**Response to comments on the SEAC draft opinion**

**on the Annex XV dossier proposing**

**restriction on**

**FOUR PHTHALATES (DEHP, BBP, DBP AND DIBP)**

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

**EC number:** 204-211-0, 201-622-7, 201-557-4, 201-553-2 **CAS number:** 117-81-7, 85-68-7, 84-74-2, 84-69-5

**15 June 2017**

Comments on the SEAC draft opinion

SEAC has concluded that there is a need for derogations for certain articles containing DEHP, DBP, DIBP and BBP in excess of 0.1% w/w, individually or in combination. If there are other articles for which industry will experience difficulties transitioning to alternatives within 3 years of the entry into force of the proposed restriction (i.e., assumed to be in 2020), the affected parties are invited to submit relevant socio-economic information to assist with the assessment of their requested derogations. Examples of information essential for the justification of a possible derogation include:

* description of the articles for which you are requesting a derogation (e.g., spare parts for vehicles already in use, aerospace articles subject to certification requirements, articles used in motor vehicles) and a definition of the article category to be used in the legal text of the proposed restriction;
* detailed reasons for not being able to transition to the alternatives and justification for the time required to transition (e.g., timelines for requalification);
* volumes of articles placed on the EU market for which you are requesting a derogation (historical data per annum and projections, zif possible) and tonnages of the four phthalates contained in the articles;
* other impacts (benefits and costs) in the event a derogation is not granted.

|  |  |  |
| --- | --- | --- |
| **Ref.** | **Date/Name/Org.** | **Comments** |
| 306 | **Date/Time:** 2017/05/17 13:43  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  ACEA  **Org. country:**  Belgium | **Comments on the SEAC draft opinion:**  In response to the request for further information for the phthalate restriction proposal, ACEA members have further evaluated their data under consideration of the latest draft wording:  “Restriction Proposal  1. The following articles or any parts thereof containing DEHP, DBP, DIBP, and BBP in a concentration, individually or in any combination, greater than or equal to 0.1% by weight of each plasticised material shall not be placed on the market:  a. any articles whose phthalate containing material may be mouthed or is in prolonged contact with human skin or any contact with human mucous membranes, and  b. any phthalate containing articles that are used (including stored) in an interior space where people are present under normal and reasonably foreseeable conditions and potentially exposed via inhalation.  This does not apply to articles that are used only in industrial or agricultural workplaces by workers. “  Regarding Clause 1a - Prolonged skin contact  Based on actual assessments ACEA members can confirm that they do not have any articles in a vehicle that contains one of the four phthalates and giving rise to prolonged skin contact during regular use.  We have also evaluated spare parts that may fall under this clause and can confirm that potentially only a very small number of spare parts would have potential for prolonged skin contact. These parts are not safety critical and volumes are so low that substitution for these spare parts would be possible.  Therefore, an exemption for spare parts for this clause is not required.  Regarding Clause 1b - Exposure via inhalation.  ACEA members test the interior air of their vehicles according to the requirements of different regions.  The Japanese Manufacturers Association (JAMA) has a requirement for DEHP in interior air of 120µg/m³.  During testing by our members, we are consistently well below an interior threshold of 100µg/m³.  For an interior air concentration of 100µg/m³, exposure to DEHP is well below the DNEL of 0.034mg/kg/bw/day under normal and reasonably foreseeable conditions.  We therefore consider that we are not impacted by the exposure by inhalation restriction proposal.  In conclusion, due to the efforts already spent in the European automotive industry on the phase out of the four phthalates, there is no need for a specific exemption.  We however would like to note that if the finalised restriction would cover parts that have not been considered in the current draft text (i.e. parts where no prolonged skin contact occurs), we may be required to revisit the impact upon spare parts). |
| **SEAC Rapporteurs response:**  This comment is superseded by your comment #320 for which our response is given below. |
| 307 | **Date/Time:** 2017/05/18 17:47  **Type:** BehalfOfAnOrganisation  **Org. type:**  International NGO  **Org. name:**  ChemSec  **Org. country:**  Sweden | **Comments on the SEAC draft opinion:**  We continue to support the restriction as it is the logical step after an authorisation procedure. As previously stated we are of the opinion that as few derogations as possible should be given. One derogation that should be mentioned in particular is the one for vehicle spareparts where there are alternatives available and no proper justification. This derogation should therefore not be accepted. Additionally the derogation for wellingtons and boots is not justified and should not be allowed. |
| **SEAC Rapporteurs response:**  Thank you for your support and comments, which are noted and taken into account together with comments of other third parties on the same subjects and which are reflected in the final draft opinion.  Based on the information provided during this public consultation by the automotive and the aerospace industry, the SEAC Rapporteurs are of the opinion that:   * An exemption for spare parts for aerospace industry is justified (when the type certificate has been issued prior to the entry into force of the proposed restriction); * A derogation for articles for automotive vehicles produced prior the date in paragraph 6 plus 2 years is justified and for spare parts. |
| 309 | **Date/Time:** 2017/05/19 11:16  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. country:**  Belgium | **Comments on the SEAC draft opinion:**  In order to ensure regulatory consistency and guarantee continued use of DEHP in blood containers and blood sets, as defined in the Medical Devices Regulation (MDR), we consider it very important that SEAC in its final opinion supports a derogation for medical devices and components. There is currently no viable alternative providing the same performance as DEHP in the manufacturing of blood bags and blood sets. DEHP, a typical plasticizer used for polyvinyl chloride (PVC), is eluted from PVC-made blood containers and protects against red blood cell (RBC) haemolysis. DEHP is therefore a critical substance for the performance of blood containers and blood sets and it is very important to ensure that the use of DEHP will not be restricted for the next 10 years. |
| **SEAC Rapporteurs response:**  Thank you for your comments. Medical devices and components are derogated in the draft opinion. The SEAC Rapporteurs confirm their support for this derogation as explained in the draft opinion. |
| 310 | **Date/Time:** 2017/05/22 11:21  **Type:** MemberState  **MS name:**  Sweden  **Attachment:** | **Comments on the SEAC draft opinion:**  See the attached document for the Swedish Chemical agencies comments. |
| **Additional information:**  See the attached document for the Swedish Chemical agencies comments. |
| **SEAC Rapporteurs response:**  Thank you for the information on the new Directives regarding the medical sector. The information provided has been added to the SEAC opinion.  Regarding your suggestion that a transitional time of 12 months is achievable and preferable, and in relation to the supporting information that you have provided, we have the following observations:   * The global advancement of the substitution in a sector (vinyl flooring) is a different issue than the time required for a single actor to achieve full substitution; * The time needed for public procurement to switch to non-phthalate alternatives is the time needed to switch suppliers, but not necessarily representative of the time needed by an individual supplier to fully move to alternatives for all its products.   Therefore, even though we agree that the transition to the alternatives is well advanced in the EU, we cannot use the information provided to shorten the transition period. |
| 311 | **Date/Time:** 2017/05/22 11:20  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Japan Plasticizers Industry Association  **Org. country:**  Japan  **Attachment:** | **Comments on the SEAC draft opinion:**  Comments on  SEAC’s draft opinion on DEHP, DBP, DIBP, and BBP  in articles  The Japan Plasticizer Industry Association (JPIA) is the industry group consisting of the Japanese enterprises manufacturing and marketing plasticizers, including phthalates. The JPIA has been paying attention to the changing EU regulations against certain phthalates for the past several years and, based on scientific grounds, submitted a dissenting opinion against the Restriction Proposal of April 1, 2016 for diisobutyl phthalate (DIBP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl) phthalate (DEHP) presented by the European Chemicals Agency (ECHA) and the Danish association.  The JPIA understands that the draft opinion prepared by the Committee for Socio-economic Analysis (SEAC) concerning DEHP, DBP, DIBP and BBP in articles is very critical of the proposed restriction. We, the JPIA, disagree with the proposed restriction of the four phthalates in the EU, and the JPIA requires either the immediate withdrawal or a scope reduction of the proposed restriction. The JPIA presents some comments below, considering the responses given by the dossier submitter, the Risk Assessment Committee (RAC) and SEAC to our previous comments, as our work to create fruitful and globally feasible regulations for chemical substances. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  First of all, we would like to make clear that the SEAC opinion is supporting the proposed restriction without ambiguity. Our comments mainly relate to several uncertainty sources but we conclude that the restriction is an adequate and justified risk management option.  Regarding the detailed comments in the attachment:   * Comment 1: This is in the remit of RAC. * Comment 2.1: SEAC does not think that the socio-economic calculations carried out by the Dossier Submitter are not understandable. SEAC was able to understand and agree with the calculations, with the comments made in the draft final opinion. The Rapporteurs consider that the socio-economic calculations are based on reliable information as described in section B.3.3.1.3. of the draft final opinion as well as on reasonable assumptions in relation to forecasts. As explained in that section, substitution of DEHP takes place internationally and is expected to continue in the future due mainly to rapid increase in use of non-phthalate plasticisers and the discontinuation of large-scale production of linear phthalates.   We also clarify that regarding the previous restriction proposal, SEAC concluded that there were alternatives available to replace the four phthalates in most situations. SEAC was unable to support the proposed restriction at that time due to issues in the justification for proportionality and not due to significant concerns on the availability and feasibility of alternatives.   * Comment 2.2: This is in the remit of RAC, but SEAC found that the evidence provided by epidemiological studies was supporting the proposed restriction. * Comment 2.3: Please see section B.3.3.4.3 of the draft final opinion, where SEAC explains the rationale for concluding on the proportionality of the restriction despite the uncertainties. There it is stated that the quantification of benefits is only one of several aspects considered by SEAC to come to a conclusion on the proportionality of the proposed restriction. * Comment 2.4: The assessment by SEAC is based on past experience with similar restrictions. The draft final opinion also takes into account the costs to the recycling sector, which are quantified in the opinion (please see section B.3.3.1.3.e, p.31) and estimated to be €1.6 mil per year. * Comment 2.5: Based on available information the Rapporteurs are convinced that alternatives exist for all uses imparting to articles at least the same quality as that imparted by the four phthalates. As stated in the draft final opinion, many of the similarly priced alternatives have very similar performance characteristics as those of DEHP, DBP, DIBP, and BBP. Advantages of some alternatives are documented in the Background Document and studies quoted in the Background Document. SEAC found the restriction proportionate assuming the alternatives are of similar quality (and not better) for simplicity. * Comment 2.6: It seems that you are referring to the benefits (and not costs) of the proposed restriction, between €12.2 and €558 (not €58) million. SEAC has assessed the calculations, underlining the uncertainties, but concludes that these estimates can be taken into consideration. The absence of a general legal definition of Endocrine Disruptor Chemicals is not an obstacle to assess the health impacts for a specific case, as it is carried out in the Background Document. * Comment 3: Since SEAC agrees that there are technically feasible, with lower risk and similar or slightly higher cost alternatives to the four phthalates, the proposed restriction will not have an impact on the PVC market. The European chemical industry did not mention such possibility.   We agree that plasticiser demand will increase in the EU and this is in agreement with the baseline scenario (i.e. without restriction) for the four phthalates on which the SEA is based. But it is noted that the share of DEHP to the total plasticisers volume used in the EU is only about 10% and following a decreasing trend. EU manufacturers are likely to face only negligible costs compared to material substitution costs due to the proposed restriction. These costs are likely to be distributional and would be compensated by gains of the manufacturers of alternatives (including the EU manufacturers). Any further closures or capacity reductions could not be solely associated with the proposed restriction, due to the downward trend of the volumes of the four phthalates that is taking place internationally- see section B.3.3.1.1d) p31.   * Comment 4: It is likely that improving the enforcement of legislation already in place could play a role in decreasing the overall exposure to the four phthalates. The Dossier Submitter has shown that there is a risk coming from the articles under scope of the proposed restriction, and that this proposed restriction will be effective at reducing the risk. In sections B.2 and B.3 of the draft opinion an analysis is included on other legislative measures and the reasons which necessitate the implementation of the present proposal. * Comment 5-1/2/3/4/5/6: These comments are on topics within the remit of RAC. |
| 312 | **Date/Time:** 2017/05/22 12:59  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  DEZA a.s.  **Org. country:**  Czech Republic  **Attachment:** | **Comments on the SEAC draft opinion:**  Please find DEZA a.s.' comments in the attached PDF file. |
| **Additional information:**  Please see the attached PDF file with DEZA a.s.' comments on the scope of the proposed Restriction. |
| **SEAC Rapporteurs response:**  Restriction of non-authorised uses:  SEAC can consider derogating a particular use from the restriction scope if it has been provided data and evidence showing that leaving this use in the scope would affect severely economic actors or could affect the proportionality of the restriction. The comment fails to provide data/information discussing the rationale developed by SEAC in its draft opinion, and therefore cannot be taken into account. The aim of the restriction is also to manage the risk of all articles containing the four phthalates.  Use of out of date market information:  Please see response already provided by RAC during the previous Public Consultation, showing that the calculations by the Dossier Submitter are correct.  Concerns with regard to the ‘attributable fraction’ approach:  The SEAC Rapporteurs and the current opinion recognise the very high uncertainty regarding the benefits quantification, and in particular the choice of attributable fractions. We also underline that the SEAC conclusion regarding the proportionality is not based only on the consideration of quantified benefits, but also on non-quantified benefits, and on other arguments developed in the “proportionality” section of the opinion.  Percentage of cases attributable to exposure to the four phthalates in articles:  The 13% figure is an error that has been corrected for 11% in the last version of the Background Document Annex, and the explanation for the 11% figure is provided in SEAC opinion. The report by Kortemkamp that you have identified is indeed the one that has been used by the Dossier Submitter.  Cryptorchidism calculation issues:  The problem has been noted and was corrected in the last version of the Annex to the Background Document. It comes from the fact that the starting incidence rate in row a, was rounded to 2%, whereas the precise figure used in the calculations was 2.4% and 2.4%\*(1 – 4%) = 2.30%.  Human health costs in relation to hypospadias (incidence):  The SEAC Rapporteurs agree that it is difficult to have a reliable figure regarding the incidence rate of this disease, because its definition is varying among sources providing information, and therefore widely varying incidence rates are reported in the literature.  We agree that the Dossier Submitter considers that 100% of hypospadias require surgery (following the NORDEN study and other sources of information that suggest or recommend surgery), whereas other sources of information point to lower percentage (30% in the case of BAPRAS as pointed out in the comment).  A first observation is that in the NORDEN study, lower incidence rates than 3% are used, as pointed out in the comment, but since surgery is assumed for all cases, this is likely to be the consequence of a narrow definition of hypospadias. Therefore, the 3% incidence rate taken up by the Dossier Submitter is justified, as long as surgery costs are not assumed to occur for all cases.  Surgery costs represent close to 50% of total direct tangible costs of hypospadias in the NORDEN study. If surgery is required in only 30% of cases, total direct costs would be lower by (70%\*50% that is) 35%, leaving other costs unchanged. In this case, the total social costs of hypospadias are €6.8 million annually.  The SEAC Rapporteurs have reflected this in the draft final opinion. However, the SEAC Rapporteurs also consider that highlighting this particular uncertainty (among many) in the range of quantified benefits does not change their conclusion on how the comparison of costs and benefits (both quantified and non-quantified) are supporting the proposed restriction. Other arguments (in particular the break-even analysis) also remain unchanged, and the SEAC Rapporteurs still think the proposed restriction is proportionate.  Enforcement costs:  The cost of analysis was considered at 2014 price level based on the Danish Report to be €221. Also the number of samples per Member State was considered as 20 times the annual average number of indicated as non-compliant samples through RAPEX during the period 2006-2015 (please see footnote 17 under section B3.3.1.3.f of the draft final opinion).  The number of samples considered by the Rapporteurs (100) does not differ much from the number of samples referred to in the Swedish Report you refer to. Indeed, from the Swedish report it is extracted that the samples taken and belonging to scope are 473 in total in two years. Please note that from the total of 1 927 samples (Fig.13 of the Swedish report) the following samples should be subtracted as not under scope: 1 162 belonging to the jewellery category, 28 from electrical and metal toys, 127 from electrical products, 18 from wood products, 49 from chemical products (analysed for prohibited solvents and preservatives), reducing the total number of samples for the two years to 473.  Based on the above and the assumptions on the RAPEX samples referred to previously, the Rapporteurs consider that the EU average number of samples taken as a basis for calculating the costs of analysis is a reasonable one.  Justification for an EU wide basis measure:  An analysis and justification of the necessity of an EU wide measure to control exposure to the four phthalates is included in sections B.2 and B.3 of the draft final opinion.  FCM legislation:  Regarding your belief that the option of addressing food-related exposure risks through the existing FCM legislative framework would offer distinct advantage, the Rapporteurs agree with it and note their agreement with the Dossier Submitter's draw the attention of the Commission on the issue.  The Rapporteurs are convinced that for the reasons provided in section B.3.3.1.1.b) of the draft final opinion, testing costs are negligible compared to material substitution costs. The example referred to in the draft final opinion for the case of NPE shows simply that it is not unusual that testing costs are relatively minor.  The SEAC Rapporteurs agree that it is difficult to have a reliable figure regarding the incidence rate of this disease, because its definition is varying among sources providing information, and therefore widely varying incidence rates are reported in the literature.  We agree that the Dossier Submitter considers that 100% of hypospadias require surgery (following the NORDEN study and other sources of information that suggest or recommend surgery), whereas other sources of information point to lower percentage (30% in the case of BAPRAS as pointed out in the comment).  A first observation is that in the NORDEN study, lower incidence rates than 3% are used, as pointed out in the comment, but since surgery is assumed for all cases, this is likely to be the consequence of a narrow definition of hypospadias. Therefore, the 3% incidence rate taken up by the Dossier Submitter is justified, as long as surgery costs are not assumed to occur for all cases.  Surgery costs represent close to 50% of total direct tangible costs of hypospadias in the NORDEN study. If surgery is required in only 30% of cases, total direct costs would be lower by (70%\*50% that is) 35%, leaving other costs unchanged. In this case, the total social costs of hypospadias are €6.8 million annually.  The SEAC Rapporteurs have reflected this in the draft final opinion. However, the SEAC Rapporteurs also consider that highlighting this particular uncertainty (among many) in the range of quantified benefits does not change their conclusion on how the comparison of costs and benefits (both quantified and non-quantified) are supporting the proposed restriction. Other arguments (in particular the break-even analysis) also remain unchanged, and the SEAC Rapporteurs still think the proposed restriction is proportionate.  Enforcement costs:  The cost of analysis was considered at 2014 price level based on the Danish Report to be €221. Also the number of samples per Member State was considered as 20 times the annual average number of indicated as non-compliant samples through RAPEX during the period 2006-2015 (please see footnote 17 under section B3.3.1.3.f of the draft final opinion).  The number of samples considered by the Rapporteurs (100) does not differ much from the number of samples referred to in the Swedish Report you refer to. Indeed, from the Swedish report it is extracted that the samples taken and belonging to scope are 473 in total in two years. Please note that from the total of 1 927 samples (Fig.13 of the Swedish report) the following samples should be subtracted as not under scope: 1 162 belonging to the jewellery category, 28 from electrical and metal toys, 127 from electrical products, 18 from wood products, 49 from chemical products (analysed for prohibited solvents and preservatives), reducing the total number of samples for the two years to 473.  Based on the above and the assumptions on the RAPEX samples referred to previously, the Rapporteurs consider that the EU average number of samples taken as a basis for calculating the costs of analysis is a reasonable one.  Justification for an EU wide basis measure:  An analysis and justification of the necessity of an EU wide measure to control exposure to the four phthalates is included in sections B.2 and B.3 of the draft final opinion.  FCM legislation:  Regarding your belief that the option of addressing food-related exposure risks through the existing FCM legislative framework would offer distinct advantage, the Rapporteurs agree with it and note their agreement with the Dossier Submitter's draw the attention of the Commission on the issue.  The Rapporteurs are convinced that for the reasons provided in section B.3.3.1.1.b) of the draft final opinion, testing costs are negligible compared to material substitution costs. The example referred to in the draft final opinion for the case of NPE shows simply that it is not unusual that testing costs are relatively minor. |
| 313 | **Date/Time:** 2017/05/22 14:11  **Type:** BehalfOfAnOrganisation  **Org. type:**  International NGO  **Org. name:**  European Environmental Bureau  **Org. country:**  Belgium | **Comments on the SEAC draft opinion:**  The EEB firmly rejects the inclusion by SEAC of new derogations at this stage of the opinion development of the restriction proposal as it is opening a back door to the continued use of four phthalates, substances of very high concern, without an assessment by RAC of the risks that it may pose to Europe’s population and environment.  Industry needing a derogation for any use of the four phthalates had already several years to raise this issue, both through the consultation run by the dossier submitter during the preparation of its restriction proposal and also through the public consultation during ECHA’s committees opinion development process. |
| **Additional information:**  RAC has already rejected in its opinion development process the derogation request for spare parts for vehicles already in use, aerospace articles subject to certification requirements and articles used in motor vehicles. This derogation was submitted by industry through the public consultation at a very late stage. The request has not been justified from a risk assessment point of view, it concerns potentially a high volume of phthalates in view of the broad definition of vehicle (including buses, trains, planes, cars), the vast number of vehicles in use, and the long useful life of vehicles. Therefore, the impact of this derogation on the risk reduction potential of the restriction can potentially be very high. SEAC has not the capacities nor the role to assess the risk of the proposed derogation.  No justification for the lack of alternatives to all the uses covered by this broad derogation request have been provided. SEAC should restrain from accepting such broad derogations, in particular at this stage of the opinion development process. |
| **SEAC Rapporteurs response:**  Thank you for your support and comments, which are noted and taken into account together with comments of other third parties on the same subjects and which are reflected in the draft final opinion.  Based on the information provided during this Public Consultation by the automotive and the aerospace industry, the SEAC Rapporteurs are of the opinion that:   * An exemption for spare parts for aerospace industry is justified (when the type certificate has been issued prior to the entry into force of the proposed restriction); * A derogation is justified for articles automotive vehicles produced prior to the date in paragraph 6 plus 2 years as well as for spare parts. |
| 314 | **Date/Time:** 2017/05/22 14:49  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. country:**  Germany | **Comments on the SEAC draft opinion:**  This is a general comment to the proposed restriction of DBP, DIBP and other phthalates. While our industry association’s members are, to our current knowledge, not directly affected by the proposed restriction, we would like to urge the European Commission, RAC and SEAC members to reconsider the scope of the restriction with reference to the proposed wording of “in a concentration, individually or in any combination, greater or equal to 0.1% by weight”.  By means of Article 33, REACH imposes information duties along the supply chain only if a candidate list substance is present in a concentration “above 0.1% weight by weight”. Therefore, it is legally not mandatory (and thus not current practice) to inform customers if a candidate list substance is present in a concentration “equal to 0.1%” or below that threshold. However, in order to determine whether the named substances are present “in any combination” up to the threshold of 0.1%, industry participants would need to have information also on the presence of the named substances when present in concentration less than 0.1%.  To conclude: it will be very likely impossible for many industry participants to comply with the restriction requirements of “in any combination” and “equal to 0.1%”, because these two aspects go beyond the current information requirements of Article 33 REACH. We therefore urge to change the restriction scope to comply with the current Article 33 informational needs, i.e. to limit the restriction to cases where the named substances are present in the plasticized material individually in concentrations above 0.1%. |
| **SEAC Rapporteurs response:**  The SEAC Rapporteurs think that the proposed change is not justified, because this would undermine the aim of the proposed restriction, which is to address the risk posed by the combination of exposures to the four phthalates, that all have the same anti-androgenic mode of action. |
| 315 | **Date/Time:** 2017/05/22 16:01  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  European Plastics Converters  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  See attached. |
| **Additional information:**  See attached. |
| **SEAC Rapporteurs response:**  Thank you for your comments and the example you included to justify your concerns due to the increase of the raw material. We also take note of the costs and gross profits presented in your example.  However, we should stress that the costs for raw materials will be increased equally to EU producers as well as to non-EU producers of articles placed on the EU market. And that labour costs differences between EU and non-EU areas, to which you refer as the cause that will result in Retailers' and Distributors' preferences for non-EU produced articles, exist already under the current situation.  Therefore, passing on the increased cost due to the proposed restriction to the consumers is plausible and the impacts on the sector seem bearable.  In addition to the above, it is noted that the possibility of exporting articles containing recyclates exist, as they are not under the scope of the proposed restriction. SEAC also concluded as a whole that the proposed restriction is proportionate with boots and wellingtons included under its scope. |
| 317 | **Date/Time:** 2017/05/22 18:27  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  ORGALIME  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  Orgalime thanks ECHA for the consultation on its Socio-Economic Assessment Committee’s (SEAC) draft opinion on a 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 reiterates that the RoHS Directive already restricts the use of DEHP, DBP, BBP and DIBP in electrical and electronic equipment (EEE) with a maximum 0.1% concentration values tolerated by weight in homogeneous materials, following the adoption of Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending the list of RoHS restricted substances in Annex II.  Orgalime would therefore like to express its general support for point 3d) in the text of the draft restriction. Point 3 lists articles that would be excluded from the scope of the restriction. Indent d) refers to EEE covered under Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive).  However, since the reworded draft REACH restriction now suggests to be applied not only to certain articles but also any parts thereof, this approach should be also reflected in the subparagraph 3d) to further on ensure legal consistency. This is well suggested for paragraph 3c) but not 3d).  Therefore, similarly to paragraph 3c) the notion “or components for such equipment” should also be added to paragraph 3d) regarding EEE covered by the RoHS Directive. |
| **Additional information:**  Orgalime thanks ECHA for the consultation on its Socio-Economic Assessment Committee’s (SEAC) draft opinion on a 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 reiterates that the RoHS Directive already restricts the use of DEHP, DBP, BBP and DIBP in electrical and electronic equipment (EEE) with a maximum 0.1% concentration values tolerated by weight in homogeneous materials, following the adoption of Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending the list of RoHS restricted substances in Annex II.  Orgalime would therefore like to express its general support for point 3d) in the text of the draft restriction. Point 3 lists articles that would be excluded from the scope of the restriction. Indent d) refers to EEE covered under Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive).  However, since the reworded draft REACH restriction now suggests to be applied not only to certain articles but also any parts thereof, this approach should be also reflected in the subparagraph 3d) to further on ensure legal consistency. This is well suggested for paragraph 3c) but not 3d).  Therefore, similarly to paragraph 3c) the notion “or components for such equipment” should also be added to paragraph 3d) regarding EEE covered by the RoHS Directive. |
| **SEAC Rapporteurs response:**  The SEAC Rapporteurs note your comment but as the wording for items under RoHS refers to ''articles'' and not to ''devices'' as in the medical legislation, we believe that the components of RoHS equipment are adequately covered by the restriction text. |
| 318 | **Date/Time:** 2017/05/22 19:37  **Type:** BehalfOfAnOrganisation  **Org. type:**  National NGO  **Org. name:**  Breast Cancer UK  **Org. country:**  United Kingdom | **Comments on the SEAC draft opinion:**  Breast Cancer UK is dedicated to the prevention of breast cancers by reducing public exposure to the carcinogenic, hazardous and hormone disrupting chemicals which are routinely found in the environment and everyday products.  Breast Cancer UK welcomes the restrictions placed on the four phthalates, bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), and benzyl butyl phthalate (BBP), in articles that cause exposure through being mouthed, through the skin, or by inhalation. However, we disagree with several of the derogations that are proposed (see below).  Our concerns relate to the potential role of the four phthalates DEHP, BBP, DBP and DBIP in harming human health, as outlined in the annex XV dossier, and to their potential role in increasing breast cancer risk. All four phthalates have been classified as endocrine disrupting chemicals (EDCs) due to their anti-androgenic properties. The dossier describes numerous detrimental health effects, mostly associated with male reproduction and development. It also includes potential effects on female reproduction and mammary gland development (which may affect breast cancer risk), and immune system, metabolic and neurological effects. Furthermore, recent in vitro studies demonstrate that at very low concentrations, BBP, DBP, and DEHP show oestrogenic activity, increase breast cell proliferation and prevent apoptosis (cell death), suggesting low, environmentally relevant concentrations of these phthalates may increase breast cancer risk (1). There is also evidence that low concentrations of BBP and DBP promote tumour growth of oestrogen receptor negative breast cancer cells through activation of the aryl hydrocarbon receptor (2), thereby increasing breast cancer risk through mechanisms independent of oestrogenic activity. BBP has been shown in vitro to reduce the effectiveness of breast cancer chemotherapy (3).  For these reasons, Breast Cancer UK welcomes the committees’ conclusion that action should be taken on the restriction of the four phthalates used in articles however we do not agree there should be derogations for products used outdoors (provided articles do not come into prolonged contact with human skin or membranes), or in industrial or agricultural workplaces (provided they do not come into prolonged contact with human skin); or for measuring devices for laboratory use.  Such products will continue to contribute to emissions. All four phthalates are now classified as Substances of Very High Concern (SVHC) due to their classification as toxic for reproduction in category B and as EDCs for human health. In addition, DEHP has been classified as an EDC due to its effects on the environment. Phthalates are widespread in the environment, including air, water, soil, sediment and biota and their metabolites are detected regularly in human body fluids (4). In addition, DEHP DIBP and DEP metabolites have been detected in breast milk (5). This is especially relevant as early exposures to endocrine disrupting chemicals are likely to be of greatest significance and are most hazardous to health. We therefore object to the presence of these phthalates in articles suitable for outdoor use, as these will continue to contribute to pollution of the outdoor environment.  We are disappointed the proposed restrictions derogate food contact materials, but appreciate this is considered through separate legislation.  References  1. Chen, F.-P. et al. (2016). Impact of low concentrations of phthalates on the effects of 17beta-estradiol in MCF-7 breast cancer cells. Taiwanese Journal of Obstetrics & Gynecology 55:826-834  2. Hsieh, T.-H. et al. (2012). Phthalates induce proliferation and invasiveness of estrogen receptor-negative breast cancer through the AhR/HDAC6/c-Myc signaling pathway. FASEB Journal, 26(2), 778–787.  3. Hsu, Y.-L. et al. (2015). Benzyl butyl phthalate increases the chemoresistance to doxorubicin/cyclophosphamide by increasing breast cancer-associated dendritic cell-derived CXCL1/GROα and S100A8/A9. Oncology Reports 34(6):  4. Dobrzyńska, M. M. (2016). Phthalates - widespread occurrence and the effect on male gametes. Part 1. General characteristics, sources and human exposure. Annals of the National Institute of Hygiene 67(2): 97-103.  5. Kim, S. et al. (2015). Concentrations of phthalate metabolites in breast milk in Korea: Estimating exposure to phthalates and potential risks among breast-fed infants. Science of the total Environment 508: 13-19. |
| **SEAC Rapporteurs response:**  Thank you for your comment. We do recognise that the uses exempted in the proposed restriction contribute to the release of the four phthalates to the environment and therefore contribute to ecosystems and human exposure.  However, according to the RAC Rapporteurs, the Dossier Submitter has demonstrated that the proposed restriction with a scope focusing of articles giving rise to more direct exposure is efficiently reducing the risks for reproductive health and asthma addressed in the proposal. The Dossier Submitter recognised the potential effects regarding cancer, but in agreement with RAC considered there was not enough information to assess quantitatively the risk reduction or these effects. |
| 319 | **Date/Time:** 2017/05/22 22:24  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. country:**  United States | **Comments on the SEAC draft opinion:**  See confidential attachment. |
| **Additional information:**  See confidential attachment. |
| **SEAC Rapporteurs response:**  Thank you for your comment.  The Rapporteurs take note of your requests and SEAC has taken them into account when producing their final opinion. |
| 320 | **Date/Time:** 2017/05/22 23:44  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  ACEA  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  In addition to our comments submitted earlier and after further discussion with ECHA representatives it was explained to us that the risk-based approach we had chosen in our earlier considerations might not be considered as valid.  We therefore would like to provide additional comments and a request for derogations for Automotive applications. |
| **Additional information:**  Please find our comments and further explanation in the document provided. |
| **SEAC Rapporteurs response:**  Thank you for your comments.  Regarding the comment on paragraph 1b of the proposed restriction on exposure via inhalation, we note that the scope of the restriction does not rely on any threshold in terms of indoor air concentration, but is based on a limitation of DEHP content that all articles under scope should comply with. We also mention that RAC confirmed the approach taken in the Dossier was appropriate in order to control the cumulated exposure that gives rise to the risk.  We also note that the information provided on your comment paragraph 1b only refers to DEHP and not to the 4 phthalates.  The SEAC Rapporteurs consider justified for derogations for articles for vehicles produced prior to the date in paragraph 6 plus 2 years as well as for spare parts. The Rapporteurs acknowledge the high number of vehicles and the higher complexity of automotive industry supply chains in comparison to other supply chains under the scope of the proposed restriction. |