

## **Committee for Socio-economic Analysis (SEAC)**

### **Response to comments on the SEAC draft opinion on the Annex XV dossier proposing restrictions on four phthalates**

**ECHA/SEAC/RES-O-0000001412-86-10/S2**

<b>SUBSTANCE NAME</b>	<b>EC NUMBER</b>	<b>CAS NUMBER</b>
Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7
Benzyl butyl phthalate (BBP)	201-622-7	85-68-7
Dibutyl phthalate (DBP)	201-557-4	84-74-2
Diisobutyl phthalate (DIBP)	201-553-2	84-69-5

**5 December 2012**

Substance: **Diisobutyl phthalate, Dibutyl phthalate, Benzyl butyl phthalate, Bis(2-ethylhexyl) phthalate**  
CAS number: **84-69-5, 84-74-2, 85-68-7, 117-81-7**  
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Comments and response to comments on the SEAC draft opinion on Annex XV restriction dossier proposing restriction on **Diisobutyl phthalate, Dibutyl phthalate, Benzyl butyl phthalate, Bis(2-ethylhexyl) phthalate**  
Annex XV report submitted by Denmark 12 August 2011.  
Public consultation on the SEAC draft opinion started on 6 July 2012.

Ref	Date/ Country/ Organisation/ MSCA/Organisation Name	Comment	Response
77	2012/09/03 13:37  Denmark/ Denmark/ MemberState	<p>Denmark has a number of comments to the SEAC draft opinion the restriction proposal on the four phthalates. We have looked into the share of imported articles and where these articles originate from and have pointed to the fact that this have a very big effect on the exposure of the individuals and thereby also on the SEAC draft opinion as the use in Asia of these phthalates differs vary much from the use in EU. The comments made are very closely interrelated and our submission should therefore be seen as a whole.</p> <p>The comments are divided into the following subjects:</p> <ol style="list-style-type: none"> <li>1) Individuals are exposed to an unacceptable exposure</li> <li>2) The use of biomonitoring data</li> <li>3) The number of individuals to be protected</li> <li>4) The exposure scenarios</li> <li>5) Imported articles and the authorisation process</li> <li>6) Detailed comments</li> </ol>	<p>SEAC rapporteurs considered essentially point 5 and 6 since other points are related to RAC remit.</p> <p><u>Regarding point 5 :</u></p> <p>Thank you for providing comments on the amount and trend of the four phthalates in imported articles.</p> <p>The rapporteurs agree that imported articles have to be considered carefully when estimating the future stock of phthalates in the EU.</p> <p>Regarding the claim that amounts of the four phthalates in imported articles are much higher than those presented in the BD, the rapporteurs have assessed the data provided by DK in the Public consultation on the SEAC draft opinion and found several aspects that were</p>

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			<p>not clear or seem inconsistent:</p> <p>The conclusion that the amount of the 4 phthalates in imported articles is much higher than originally assumed is based on two article categories only (i.e. flooring and cables and wires). Such an assessment cannot be seen as representative for all articles.</p> <p>Regarding the assumption that the plasticiser content in imported articles is 40%, we think this assumption is very arbitrary. We asked the submitter of the comment for further clarification and based on this understood that the 40% figure is based on the assumption that the content of the four phthalates in articles under the scope is proportional to their total market share. Furthermore, knowing the ratio content/market-share for EU, and the market share in Asia, (the submitter) of the comment therefore derives the content for articles in Asia and then proposes some qualitative correction from that initial figure to propose 40% for content in imported articles from Asia. We think that the proportionality assumptions, and the qualitative correction, are very uncertain, with at least the two following reasons: firstly, uncertainty is caused by the fact that the content in imported articles manufactured in Asia for the EU market is very likely to be significantly different than in articles produced for the domestic market, as Asian manufacturers (and EU retailers) are</p>

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			<p>certainly aware of EU regulation and customer preferences in the EU (this is also illustrated by the information gathered on market prices and future market trends for this opinion making). Secondly, there is wider use of the four phthalates in Asia than in EU in terms of applications and variety of articles: the ratio "content in articles under scope/market share" is probably very different in Asia than in the EU.</p> <p>The rapporteurs consider the information presented to be only partial and the underlying assumptions questionable. Therefore they see no reason to modify the range of amounts from imported articles that are presented in the BD.</p> <p>Regarding the strength of the declining trend, SEAC rapporteurs maintain that the effect of the outcome of this restriction proposal on imports could only be very minor in comparison to the numerous other drivers causing the overall declining trend of the 4 phthalates use in the world, and in Asia, especially for exported articles.</p> <p>6) The SEAC rapporteurs have considered the suggestions by the DK. SEAC draft opinion has been modified to recognize that the difficulty to demonstrate benefits of the proposed restriction is also related to the lack of scientific knowledge on actual degree of</p>

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		<p>The Danish comments can be found here:  <a href="http://cms.mim.dk/NR/rdonlyres/16D50519-7A3E-47E3-A956-11242E71563F/0/DanishsubmissionSEACopinionSeptember2012.pdf">http://cms.mim.dk/NR/rdonlyres/16D50519-7A3E-47E3-A956-11242E71563F/0/DanishsubmissionSEACopinionSeptember2012.pdf</a>            A supporting report on the data concerning the import data on different groups of articles can be found here:  <a href="http://cms.mim.dk/NR/rdonlyres/1825C330-D535-46D4-B3C8-E471D9E2E519/0/Importstatisticsreport.pdf">http://cms.mim.dk/NR/rdonlyres/1825C330-D535-46D4-B3C8-E471D9E2E519/0/Importstatisticsreport.pdf</a></p>	<p>responsibility of specific reprotoxic substances on reproductive impairment in society</p>
76	2012/09/03 11:55  Germany/ National Authority/ Germany/ BehalfOfAnOrganisation	<p><i>[ The commenter did not want to disclose the name of the organization ]</i></p> <p>RAC considers that the proposed restrictions are not justified because there is no risk indicated from combined exposure to the four phthalates DEHP, BBzP, DnBP and DiBP.</p>	<p>Thank you for your comments.</p> <p>As the comments refer to the RAC opinion on the restriction proposal they are not applicable for the public consultation on the SEAC draft opinion.</p>

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		<p>This conclusion can be followed only in some parts. Concerning the assumption, that phthalate body burden has decreased over the last years we agree with the RAC opinion. However, there is still a fraction of 1,4% of the children aged 6 to 11 years which excrete DEHP-metabolites higher than the HBM-I value. In contrast to RAC we believe that a small group of children may be at risk from combined phthalate exposure.</p> <p>1) RAC regards HBM as a valuable tool to assess exposure. Why did RAC abandon the option to assess all relevant HBM data?          RAC stated that „biomonitoring data are expected to give a good representation of the total/combined levels of phthalates that the population has been exposed to“. We certainly do agree but on the same time are wondering why RAC did not take more recent biomonitoring data into account. For us it is also to question why RAC did not take the German "Human Biomonitoring values (HBM values) into account.</p>	

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		<p>The German Human Bio monitoring Commission has defined HBM-I-values for the metabolites of DEHP in human urine. They are 500 µg/l for 6 to 13 year old children, 300 µg/l for women in childbearing age and 750 µg/l for males 14 years of age and older and all other population groups. These values are based on the sum of the secondary metabolites 5OH-MEHP and 5oxo-MEHP and were modeled on the basis of the TDI (tolerable daily intake). They are therefore based on toxicology (HBMC 2007). According to the commission exceedance of these values in the respective group means exactly "that damage to health cannot be excluded with sufficient certainty". The value opens the possibility to assess HBM data without modeling the daily intake.</p> <p>The HBM value can be used to assess recent German data that were not included by RAC but we do consider them as very relevant. This is data from GerES IV (The German Environmental Survey for children) conducted between 2003 and 2006 (Becker et al. 2009) and from the German part of DEMOCOPHES, a European Pilot Study on HBM conducted in 2011 in 17 European countries (<a href="http://www.eu-hbm.info/democophes">http://www.eu-hbm.info/democophes</a>).</p>	

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		<p>RAC stated that "it is not unreasonable to assume that the phthalate body burden will have decreased over the last five years in Europe". If we compare the German median levels in the age group of 6 to 11 year old children from GerES IV and DEMOCOPHES (Tab. 1) we do agree to this statement. Although GerES is a nationwide representative study and DEMOCOPHES was conducted in two sampling locations in North Rhine-Westphalia both surveys might be tentatively compared to show the trend. The median levels of all metabolites measured in DEMOCOPHES are less than half of the level that had been determined in GerES IV.</p>	



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		<p>Median levels of phthalate metabolites in children aged 6 to 11 years from GerES and the German part of DEMOCOPHES (unpublished data).</p> <table border="1"> <thead> <tr> <th></th> <th>MEHP</th> <th>5OH-MEHP</th> <th>5oxo-MEHP</th> <th colspan="2"></th> </tr> <tr> <th></th> <th>P50</th> <th>P90</th> <th>P50</th> <th>P90</th> <th>P50</th> <th>P90</th> </tr> </thead> <tbody> <tr> <td>GerES IV n=294</td> <td>6.6</td> <td>17.4</td> <td>49.4</td> <td>113</td> <td>39.2</td> <td>87.5</td> </tr> <tr> <td>DEMO-COPHES N=120</td> <td>2.3</td> <td>7.2</td> <td>21.1</td> <td>50.8</td> <td>14.3</td> <td>34.1</td> </tr> <tr> <th></th> <th>MBzP</th> <th>MiBP</th> <th>MnBP</th> <th colspan="2"></th> </tr> <tr> <th></th> <th>P50</th> <th>P90</th> <th>P50</th> <th>P90</th> <th>P50</th> <th>P90</th> </tr> <tr> <td>GerES IV n=294</td> <td>16.9</td> <td>52.6</td> <td>90.2</td> <td>220</td> <td>94.7</td> <td>221</td> </tr> <tr> <td>DEMO-COPHES N=120</td> <td>6.1</td> <td>21.9</td> <td>37.7</td> <td>111</td> <td>46.1</td> <td>150</td> </tr> </tbody> </table>		MEHP	5OH-MEHP	5oxo-MEHP				P50	P90	P50	P90	P50	P90	GerES IV n=294	6.6	17.4	49.4	113	39.2	87.5	DEMO-COPHES N=120	2.3	7.2	21.1	50.8	14.3	34.1		MBzP	MiBP	MnBP				P50	P90	P50	P90	P50	P90	GerES IV n=294	16.9	52.6	90.2	220	94.7	221	DEMO-COPHES N=120	6.1	21.9	37.7	111	46.1	150	
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		<p>However, if assessing the GerES IV data for the DEHP metabolites it could be shown that 1.7 % of the analysed 6 to 11 year old children (five of 294 children) had a concentration of the sum of the two metabolites in urine higher than the HBM-I value. DEMOCOPHES conducted in 2011 revealed that still 1.4% of the analysed children (2 of 120 children) have concentrations of the two DEHP metabolites higher than the HBM-I value (data not published yet).</p> <p>This shows to our opinion that the RAC conclusion depends on the fraction of children which might live with a not covered hazard. To us it is "not unreasonable to assume that the phthalate body burdens especially the DEHP burdens are still too high although a decrease of the mean values can be observed over the five years between 2006 and 2011". Exceedance of HBM-I still occurs and this fact justifies further measures.</p>	

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		<p>2) When assessing the internal exposure RAC used the 95th percentiles as "realistic worst case". Why?            To our knowledge the 95th percentiles are used in complex models in which multiple pathways are combined to build a close to realistic scenario of exposure. In our view it is different if measured data is compared with threshold values. In this case the 5% highest values should not be cut.            This is especially true in the case to the phthalates. The phthalate intakes do not show the typical frequency distribution of environmental pollutants that means a lot of low values and only some but then very high values. In the contrast the values are nearly uniformly distributed over the range.            References            Becker K, Göen T, Seiwert M, Conrad A, Pick-Fuss H, Mueller J, Wittassek M, Schulz C, Kolossa-Gehring M: GerES IV: Phthalate metabolites and bisphenol A in urine of German children. Int. J. Hyg. Environ. Health 212 (2009) 685-692.</p>	

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75	2012/09/03 11:43  United States/ Company-Downstream user/ Belgium/ BehalfOfAnOrganisation / Hewlett-Packard	<p>Hewlett-Packard (HP) evaluates environmental impact across the product life cycle when selecting materials for use in our products. We design products to use less material, and we seek alternatives to materials of concern. HP proactively evaluates materials of concern. We may restrict substances because of customer preferences, legal requirements, or because we believe it is appropriate based on a precautionary approach. When scientific analysis reveals a potential health or environmental concern, we seek to replace substances with commercially viable alternatives.</p> <p>HP believes that EU legislation plays an important role in promoting industry-wide transition to restrict substances of concern. HP supported the restriction of the four priority substances identified by the EU Commission in its 2008 proposal for a revision of the RoHS Directive; DEHP, BBP, DBP and HBCDD. HP will complete the phase-out of DEHP, DBP, BBP and HBCDD in newly introduced personal computing products by the end of 2012.</p>	Thank you for your comments.

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		<p>Despite the cessation of the REACH Restriction process, HP will proactively phase out the use of these phthalates in line with the Authorisation timelines for these substances of concern for most of HP products. While the SEAC's draft opinion concludes, based on the RAC's opinion, that it has no basis to support the proposed restriction, it does conclude that the proposed restriction might have led to benefits. HP will proceed with the phase-out of the use of the four phthalates in its products on a voluntary basis.</p> <p>Replacement technologies or substances however, need to be properly assessed against environmental and human health criteria in advance of their widespread adoption. When replacing substances of concern, HP seeks to identify alternatives with a reduced risk of potential human health and</p>	

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		<p>environmental impacts that also meet our performance and cost criteria. In order to avoid regrettable substitutions (alternative options that are of equal or greater concern than the substances restricted), HP employs a comparative chemical hazard screening is based on the GreenScreen™ for Safer Chemicals framework developed by the nongovernmental organization Clean Production Action. HP has identified commercially available alternative plasticizers to the phthalates proposed for restriction for HP applications, and these have been assessed to ensure that the replacement substances are safer than those being replaced.</p>	
74	<p>2012/08/31 22:01  Belgium/ Company-Downstream user/ /Belgium/</p>	<p>The Boeing Company ("Boeing") appreciates the opportunity to provide comments on the draft opinion of the Committee for Socio-economic Analysis (SEAC) on the Annex XV dossier for bis(2-ethylhexyl) phthalate, benzyl butyl phthalate, dibutyl phthalate, and diisobutyl phthalate.</p>	<p>Thank you for your comments.</p>

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	BehalfOfAnOrganisation /Boeing International Corporation	<p>Boeing is one of the world's leading aerospace companies and the largest manufacturer of commercial jetliners and military aircraft combined, employing more than 170,000 people in 70 countries. Boeing has customers and suppliers in more than 90 countries, and with many of them in Europe, we are an integral part of the European aerospace community. Boeing's extensive, international supply chain includes approximately 50 European sub-tier chemical processors located in 11 different countries.</p> <p>In general, Boeing concurs with SEAC's decision not to support the proposed restriction and agrees with the opinion that it is not justified. We appreciate the foresight that SEAC has shown in recognizing the limitations of the proposed restriction and believe that SEAC's draft opinion is correct.</p> <p>There is an existing fleet of aircraft operating in the EU that incorporate phthalate-containing parts and components. Aircraft operators must maintain and repair these aircraft in accordance with existing designs and type certifications in order to maintain airworthiness certifications required for continued operation of the aircraft within the EU. A restriction could prevent these aircraft operators from obtaining replacement parts and components for this existing fleet.</p>	

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		<p>Specifically, we share the assessment that the amount of phthalates being placed on the market is declining significantly, and will continue to do so. Given this trend, we agree that the risk assessment has not proven a need for the proposed restriction. Boeing also appreciates SEAC's recognition that not all articles contribute equally to exposure and thus, the proposed restriction is not the most appropriate measure for the EU community. We believe a blanket restriction would not have been the most suitable solution.</p> <p>In addition, Boeing supports the conclusion that the proposed restriction does not demonstrate that potential benefits would be proportional to the costs incurred. As we noted in our previous submission (from 16 December 2011), the cost analysis in the proposed restriction does not adequately capture the vast majority of the costs incurred in developing, qualifying, implementing, and certifying new materials in the aerospace industry. Combined with the lack of specifics regarding the benefits (highlighted in SEAC's draft opinion), any cost-benefit analysis is difficult to verify.</p>	<p>To clarify, SEAC intended to compare the costs of the proposed restriction, with the benefits in terms of avoided infertility cases in EU couples (see BD), however, SEAC found it was not possible to make a comparison between costs and benefits, due to the lack of information in the BD, and as noted by RAC the lack of scientific knowledge on the contribution of the four phthalates to the infertility problem.</p>



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Comments and response to comments on the SEAC draft opinion on Annex XV restriction dossier proposing restriction on **Diisobutyl phthalate, Dibutyl phthalate, Benzyl butyl phthalate, Bis(2-ethylhexyl) phthalate**  
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		<p>Boeing is working diligently with suppliers to develop replacements for phthalate-containing specialty aerospace materials. However, these efforts to complete new supplier material formulation, and aerospace industry testing, qualification, certification, and implementation in the supply chain will require several more years. Boeing appreciates SEAC's recognition of the long lead times required in the aerospace industry and its understanding of the complexity involved in developing suitable alternative materials.</p> <hr/> <p>Boeing is committed to environmental stewardship that is protective of human health and the environment, while maintaining our responsibilities for flight safety and airworthiness. SEAC's draft opinion, should it be adopted, will enable the aerospace industry to move forward with material replacements in an efficient, organized manner, while sustaining these commitments.          We appreciate your consideration of our comments.</p>	

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73	2012/08/31 17:45  Belgium/ Industry or trade association/ /Belgium/ BehalfOfAnOrganisation /VinylPlus	<p>VinylPlus submitted earlier on 31/08/2012 a short comment announcing a summary socio-economic assessment of the impact of the potential restriction on the recycling of flexible PVC. We were advised afterwards to write the key points in this window, and to provide a link to the document.</p> <p>The summary SEA can be downloaded from <a href="http://www.vinylplus.eu/uploads/SOCIO-ECONOMIC_ASSESSMENT_OF_THE_IMPACT_OF_THE_RESTRICTIONS_ON_ARTICLES_CONTAINING_LOW_MOLECULAR_WEIGHT_PHTHALATES.PDF">http://www.vinylplus.eu/uploads/SOCIO-ECONOMIC_ASSESSMENT_OF_THE_IMPACT_OF_THE_RESTRICTIONS_ON_ARTICLES_CONTAINING_LOW_MOLECULAR_WEIGHT_PHTHALATES.PDF</a></p> <hr/> <p>The conclusions of this SEA are:          The 2005 European strategy on waste sets out the guidelines and the following principles, in order of priority, for waste management in Europe: waste prevention; reuse and recycle; and finally, waste disposal (with incineration first and landfill only used as a last resort). Over the last few years, there have been increasing efforts by the Member States to collect and separate post-consumer waste to increase the amount of recycling in line with community principles. The PVC industry has also joined these efforts.</p>	<p>Thank you for your comment. The information provided does support the SEAC draft opinion and does not require any changes in the opinion text.</p>

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		<p>VinylPlus wishes the recycling of PVC to grow in order to meet regulatory objectives on recycling, in line with sustainability objectives and boosting resource efficiency. To ensure the increased recycling of PVC, new markets will have to be developed. If the focus remains on current markets only, the VinylPlus goal will not be achieved. Industry must develop technologies to produce high quality recyclate material. One driver for expansion of PVC recycling is to replace the post-industrial waste used today with post-consumer waste. Another is to replace the typically virgin PVC products that PVC converters make. A third driver is to create new applications for the PVC recyclate so that it replaces competing materials. A Restriction on the four low molecular weight phthalates would have a negative impact on these efforts to make post-consumer PVC waste (and PVC waste more generally) an increasingly attractive raw material.</p> <p>The Restriction would have an impact on the viability of the recycling of post-consumer PVC waste, as the content of the four low molecular weight phthalates (DEHP, DBP, BBP and DIBP) is unlikely to reach the 0.1% threshold concentration by weight in unsealed indoor articles and articles coming into direct skin or mucous membrane before 2020; it may be many years until this is achieved.</p>	

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		<p>As a result, the Restriction could result in a cessation of soft PVC waste recycling activities. Such a development would have a very significant effect on the PVC recycling market, as a minimum it would stifle further development of new applications for recycled PVC. Another possibility is that recyclers would need to turn to other waste, maybe post-industrial waste, where there is strong competition to obtain the available material (which is also priced differently to post-consumer waste).</p> <p>The viability of the unaffected end-applications could also be threatened. Converters of PVC recyclate may be very reluctant to continue using PVC waste if they cannot be certain that it meets the requirements of the Restriction. Faced with the costs of external testing (normally higher than current profit margins), smaller converters may substitute recyclate by new material, at increased cost, to ensure that there is no restricted plasticiser in their product. As a result, there are likely to be significant impacts on the recycling of flexible PVC waste and hence on the EU recycling industry, especially on smaller companies. The loss of economic margin for the recycling industry and PVC converters could have detrimental impacts on employment now and in the future.</p>	

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		<p>The shift of PVC waste from recycling will have the following detrimental consequences:</p> <ul style="list-style-type: none"> <li>• economic costs from alternative disposal (i.e. incineration and landfilling) ranging from €47m to €58m and accruing to waste owners;</li> <li>• economic costs from having to replace recycle with virgin PVC material estimated to range from €263m to €348m accruing to producers of end-products; and</li> <li>• externality costs ranging from €89m to €107m and including the externality costs from additional incineration, landfilling and the production of virgin PVC and accruing to the general public (human health) and the environment.</li> </ul>	

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		<p>Although these preliminary estimates are heavily reliant on estimates of the amount of soft PVC recycled between 2010 and 2020, they suggest that the total costs arising from the proposed Restriction on the recycling of post-consumer PVC would be in the order of €400m to €510m, discounted, for the period from 2014 to 2020 (N.B Figures may not add up due to rounding). Added to these costs, there could be employment impacts from the cessation of some recycling activities. The total employment impacts could amount to nearly 2,000 job losses in 2014 across the economy and, although this may overestimate the impacts, there certainly would be lost opportunities for the creation of more jobs in a sustainable industry. Moreover, the impacts will be significantly greater on SMEs as opposed to larger companies.</p>	

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72	2012/08/31 16:09  Belgium/ Company- Manufacturer/ /Belgium/ BehalfOfAnOrganisation /LMW Coalition	<p>Low Molecular Weight Group Manufacturers (LMW) Danish Restriction Proposal on four Lower Molecular Weight Phthalates Comments on the SEAC draft opinion of 15 June 2012</p> <p>Members of the European Council for Plasticizers and Intermediates include major European producers of the low molecular weight phthalates DIBP, DBP, and DEHP, three of the four phthalates targeted in the restriction proposed by Denmark. Each company in this Group of manufacturers is also involved in the authorisation process for one or more of the Annex XIV-listed phthalates DEHP, DBP and DIBP.</p> <p>This brief report is a comment on the draft opinion of the ECHA Socio-Economic Analysis Committee, in the context of the 2nd Public Consultation period for this restriction proposal.</p> <p>PART TWO - REPOSENSE TO PAGES 4 TO 7 OF THE DRAFT OPINION        (PART ONE - REPOSENSE TO PAGES 2 TO 3, SUBMITTED SEPARATELY. YOU ARE KINDLY REQUESTED TO READ PART 1 FIRST)</p> <p>Comments on SEAC views on proportionality</p> <p>1. SEAC refers to the potential adverse effect of the four phthalates being reported [Page 4 - Paragraph 2]. We would like to strongly emphasise that this statement does not refer to facts that have been proven. DEHP is one of the most deeply, broadly and widely researched substances, there are numerous</p>	<p>Thank you for your comments.</p> <hr/> <p>1. All of the four phthalates have been classified as being toxic to reproduction. We do mention that other potential adverse effects are not assessed in the BD as the focus is on reprotoxic health.</p>

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		<p>reports of all types of research. There are also "positive" research reports, on DEHP for example, but these reports are not given reference in this opinion. In addition, the RAC concluded that there is no exposure risk to the population of the EU. To maintain objectivity and impartiality, we request that this sentence be deleted from the SEAC opinion.</p> <p>1. We welcome the recognition of the adverse economic impact on recycled PVC and we suggest that this statement is made clearer and reads: "The proposed restriction would have an adverse impact resulting in reduced flows of recycled PVC..."</p> <p>2. The explanation given by SEAC regarding the market decline [Page 4 - Paragraph 9 ]- among others, the "affordability of substitution" does not reflect the fact that current availability and affordability is not guaranteed going forward. In addition, it does not reflect industry concerns about regulatory scrutiny of alternatives and the current or potential future regulatory status of these alternatives. We request that this sentence be deleted from the opinion.          Comments on availability and technical feasibility of alternatives</p>	<p>1. As the possible impact of the restriction on the recycling of PVC could not be assessed in detail, the rapporteurs find the original text more suitable.</p> <p>2          We agree that the trend in the use of the four phthalates does involve uncertainties and that the regulatory status of the alternatives theoretically could have an effect on this trend. However, the future decline is substantiated by available information and the rapporteurs consider it unlikely that it would be reversed by the drivers suggested in the comment. Therefore, the conclusion remains unchanged.</p>



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		<p>3. As the full extent of the use of these phthalates was not addressed in the Restriction Proposal, and as this can and will only become clearer when relevant applications for authorisation are submitted, we request that this sentence be changed to end with "... authorisation procedures." [Page 4 - Last line]            Comments on the affordability of substitution</p> <p>4. SEAC rightly points the potential implications for the aerospace industry [Page 6 - Paragraph 2]. We believe there are other industries definitely or potentially as affected as the aerospace industry, so we request that this be changed to read "for example, the aerospace industry".</p> <p>5. We would like to stress that in the case of complex supply chains, there is no doubt that substitution will [Page 6 - Paragraph 2, instead of "might require" ]"require more time".            Comments on the future decline in volumes</p> <p>6. Given that there are several regulations for food contact materials, we request that this be reference in the opinion be changed to read "The recent EU directive on DEHP in food contact material" [Page 6 - On the future decline].</p>	<p>3. From the BD, it is estimated that about 85 % of phthalates in articles are included in the restriction proposal. Therefore we acknowledge that this sentence refers to the four phthalates in articles and rapporteurs will change the original text to replace "of their use" by "of their use in articles".</p> <p>4. SEAC rapporteurs recognize they cannot exclude other sectors could be as affected as the aerospace industry. Therefore "in particular" is changed by "for example".</p> <p>5. The rapporteurs partly agree. However, as there is only limited information available on substitution processes in complex supply chains the rapporteurs prefer to qualify the wording reading: "...is likely to require more time to carry out."</p> <p>6. The rapporteurs agree with the suggestion - a clarification has been made.</p>

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		<p>7. The comment on the substitution process seemingly continuing after Annex XIV listing [Page 6 - "The substitution process seems ...REACH"] is not substantiated, and we would respectfully request SEAC to withdraw it.            Comment on outcome of the authorisation application process</p> <hr/> <p>8. We would like to make some important remarks regarding the assumption of SEAC that "...not necessarily all requested authorisations will be granted" [Page 7, paragraph 2].            While this is strictly speaking true and theoretically correct, it nevertheless suggests and implies a prejudgement of the outcome of the applications for authorisation. In the interests of objectivity and impartiality, we request that this sentence be deleted. Industry has the right under REACH to apply for authorisation and to have those applications assessed objectively and on their merits, without prejudice.</p>	<p>7. In fact, the data available to SEAC (such as market projections referred to in the BD) does substantiate the conclusion of the opinion text. Therefore, the rapporteurs find the original text suitable</p> <hr/> <p>8. The rapporteurs do not agree that the assumption of SEAC on the outcome of the authorisation process does imply a prejudgement as already stated in footnote 4 on page 7 of the draft opinion. It is based on the information available regarding the feasibility of substitution. Therefore, the rapporteurs find the original text suitable.</p>

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		<p>Comment on the baseline scenario data</p> <p>9. Regarding the baseline scenarios data, and the SEAC statement that there are some uncertainties regarding the baseline scenario, we would like to confirm that our independent 3rd party consultants advise that volume information being gathered as part of our DEHP authorisation application process (concerning EU production of DEHP for the EU market) is in line with the figures used in the baseline scenario for the years up to 2011, though we would add that the baseline data appears somewhat on the high side.</p>	<p>9. Thank you for this information.</p>
71	<p>2012/08/31 16:08</p> <p>Belgium/ Company- Manufacturer/ /Belgium/ BehalfOfAnOrganisation /LMW Coalition</p>	<p>Low Molecular Weight Group Manufacturers (LMW) Danish Restriction Proposal on four Lower Molecular Weight Phthalates Comments on the SEAC draft opinion of 15 June 2012</p> <p>Members of the European Council for Plasticizers and Intermediates include major European producers of the low molecular weight phthalates DIBP, DBP, and DEHP, three of the four phthalates targeted in the restriction proposed by Denmark. Each company in this Group of manufacturers is also involved in the authorisation process for one or more of the Annex XIV-listed phthalates DEHP, DBP and DIBP.</p> <p>This brief report is a comment on the draft opinion of the ECHA Socio-Economic Analysis Committee, in the context of the 2nd Public Consultation period for this restriction proposal.</p> <p>PART ONE – REPOSE TO PAGES 2 TO 3 OF THE</p>	<p>Thank you for your comments.</p>

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		<p>DRAFT OPINION:            (PART TWO - REPOSE TO PAGES 4 TO 7 SUBMITTED SEPARATELY)            Comments on the opinion [Opinion - Page 2]</p> <hr/> <p>1. Introductory comment            We note in the first place that demonstration of the existence of a risk is a pre-condition for the introduction of a restriction, and it is in the RAC remit to assess the risk. So if RAC takes the view that no risk exists or has been demonstrated, it might be considered that there is no need to issue a SEAC opinion.</p> <hr/> <p>With regard to the SEAC draft opinion published on 15 June 2012, and given the opinion of RAC, we would respectfully request that SEAC amends the first statement of the draft opinion in particular.            The text of the opinion states that "SEAC has no basis to support the restriction". We request the wording to be made fully impartial, for example "SEAC ...does not support ...."            Below we provide comments on specific aspects of the draft SEAC opinion.</p>	<p>According to REACH, SEAC has the obligation to develop an opinion on all restriction proposals (conforming to Annex XV).</p>

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		<p>2. Comments on specific parts of the draft SEAC opinion            We welcome the position of SEAC which, like RAC, does not support the proposed restriction. We would like to make the following points and requests for amendments to the text:            Regarding the opinion of the Risk Assessment Committee (RAC) [Page 2 – “the available data ..the four phthalates”]</p> <hr/> <p>Industry provided comprehensive data during the first public consultation period. The Risk Assessment Committee in fact concluded that the available data indicate that currently (2012) there is no risk from the combined exposure of these four phthalates in articles. We acknowledge that the SEAC quotes the RAC opinion wording correctly, however in the interests of accuracy we request that the actual RAC findings of no risk are clearly stated in the SEAC draft opinion.            On the subject of the combined effect, we wish to note that at the Community level, this discussion is only starting now, with the Commission recently having issued a discussion document. Legal certainty is required before this approach can be included in proposed legislative amendments such as listing on REACH Annex XVII.</p>	<p>2. The rapporteurs find the original text more suitable – no modifications made.</p> <hr/> <p>The conclusion of RAC is already clearly stated on page 2 and 4 of the SEAC draft opinion. The rapporteurs see no need for further clarification.</p> <p>As this comment refers to the RAC opinion on the restriction proposal it is not applicable for the public consultation on the SEAC draft opinion.</p>

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		<p>Comments on the justification for the SEAC opinion            Justification of action on a Community-wide basis</p> <p>1. We welcome the confirmation of the SEAC that any additional measures, should they be required, would need to be introduced at a community-wide level, as we understand this is a fundamental objective of the REACH Regulation: to ensure community-wide consistency regarding chemical substances.</p> <p>2. In the introduction [Page 3] SEAC refers to "articles containing phthalates". As there are more phthalates than the 4 targeted in the Danish Proposal, we request the wording to be changed to "SEAC acknowledged....containing the four specified phthalates .....affecting these .... materials). [note: proposed new wording in italics].</p> <p>Effectiveness in reducing the risks, proportionality</p> <p>1. SEAC rightly notes the trend of a further decrease for the four phthalates on the EU market. However, the statement [Page 3 - Paragraph 4 of "Effectiveness in reducing the identified risks", last sentence] made on assessment of the dynamics of this trend is not clear, especially the reference to "particular exposure thresholds". The definition of these thresholds and the purpose of their assessment is not explained. We request that the sentence be changed to read ".the dynamics of this trend cannot be assessed quantitatively."</p>	<p>2. The rapporteurs agree with the suggestion, the opinion text has been modified.</p> <p>1. The rapporteurs agree that the notion of thresholds is unclear, and we replace it with a more appropriate wording.</p>



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	Council	<p>and thus risks, were over-estimated and the proposed ban is not justified.            However, VEC remains concerned with the approach of so called "combined effects", which are not established yet with solid science. Such an approach can lead to arbitrary regulations, confusing both the society and the industry and may increase economic costs without meaningful contributions to risk reductions.            VEC keeps the view that new regulation proposal must be consistent with REACH and fully respect the ongoing processes.</p> <p>-----            PVC monomer and resin manufacturers' Association in Japan. <a href="http://www.vec.gr.jp/english/about.html">http://www.vec.gr.jp/english/about.html</a>            Please refer to the comments VEC submitted to ECHA on the Danish Proposal on 14 December, 2011.</p>	of SEAC.
68	2012/08/29 11:46  Japan/ Industry or trade association/ /Japan/ BehalfOfAnOrganisation	<p>August 29 , 2012            The JPIA on the Committee for Socio-Economic Analysis's (SEAC) Opinion (Draft) on the Restriction Proposal from Denmark            Japan Plasticizer Industry Association ( JPIA )</p>	Thank you for your comments.



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

Comments and response to comments on the SEAC draft opinion on Annex XV restriction dossier proposing restriction on **Diisobutyl phthalate, Dibutyl phthalate, Benzyl butyl phthalate, Bis(2-ethylhexyl) phthalate**  
 Annex XV report submitted by Denmark 12 August 2011.  
 Public consultation on the SEAC draft opinion started on 6 July 2012.

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	/Japan Plasticizer Industry Association	<p>[Introduction]</p> <p>The JPIA hails the opportunity given to comment on SEAC's opinion.</p> <p>The JPIA is an industrial association organized by companies producing and distributing plasticizers in Japan.</p> <p>SEAC recently published its opinion by adopting substantial parts of the description from our opinion document.</p> <p>Both SEAC's and RAC's opinion also include essential problems with the science-based risk assessment methodology, the common interpretation in implementing REACH Regulations, and others.</p> <p>Both SEAC's and RAC's opinion include the possibility for the regulation to be widely applied without limitation to the relevant phthalates and particular chemicals, which could lead to abusing the precautionary principle. This creates serious doubt about it for the JPIA.</p> <hr/> <p>[Request]</p> <p>Both SEAC's and RAC's opinion on the restriction of four phthalates proposed by Denmark includes some serious problems from the perspective discussed below. The JPIA therefore requests establishing more meticulous criteria and using due process to establish how the regulations will be applied.</p>	<p>The rapporteurs would like to emphasize that SEAC takes note of all the comments provided and the draft opinion is modified if and where seen necessary, however, no comments or parts of them are officially "adopted" in the draft opinion.</p>

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		<p>[Justification for Request]</p> <p>1. Strict application of combined effects            The term combined effects here refers to combined exposures, dose addition, combination effects, etc. used in Denmark's restriction proposal; the term may also refer to chemical mixtures, cumulative risk and other terms with almost identical meaning. Considering RAC's conclusion that the risk from combined exposures (dose addition) to the four phthalates, as proposed by Denmark, is not justified,</p> <p>SEAC states that there is no basis to support Denmark's restriction proposal.</p> <p>In the dose addition section of RAC's document, applying this approach is limited to risk assessment at the early stage (this approach can be used only as a method of rough screening) by considering uncertainty and conservativeness. Later, when the risks are identified, this approach is applied to evaluating cumulative exposure in humans, for example, by citing the idea that a number of biology-based methods are assured.</p>	<p>1. As this comment refers to the RAC opinion on the restriction proposal it is not applicable for the public consultation on the SEAC draft opinion.</p>

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		<p>Furthermore, the European Commission, in its reply to the European Council, agreed that the dose addition approach is appropriate to ensure safety in the "Assessment of Chemical Mixtures"* of May 31, 2012. It also expressed concern about overestimation and recommended establishing a new working group for conducting mixture risk assessment and to fill a gap in scientific knowledge.</p> <p>Since an infinite number of combinations can be expected for the myriad of existing chemicals other than mixtures of the four phthalates, a transparent process using more objective and scientific definitions, criteria and testing/assessment methods should</p> <p>determine if the regulation will be applied to these mixed chemicals.</p> <p>*<a href="http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/541&amp;format=HTML&amp;aged=0&amp;language=EN&amp;guiLanguage=en">http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/541&amp;format=HTML&amp;aged=0&amp;language=EN&amp;guiLanguage=en</a></p> <p>2. Authorization and concurrent restriction in REACH Regulation</p>	<p>2. As already stated in the RCOM for the public consultation on the Annex XV restriction dossier: Rapporteurs agree with the dossier submitter's interpretation that a member state is allowed to submit a restriction proposal for an Annex XIV substance if it relates to substances in articles. REACH Article 69(2) also places an obligation on ECHA to consider, after the sunset date for an Annex XIV substance, whether the use of that substance in articles poses a risk to human health or the environment that is not adequately controlled and, if this is the case, to present an Annex XV dossier for a restriction. This provision does not stipulate that only ECHA can compile such a dossier, or that ECHA (or a MS) cannot do so before the sunset date. If a member state wishes to prepare an Annex XV</p>

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		<p>Deviating from the REACH Regulations, Denmark's restriction proposal imposes restrictions on groups of substances designated as those requiring authorization, resulting in authorization and restriction progressing simultaneously.</p> <p>SEAC's opinion statement makes little mention of this problem. Such a restriction proposal without any convincing base does not follow the implementing bylaws of REACH Regulations and will create confusion for complying with REACH Regulations. The authorization process presently in progress should be moved ahead first in accordance with Article 69 (2) of the Regulations.</p>	<p>dossier justifying a restriction on a substance in articles, it may do so, and this would not be in contradiction to REACH Article 69(2).</p> <p>Furthermore, the guidance for preparing an Annex XV restriction dossier does note that Article 69(2) of REACH requires ECHA to consider if new restrictions are needed on Annex XIV substances with regard to their use in articles, but also here it is not stated that only ECHA could compile such dossiers.</p>

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		<p>3. Strict definition of endocrine disruption and establishment of its testing method            RAC states that the dose addition approach is appropriate for the initial step of risk assessment because the four phthalates have a mode of action similar to anti-androgen substances.</p> <p>Denmark's restriction proposal suggests that the four phthalates would cause reproductive toxicity in humans (such as infertility) based on a relationship between the anti-androgen effect and endocrine disruption. In contrast, SEAC's opinion states that such a relationship cannot be clearly demonstrated.</p> <p>Concerning endocrine disruption, no science-based consensus exists on a worldwide scale yet. Even the European Commission Report issued this January and counterarguments ** to this report and the Symposium held by the Commission this June have not reached any scientific consensus. Therefore, continued efforts to establish science-based definitions, criteria and test/analysis methods should be made, and the application of regulations by citing endocrine disruption should be simultaneously discussed and decided by a transparent and objective process.</p> <p>**  <a href="http://informahealthcare.com/doi/pdf/10.3109/10408444.2012.690367">http://informahealthcare.com/doi/pdf/10.3109/10408444.2012.690367</a></p>	<p>3. As this comment refers to the RAC opinion on the restriction proposal it is not applicable for the public consultation on the SEAC draft opinion.</p> <p>The rapporteurs do not agree. The SEAC draft opinion does not conclude on the hazards of the four phthalates (as this issue is considered by RAC). It only states that the restriction dossier did not demonstrate health benefits from the proposed restriction.</p> <p>As this comment refers to the RAC opinion on the restriction proposal it is not applicable for the public consultation on the SEAC draft opinion.</p>