account in the Background document after being weighed against information from other sources, such as the applications for authorisation and market intelligence. |
| **RAC Rapporteurs comments:**  RAC agrees with the Dossier Submitter’s response and notes that the additional information you refer to has been addressed in the Background Document.  As to the requested additional derogation for wellingtons and boots, RAC acknowledges that this derogation as such might have a limited effect on the risk reduction capacity as a result of the limited volumes involved and the likelihood of limited exposure. Whereas this might be true for these individual articles, RAC notes the restriction is aimed at limiting the overall risk from combined exposure (i.e., from the sum of individual articles). Also, from that perspective the requested derogation is not considered justified. |
| **SEAC Rapporteurs comments:**  Thank you for your comments, which have been very helpful to the SEAC Rapporteurs in preparing SEAC's Opinion. The SEAC Rapporteurs agree with the Dossier Submitter response but made some changes to the Dossier Submitter’s estimated impacts on recyclers of the proposed restriction. |
| **1504** | **Date:** 2016/12/15 18:25  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Information on costs;  Other socio economic analysis (SEA) issues  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** ECPI  **Org. country:** Belgium  **Attachment:** | **Comment:** |
| **Dossier submitter response:**  Thank you for your comments provided in three separate files. The Dossier Submitter has taken them into account in the Background Document as follows:  File 1:  1. For the following reasons a total ban on all non-authorised uses is not supported:   * Restriction options that include FCMs were discarded, see the original restriction proposal. * Including in the scope articles primarily for outdoor use with no potential for dermal or mucous membrane contact are expected to have lower contribution to risk. Therefore, a restriction on these articles would have a lower risk reduction potential (which could also be seen as a proxy for the benefits of this restriction option) and benefit-cost ratio. * A restriction option that only exempts DEHP would not be in line with the basis for the current restriction proposal. The proposal was instigated by Article 69(2) of REACH which states that after the sunset date of substances on Annex XIV, “the Agency shall consider whether the use of the substance in articles poses a risk to human health or the environment that is not adequately controlled.” Therefore, the risk to human health arising from the use of *all four* substances in articles was the leading element for the defining of restriction management options examined for their effectiveness, practicality and monitorability. Moreover, the risk reduction capacity of a restriction option with the scope of the proposed restriction but excluding DEHP from its scope would be lower than the proposed restriction.   Regarding predictability to applicants for authorisation: The restriction considers the cumulative risk from all sources of exposure to the phthalates, whereas the authorisation process only considers the risk from exposure due to individual (or joint) applicants. Therefore, it is only to be expected in some cases a restriction under Article 69(2) will mean that authorisations may not be continued after the review date. It was agreed with the Commission that in these cases any restriction would be phased in at the same time as the review period.  Regarding the reasonable transition period: As it was determined that many of the articles contributing to the risk to human health are also within the scope of some applications for authorisation, the proposed restriction has taken into account their recommended/granted review period for these authorisations (i.e., 2019) by proposing an effective date of three years following its publication in the Official Journal, i.e., 2020 at the earliest.  2. Koch et al. (2016) observed a reduction in exposure since 2011. This observation confirms the projections of the Dossier Submitter. The impact of the predicted decline in exposure from 2011 to 2020 on the RCRs is presented in the Background Document. The impact on the RCRs for the intermediate year 2015 is not explicitly shown in the Background Document because the predicted RCRs for 2015 and 2020 are nearly equal and indicate there is still a risk. The Background Document assumes a decline of 1.8% for DEHP of the 95th percentile of exposure from 2011 to 2015 whereas the data in Koch et al. (2016) suggests a decline of 11%. Similarly, for DBP, DIBP and BBP the Background Document assumed a decline of 50% of the 95th percentile of exposure whereas the data in Koch et al. (2016) suggests a decline of about 17.5%. Thus, the projections in the Background Document underestimate the decline in exposure to DEHP but might overestimate decline in exposure for DBP, DIBP and BBP. It should be stressed that the exposure to DBP and DIBP has the highest impact on the RCRs and thus, overall, based on the data in Koch et al. (2016), the RCRs for combined exposure to the four phthalates is underestimated rather than overestimated. In fact, the data suggests that for Germany, the Background Document underestimates the combined RCR with 42%. On average (all EU countries in DEMOCOPHES) the Background Document underestimated the RCRs on average by 37%. Moreover, the trend in DE is not necessarily representative of the whole EU and the population in Koch et al. (2016) is very homogeneous (students of 20-29y from 4 university cities) in contrast to the EU population. Some of the trend between 2011 and 2015 may also be due to statistical fluctuation in the relatively small sample size (n=60) in Koch et al. (2016). In conclusion, the projections made in the Background Document are reasonable and the need for a restriction is not challenged by the new study by Koch et al. (2016). See section D.3.5.3 of the Background Document.  3. See response to comment number 1475 regarding the choice of percentile.  4. The Dossier Submitters considers the Background Document sufficiently detailed to allow informed decision making.  5. First, the exposure estimates for erasers, sex toys and sandals are not included in the aggregated nor in the combined exposure estimates. The exposure to these articles is included to demonstrate that some articles may result in particularly high exposure levels that are not necessarily picked up by biomonitoring data. Second, the exposure from such articles is not necessarily of short-term and infrequent nature. Third, the Background Document clarifies that even a short elevated exposure level within the ‘critical windows of exposure’ may be sufficient to cause adverse effects on the developing foetus which makes peak exposures particularly relevant in the case of the four phthalates (as opposed to substances where the critical effects are caused following chronic exposure).  6. The Background Document reports the findings in SCENIHR (2016) in section B.8.3.2.6 and acknowledged that medical devices can lead to high exposure and that for those children (boys) and women that regularly undergo medical treatment with DEHP containing medical devices, the risk as estimated in the current risk assessment is likely to be underestimated.  Regarding the epidemiology, the conclusion by SCENIHR (2016) that the studies were either inconclusive or inconsistent are consistent with the Background Document. The Background Document highlighted the limitations of epidemiology in section B.4.2.6 and D.3.5.1, but the available epidemiology is considered as supportive evidence. This conclusion is in line with SCENIHR (2016) *“However, analysing animal and human data along with mechanistic studies in a WoE approach, allow us to conclude that male foetuses of pregnant women and male neonates are potential groups at risk based on exposure levels above those that induce reproductive toxicity in rodent animal studies.”* and importantly, the TDI supported by SCENIHR (2016) is nearly identical to the DNEL derived by RAC: *“The Tolerable Daily Intake (TDI) value of DEHP was previously established (RAR 2008 and ECB 2008) at 48 μg per kg bw per day, based on a NOAEL of 4.8 mg/kg/d for reproductive toxicity in rats and applying an assessment factor of 100. Based on the same studies, EFSA rounded the TDI to 50 μg/kg bw/d (EFSA 2005). SCENIHR supports the previously derived TDI value, considering that the new studies are in line or not sufficiently robust to justify the derivation of a new TDI.”.*    7. Based on the available data, the Dossier Submitter considers DINP has anti-androgenic properties but with lower potency than the four phthalates. This view is shared by e.g. CHAP (2014) and Health Canada (2015).  8. The Dossier Submitter included the ECPI sponsored review by Kimber and Dearman (2010) and Dearman et al. (2008) in the Background Document together with other reviews and studies. It should be noted that the review by Kimber and Dearman (2010) is not recent and does not include 7 of the 10 available oral studies. Furthermore, Kimber and Dearman (2010) do not discuss weaknesses of the 3 oral studies that were available at the time. Importantly, **all** studies (n=10) with direct oral exposure to DEHP or DBP displayed adjuvant effects in rodents. See also the reply to your comment 1475. RAC concluded in the December plenary that immunological effects will be addressed in the uncertainty analysis and SEA. RAC preliminary concluded in September (RAC 38) that metabolic and neurodevelopmental effects will be addressed in the uncertainty analysis and SEA and confirmed that conclusion in the December plenary meeting.  9. The commenter accuses the Dossier Submitter of obscuring and misreporting of data in the restriction proposal. The Dossier Submitter rejects these allegations and considers them baseless:  - In contrast to the commenter’s claims, Andrade et al. (2006) clearly did report cryptorchidism, we quote: *“A low incidence of cryptorchidism was observed in DEHP exposed groups with a lowest observed adverse effect level of 5 mg/kg/day”.*  - In contrast to the commenter’s claims, Christiansen et al. (2010) clearly reported mild dysgenesis of the external genitalia, we quote: *“Mild dysgenesis of the external genitals (score 1) was observed*  *not only in all dose groups but also in one of the male control rats (Table 3). When the two studies were combined the incidences of mild dysgenesis were significantly and dose-relatedly increased at*  *all dose levels except 30 mg/kg (p = 0.075 for litters).”.* The Dossier Submitter clarified the definition of this finding by Christiansen et al. (2010) in the Background Document for completeness.  - In contrast with the view of the commenter, the Dossier Submitter considers it reasonable to consider reduced spermatocyte development as anti-androgenic. The commenter did not provide any evidence on the contrary.  - In contrast with the view of the commenter, the Dossier Submitter considers it reasonable to regard the observed mammary gland effects as anti-androgenic. The restriction dossier justified this as follows: *“A 28-day study on the androgen receptor antagonist flutamide showed a dose-related induction of lobular atrophy in male mammary glands (Toyoda et al., 2000). The authors suggested that the observed lobular atrophy of the mammary glands may be due to an anti-androgenic action on acinar cells, as also seen in in vitro studies (Toyoda et al., 2000; Boccuzzi et al., 1995; Sourla et al., 1998). The same mechanism of action may apply to the lobular atrophy observed with DBP in the study by Lee et al. (2004).”.* This is supported by OECD (2009) which considers alveolar atrophy in the male mammary gland may result from a decreased level of serum testosterone. The commenter did not provide any evidence on the contrary.  See also the reply to comment number 1475.  10. See response to comment number 1475 regarding species differences.  11. In contrast to the commenters’ claims the word “off-gassing” is not used in the restriction proposal or Background Document. The commenter does not present any evidence that would contest the data or assumptions taken in the exposure modelling regarding migration rates.  File 2:  1. Please see the response to your identical comment provided in point 1 of File 1.  2. Regarding the substantial costs invested by industry to identify alternative plasticisers over the past 20 years, please see the response to your similar comment part of comment number 1493.  3. Please see the response to your identical comment provided in point 6 of File 1.  4. Please see the response to your identical comment provided in point 10 of File 1.  5. Thank you for confirming that the main alternatives to the four phthalates are as described in the dossier. Please see the response to your similar comment provided in point 7 of File 1.  File 3:  Please see the response to your identical submission number 1475. |
| **RAC Rapporteurs comments:**  RAC supports the response given by the Dossier Submitter, and notes that the additional information provided has been addressed in the Background Document.  As to the request to consider an RMO restricting non-authorised uses only, RAC agrees with the Dossier Submitter’s arguments to discard this option, noting further that the current restriction proposal respects the recommended/granted review period for the authorised uses of DEHP in articles within the scope (until 2019), and that the proposed RMO is not in line with the intention of the restriction proposal to address the health risks from the use of all four phthalates in all articles presenting exposure via critical routes under normal and reasonably foreseeable conditions.  Please also see RAC Rapporteurs’ comments to comment number 1475, and section B.1 of the opinion, where most of the points raised have been considered. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. The SEAC Rapporteurs agree, for what is relevant to SEAC, with the Dossier Submitter’s responses. |
| **1505** | **Date:** 2016/12/15 21:08  **Content:** Scope or restriction option analysis;  Hazard or exposure;  Environmental emissions;  Baseline;  Description of analytical methods;  Information on alternatives;  Information on costs;  Information on benefits;  Other socio economic analysis (SEA) issues;  Transit  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** DEZA as  **Org. country:** Czech Republic  **Attachment:**      <confidential attachment removed>  **Privacy comment:** Please see justification in the attached file | **Comment:**  Please see attached file |
| **Dossier submitter response:**  Thank you for your comments provided in three separate files. The Dossier Submitter notes that many of your points have already been made in your earlier comment number 1473. The reply below provides highlights of key points discussed in detail in response to comment number 1473 and responses to new comments part of comment number 1505.  1. See response to your previous comment number 1473.  2. See response to comment number 1504 regarding the transitional period and proposal for a total ban on all non-authorised uses.  3. Please see the reply to your comment number 1473 as well as the reply to comment number 1475 regarding the choice of percentile for exposure estimates based on biomonitoring, the role of exposure modelling in the assessment (and the correspondence with biomonitoring). The Dossier Submitter considers that elimination of DEHP from formulations may contribute somewhat to reduction of exposure to this phthalate, but this contribution is likely to be insignificant. Regarding medicines, see Background Document.  4. The Dossier Submitter went to great lengths to attempt to explain the exposure estimates based on biomonitoring based on literature data as well as by attempting to attribute exposure to different sources by means of exposure modelling, see also the Background Document. The commenter does not provide information to further support this effort.  5. Enforcement costs and testing costs:  Enforcement costs of Member states enforcement authorities are reported in section D.3.2, while testing costs to be incurred by industry to ensure compliance are discussed in section D.3.1.3. The costs for enforcement authorities were estimated as a result of direct survey of these authorities summarised in the report: Estimating the administrative costs of restrictions – an update based on data on 2010-2014 (ECHA 2015b), which estimated these costs on the basis of data on the restriction related controls submitted by Member States enforcement authorities. The report has informed the enforcement costs for a number of recent restriction dossiers. For the purpose of estimating testing costs, the Dossier Submitters organised a survey of industry publicised via several channels, including ECHA’s website, industry associations, and social media. The survey concluded that: information about the presence of phthalates in articles is available via other means than testing, e.g., due to obligations under REACH or other legislation; majority of companies ensure compliance with EU and national legislation primarily using contractual obligations and by providing information on the restricted substances to their suppliers; compliance testing by the buyer is used in rare occasions, primarily for spot checks; many companies already have practices put in place (due to current regulatory requirements or voluntary actions) regarding the presence of phthalates in their products (as these actions are part of the existing industry practices, they cannot be considered instigated by the proposed restriction and therefore, cannot be considered part of the costs of industry to ensure compliance with the proposed restriction), etc. For further information see section D.3.2 in the Background document.  6, 7 and 8. Alternatives, product integration, market scope, supply chain impacts:  Thank you for providing the following information: “IHS market (2015) report on plasticisers discusses that between 2014 and 2019 there will be a rapid consumption growth for non-phthalate plasticisers as replacements for DEHP.” as well as: “According to the European Council for Plasticisers and Intermediates there has been a steady shift from low molecular weight phthalates to high molecular weight phthalates which now account for 85% of the phthalate production in the EU.” Such information sources as well as information from applications for authorisation, market intelligence reports, information from DEHP and other plasticiser manufactures confirm statements in the Background document that: the alternatives presented in the Dossier Submitter’s substitution scenario are the most likely alternatives, that industry (including compounders) has experience substituting and substitution has been taking place despite some uncertainties related to the risks of some of the alternatives (which are also recognised in the Background Document – see Table D9 and section D.2.3.2), that there are other general purpose plasticisers capable of replacing DEHP across multiple products, that there are substitutes for all uses of DEHP in articles in scope of the restriction proposal, that alternatives are available on the EU and international markets, that the EU DEHP market has become highly aggregated with only one remaining manufacturer (see submission #1504), etc. The Dossier Submitter confirms that cost differences between the four phthalates are assumed in the substitution cost scenarios and these are consistent with information submitted in your application for authorisation: DINP cost difference of 6%-11.3%, DEHT – 3%-8.2%, DIDP – 10%-15.5% in the main costs scenario, although respectfully higher and lower cost difference are tested in the high and low material costs scenarios. (See section D.3.1.1 and Annex E.)  Baseline data:  The significant substitution of DEHP and the other three phthalates suggested in (or lack of) applications for authorisation and in market intelligence reports has been taken into account in the estimation of the current and future risk of exposure to the four phthalates assuming that there is one-to-one relationship between the decline in exposure and the decline in use of the four phthalates. This overestimates the decline in exposure as the general population will continue to be exposed to existing stocks of articles used over several years. Despite this overestimation in the decline, the Background Document demonstrates that risks from the four phthalates exists in 2014 and 2020. Using similar assumptions, the Background Document demonstrates that the proposed restriction will contribute to the decline in exposure and risk from the four phthalates to a maximum degree within the mandate of REACH, while highlighting the need to address the risks further by addressing the exposure to the four phthalates via food sources.  9. Proportionality and quantification of human health benefits:  Appendix D1 explains that the cases of hypospadias estimated to be associated with exposure to the four phthalates in articles in scope are about 0.02% of male births and discusses reasons for over/underestimation. It also explains why less weight has been given to reported prevalence in registries, i.e., due to underreporting and issues with consistent definition, and why the value of €4 350/case has been used to estimate emotional damage as a result of having hypospadias in childhood which may have long term implications throughout adult life. Appendix D2 presents information of other studies discussing similar health outcomes, with the recent addition of Rijk et al (2016) which was published following the submission of the dossier. The report also references the results of HEAL (2016) and Norden (2016) for hypospadias.  The quantification and monetisation of benefits in the dossier is partial and used only to give an indication of the magnitude of the benefits of the proposed restriction. As stated in the Background Document, the majority of the benefits are not quantified and monetised. Furthermore, the ECHA guidance on Socio-economic analysis - Restrictions points out that when benefits occur far in the future a lower discount rate than 4% may be more appropriate. This approach was recently taken on board in the SEAC opinion on BPA.  10. In contrast to the commenter’s claim, the Dossier Submitter rated the strength of the relationship between exposure and effects and thereby did discriminate between effects. See section D.3.5.1 and Table D17 of the Background Document. The commenter does not present concrete evidence in support of the allegations presented in the comment.  Regarding species differences, see response to comment 1475.  The Background Document highlighted the limitations of epidemiology in section B.4.2.6 and D.3.5.1, but the available epidemiology is considered as supportive evidence. This conclusion is in line with SCENIHR (2016), see also reply to comment 1504.  Regarding testicular germ cell cancer, the Dossier Submitter indeed rated the strength of the relationship between exposure and testicular germ cell cancer as weak and it is therefore unclear what the criticism attempts to address.  The term “Testicular changes” is clearly defined in the Background Document as “testicular changes including decreased testes and epididymides weight, tubular atrophy and Leydig cell hyperplasia”.  The reference to support the entry “neurodevelopmental effects” is corrected to Braun et al. (2013), Skakkebaek et al. (2016) indeed do not report on neurodevelopmental effects.  Regarding immunological effects see the reply to comment 1475. SCENIHR (2016) indeed concluded that *“DEHP in experimental systems has shown the potential to interact with the immune system*  *depending on the exposure conditions. Interestingly from a medical device perspective,*  *immune effects were reported when parenteral routes of administration were used.”*. The Dossier Submitter did not claim phthalates are sensitisers, rather they appear to be adjuvants.  Unlike the commenter states SCENIHR (2016) does **not** state that the data were conflicting and the significance was unclear. Likewise, SCENIHR (2016) does **not** state that there was no conclusive evidence of any harmful effects of DEHP in humans.  Regarding liver carcinogenicity, activation of PPARα remains an important mode of action for DEHP carcinogenicity, but the data suggest that multiple pathways in several cell types contribute to cancer in rats and mice. In the light of the new evidence IARC has in 2011 reviewed the classification of DEHP and changed their conclusion back to ‘possibly carcinogenic to humans (Group 2B)’. See Background Document.  Finally, several studies have found negative associations between phthalate exposure and semen quality in male adults (Duty et al. 2003, Hauser et al. 2006, Pant et al. 2008, Pant et al. 2011, Jensen et al. 2015b, Huang et al. 2011, 2014). A recent meta-analysis by Cai et al. (2015) strengthens the evidence that the phthalates of concern adversely affect semen quality from exposure during adulthood. |
| **RAC Rapporteurs comments:**  RAC supports the response given by the Dossier Submitter, and notes that the additional information provided has been addressed in the Background Document.  As to the request to consider an RMO restricting non-authorised uses only, please see RAC Rapporteurs’ comments to comment number 1504.  With respect to the comments raised under point 1-4, please see RAC Rapporteurs comments to comments number 1473 and 1475. Please also see section B.1 of the opinion, where most of the points raised have been considered. |
| **SEAC Rapporteurs comments:**  Thank you for your comments. SEAC agrees with the responses by the Dossier Submitter.  Regarding enforcement costs SEAC recognises that testing of articles for enforcement of the restriction were not taken account in the Background Document. SEAC developed this point in its opinion and concluded that, under realistic assumptions, these costs are small compared to material substitution costs.  SEAC also noted your point regarding the percent of cases of hypospadias for which surgery is carried out. However, when consulting the internet page of the British association of urologist your comment refers to, we were unable to see a statement that surgery was not carried out for milder cases, but found a description how surgery is carried out for milder cases. Therefore, we did not see a need to change or comment on the Dossier Submitter’s assessment off this issue. |
| **1506** | **Date:** 2016/12/15 22:32  **Content:** Scope or restriction option analysis  **Type:** BehalfOfAnOrganisation  **Org. type:** Company  **Org. name:** <redacted>  **Org. country:** United States  **Company name confidential: Yes**  **Attachment:**  <confidential attachment removed>  **Privacy comment:** Protection of commercial interests, including intellectual property, would be undermined. | **Comment:**  The <redacted> appreciates the opportunity to provide comments on the Annex XV restriction report for Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP). <redacted> is one of the world's leading aerospace companies and the largest manufacturer of commercial jetliners and military aircraft combined, employing more than 171,000 people in 70 countries. Additionally, <redacted> designs and manufactures rotorcraft, electronic and defense systems, missiles, satellites, launch vehicles and advanced information and communication systems. <redacted> has customers and suppliers in more than 90 countries around the world.  <redacted> is primarily an exporter of manufactured articles to the EU. With nearly half of the in-service commercial fleet in Europe and hundreds of partners and suppliers in the region, we are an integral part of the European aerospace community. In 2015, <redacted> sourced more than €7.8 billion in airplane components and assemblies from tier 1 Europe based companies and hundreds of European suppliers participate in key <redacted> commercial aviation and defense programs. In addition, the company has delivered 4.500 commercial aircraft to more than 125 European customers in the last six decades and <redacted>’s advanced defense platforms are in service with 23 European armed forces.  Phthalates are used in the aerospace industry in a variety of applications as constituents of integral components of complex products ensuring airworthiness of airplanes throughout the duration of their use. However, upon reviewing the proposal and the accompanying restriction report, the proposed restriction’s applicability to the interior of transportation products such as aircraft, automobiles, trains, and ships is unclear.  Table 1 of the Annex XV Restriction Report (“Restriction Report”), which sets forth the proposed text of the restriction, states that it applies to all articles containing the restricted phthalates and then narrows the scope by way of derogation excluding certain categories of articles. However, those derogations are unclear and appear to be inconsistent with the Information Note for the Public Consultation (“Information Note”) and the Restriction Report’s discussion of scope. Specifically, derogation 2(a) exempts “articles only for outdoor use.” Transportation products are primarily used in the outdoors, with the exception of temporary storage and maintenance. However, phthalate-containing articles may be present in the interior compartments of these products. This leads to confusion and uncertainty as to the scope of the derogation when applied to these transportation products.  The uncertainty arises from discussion in the Restriction Report and Information Note which diverges from the proposed definition of “only for outdoor use” set forth in the text of the proposed restriction. Table 1 of the Restriction Report contains the text of the proposed restriction and defines the term “only for outdoor use” as follows: “articles which are not used or stored in the interior of dwellings where humans are present under normal and reasonably foreseeable conditions” (emphasis added). Ordinarily, the term “dwelling” is understood to mean a human residence, such as a home or apartment, and would therefore not be understood to mean an interior of a transportation product. Furthermore, the Restriction Report Appendix shows ECHA used models and studies which focused on data primarily from homes, specifically bathrooms and children’s play rooms, as well as children’s day care centers. This seems to indicate that ECHA does not intend the interior of transportation products to be considered “indoors.”    While the text in Table 1 seems clear, the discussion of the restriction’s scope in the accompanying Restriction Report and in the Information Note seems broader, referring to articles used in “indoor environments” rather than just dwellings. This wording suggests the restriction is intended to include the use of articles in any “indoor environment where people are present under normal and reasonably foreseeable conditions.” This could lead to the potentially mistaken conclusion that interior compartments of transportation products are included. As such, the discussion in the Restriction Report and Information Note appears to conflict with the proposed text of the restriction, as described above, and creates confusion and uncertainty.  Given the text of the proposed restriction set forth in Table 1 and the data that ECHA relied on and presented to develop the restriction (which appears focused on homes and similar dwellings), we believe the restriction is not intended to apply to the interior of transportation products. However, to avoid any confusion, uncertainty, and potential impact on articles not intended to be in scope of the restriction, we suggest that the proposed restriction be revised to more clearly define the scope and that clarifying text be added to all relevant regulatory documents. For example, ECHA may consider clarifying the definition of “dwelling” to specifically state “human residences.” |
| **Answer to specific info request 3:**  Please see confidential attachment. |
| **Dossier submitter response:**  Thank you for your comments. Following the submission of the dossier, the Dossier Submitter clarified that the articles in the scope of the RoHS directive (such as some electrical components) are outside the scope of the proposed restriction and that spare parts for vehicles placed on the market are derogated. In addition, the proposed restriction wording was amended to reflect the intent to limit the use of the four phthalates in articles in interior spaces, which includes interiors of vehicles, if they meet specific conditions, e.g., for dermal contact and contribution to indoor air. The Dossier Submitter invites you to submit additional (including quantitative) information that will help with the assessment of the impacts from the proposed restriction for the EU. |
| **RAC Rapporteurs comments:**  As to the requested additional derogation for spare parts for aircrafts, RAC notes that the justification provided for this derogation is solely based on technical and economic arguments. No data were provided on the tonnages of phthalates involved or on the degree of exposure resulting from either prolonged skin contact or inhalation. The contribution to the risk is therefore not known, and the impact this derogation would have on the risk reduction potential of the proposed restriction can thus not be assessed. Therefore, from a risk assessment perspective the requested derogation is not justified.  Due to lack of sufficient (quantitative) information provided, RAC considers the requested derogation for aerospace articles used in the interior of aircrafts not justified. |
| **SEAC Rapporteurs comments:**  Thank you for your comments, which have been noted. |
| **1506\_2** | **Date:** 2016/12/12 15:28  **Type:** BehalfOfAnOrganisation  **Org. type:** Industry or trade association  **Org. name:** ACEA  **Org. country:** Belgium  **Attachment:** | **Comment:**  Proposed restriction of the four phthalates DIBP, DBP, BBP, DEHP:  Regarding additional questions, it is difficult to determine the impact for each of these, due to the ambiguity surrounding one phrase.  The “exposure via inhalation” requirement is extremely difficult for our industry to assess, without a sensible concentration threshold.  Most interior applications that are potentially impacted by this restriction proposal are wiring harnesses, hoses, rubbers, seals and tapes that are hidden within or beneath interior components such as carpets, door casings, seats, instrument panels and headliners.  Although potentially, we only use small amounts of these phthalates in these applications, analytical techniques are so sensitive that if a vehicle interior were analysed to ng / m3, we may find that exposure via inhalation cannot be negated at these concentrations.  During routine industry measurements of vehicle interior air quality to the ISO 12219-1 test procedure, concentration of DEHP (by far the most abundant of these phthalates in our materials, accounting for more than 90% of the four phthalates in our vehicles), is below 120 µg/m3. This level is the voluntary threshold identified in the Japanese Automobile Manufacturers (JAMA) requirements.  The responses to the questions assume that if the concentration of the four phthalates is below 120 µg/m3, then no exposure via inhalation occurs.  Please find the answers to the questions you raised in your email from 13 October in the uploaded document. |
| **Dossier submitter response:**  Thank you for responding to our request for additional information. The Dossier Submitter has clarified that the intention of the restriction is not to place and request an enforcement of a concertation limit of the four phthalates in the air. We also note that your replies suggest that very few articles in vehicles will fall within the scope of the proposed restriction given the considerable effort of the automotive industry to replace the four phthalates. We recognise, however, that there may be some article required for the continuous maintenance of vehicles placed on the market prior to the entry into effect of the proposed restriction (assumed to be in 2020 for the purpose of the restriction proposal). Therefore, the Dossier Submitter supports your request for derogations and proposes the following addition to the wording of the proposed restriction: “spare parts for the maintenance of vehicles for which it can be demonstrated that they have been placed on the market for the first time in the European Union prior to the date in paragraph 5” (i.e., assumed 2020)”.  Regarding your request for derogation of “hidden” articles, the Dossier Submitter notes that sufficient information (e.g., volume of phthalates used, number of vehicles impacted, definition of “hidden” articles, etc.) for an assessment of such a derogation was not provided. In the absence of such information, such a derogation cannot be justified. |
| **RAC Rapporteurs comments:**  As to the requested additional derogation for spare parts (for automotive vehicles placed on the market prior to the entry into effect of the proposed restriction), RAC notes that the justification provided for this derogation is solely based on technical and economic arguments. No data were provided on the tonnages of phthalates involved (although one might expect this could potentially be a high volume) or on the degree of exposure resulting from either prolonged skin contact or inhalation. The contribution to the risk is therefore not known, and the impact this derogation would have on the risk reduction potential of the proposed restriction can thus not be assessed. Therefore, from a risk assessment perspective the requested derogation is not justified.  RAC concludes the same for the requested derogation for materials that are hidden within, or below, assemblies in automotive vehicles that are currently in the engineering pipeline (and thus, not on the market yet). RAC considers these articles/materials to be included in the scope, as there will be emission to indoor air, in particular in the vehicle interior where carpets, seats etc. can be found and people are present. In the absence of information on the contribution to risk, the requested derogation is not considered justified. It is further noted that the requested time-limited derogation appears not necessary, as you have indicated that for most articles a transition to alternatives is foreseen by 2020. |
| **SEAC Rapporteurs comments:**  Thank you for your comments, which have been noted. |

1. More suppliers emerging for DOTP <http://blog.phthalate-free-plasticizers.com/2012/01/05/more-suppliers-emerging-for-dotp/> [↑](#footnote-ref-1)
2. Promising future for DOTP <http://blog.phthalate-free-plasticizers.com/2014/03/24/promising-future-for-dotp/>; Oxea plans capacity increase for plasticizer Oxsoft GPO

   <http://blog.phthalate-free-plasticizers.com/2014/03/24/oxea-plans-capacity-increase-for-plasticizer-oxsoft-gpo/>; <http://www.oxea-chemicals.com/uploads/tx_nfoxcnews/140324_EN_OXEA_DOTP_Expansion.pdf> [↑](#footnote-ref-2)
3. More suppliers emerging for DOTP <http://blog.phthalate-free-plasticizers.com/2012/01/05/more-suppliers-emerging-for-dotp/> [↑](#footnote-ref-3)
4. Commission decision pending at the time of writing. [↑](#footnote-ref-4)
5. <https://echa.europa.eu/documents/10162/31ec5ce2-ec0f-4dcc-b572-b81f4d6fa7f2> [↑](#footnote-ref-5)
6. <https://echa.europa.eu/documents/10162/21961120/rac_24_dnel_dehp_comments_en.pdf/e0506f6b-35f7-433e-99da-35464a26e2df> [↑](#footnote-ref-6)