

**Committee for Risk Assessment (RAC)**

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

**Response to comments document (RCOM)**

to the opinions on the Annex XV dossier

proposing restrictions on

**four** **phthalates**

**Table 1 (Responses to individual comments)**

**Non-confidential**

**ECHA/RAC/RES-O-0000001412-86-07/S2.1**

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

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| **SUBSTANCE NAME** | **EC NUMBER** | **CAS NUMBER** |
| 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 |

**13 July 2012**

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**Reader’s guide**

Received comments have been compiled in two separate groups:

* confidential comments;
* non – confidential comments.

For each group there is a Table 0 (Compilation of all comments), Table 1 (Responses to individual comments) and Table 2 (Responses by subject). Only non-confidential tables are published on the website.

Table 0 contains all received comments in submission order by date.

Table 1 contains comments to specific issues together with responses from the Dossier Submitter (DS) and the rapporteurs from the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC).

Responses to comments in Table 2 are grouped according to the content of the comment. As several submitted comments cover the same topic, the following horizontal issues were identified (please see the list below). For ease of reference responses by DS and the Rapporteurs have been shaded in grey.

**Horizontal issues covered by Table 2:**

|  |  |
| --- | --- |
| H 01 | Appropriateness of the risk management measure (RMM) – restriction versus authorisation  |
| H 02 | Aerospace industry – need for derogation |
| H 03 | Recycling issues |
| H 04 | Combined effects – Legal aspects |
| H 05 | Combined effects – Scientific aspects |
| H 06 | Risk to human health |
| H 07 | The scope of the proposed restriction |
| H 08 | Proportionality issues |
| H 09 | Information on alternatives |
| H 10 | Exposure |
| H 11 | Socio-economic analysis (SEA) of the proposal |
| H 12 | Comments related to species differences in sensitivity |
| H 13 | Usefulness of epidemiological information |
| H 14 | Assessment factors and absorption |
| H 15 | Relevant toxicological endpoints |
| H 16 | Selection of risk management option (RMO) |

| **Ref** | **Date Country/ Organisation/** **MSCA****Comment type** | **Comment** | **DS Response** | **Rapporteurs responses****(RAC or SEAC)** |
| --- | --- | --- | --- | --- |
| **197** | Belgium / International NGO / EEB  | The view that the Restriction would have a negative effect on the competitiveness of EU industry is very debateable. There is potential for the Restriction to benefit European manufacturers by giving them a lead in the development and manufacture of alternatives to the phthalates of most concern. This is reflected in the following statement by BASF:“With Hexamoll® DINCH, both we and our customers are ideally equipped for the future”, said Prof. Dr. Rainer Diercks, president of BASF’s Petrochemicals Division. “This phthalate-free plasticizer plays a big role in human contact applications. Due to the disproportionately high demand and growing global demand for alternative plasticizers, we have decided to expand our production capacity once again. This will strengthen our market position and open up new opportunities for Hexamoll® DINCH. Expansion in the form of a second production plant will enable us to supply our customers around the world more successfully and more reliably in the future.” Source: http://basf.com/group/pressrelease/P-11-365. | We appreciate the support. DINCH is already mentioned as one of the alternatives in use - and the statement quoted by EEB from one of the main producers of plasticisers BASF documents that alternatives exist and are already in use. | **SEAC**: No further comments. |
| Finally, we note that much of the discussion of the benefits of the Restriction has focused on fertility. Other benefits, for example in relation to testicular cancer, incidence rates of which have doubled since the 1960s, should also be factored into consideration. | We recognise the argument, but have not addressed this further, as the basis for the restriction proposal is only the reprotoxic properties of the four substances.  | **RAC:** To our knowledge human data do not allow a conclusion on the association of testis cancer to phthalate exposure. Antiandrogenic effects have been speculated to be of relevance for increasing incidences of human testicular cancers. No consistent findings on testicular tumors were seen for two phthalates where carcinogenicity data in rodents were available (DEHP and BBP), no carcinogenicity studies were available for the two other phthalates. Thus the DS approach to address adverse effects on the reproductive organs by the four phthalates that are mediated by a similar mode of actions to account for combined risks was appreciated.**SEAC:** We agree that in principle other benefits (as compared with impacts related to the reprotoxic effects of the four phthalates) should be taken into account. However, neither benefits related to the reprotoxic effects nor other benefits were demonstrated in this case. |
| Remaining comments are addressed in Table II, H 03. |  |  |
| **189** | Slovenia / Other contributor /  | If the risk assessment for the individual product represent base for safety assessment of this product in accordance with the provisions of Directive 2001/95/ES, it is necessary to determine the appropriate analytical method, which will cover the corresponding realistic worst case exposure scenarios. | There is already existing legislation with the same limit value in REACH Annex XVII, and an analytical method exists in order to control this entry. | **RAC**: No further comments. |
| Remaining comments are addressed in Table II, H 09 and 10. |  |  |
| **184** | Denmark / Company / Danisco/ Du Pont | We have added comments to the Annex XV proposal for restriction report using track changes and attached to this web form. Our comments focus on the alternative named COMGHA, described in section C.5 of the report. We would kindly like to ask that the rest of the report should be updated based on the submitted comments | We see no reasons not to do this - the proposed changes will however not change anything of importance in the conclusion, that this is a good alternative in some articles; the changes are of a "secretarial" matter only. | **SEAC:** No further comments (the comments provided by Danisco were taken up in the BD). |
| Remaining comments are addressed in Table II, H 09. |  |  |
| **166** | Finland MSCA  | We also recommend displaying elimination half-lives of the substances in the dossier to give a better understanding of simultaneous exposure. | The biomonitoring data shows that there is a repetitive exposure to the phthalates as the elimination half-lives generally are relatively short.  |  |
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| Comparison of the total exposure from articles under the proposed restriction with the total exposure from all sources would give important information to estimate the impact of the proposed re-striction. Moreover, modeling the estimated exposure after restriction and comparing it with the total exposure to see the impact of the restriction is welcomed. Also, the levels of the remaining ex-posure from articles not in the scope of the restriction and exposure from food, that is generally re-garded as a major source of phthalate exposure for adults (Wittassek et al. 2011), would give valua-ble information. We consider that a more thorough analysis concerning the grounds for selecting 0.1 % as a concentration limit for the restriction proposal would be needed. By determining the impact of the restriction would in our opinion help to assess the concentration limit for the restriction. | This has been done to the extent possible.The 0.1% is chosen as this is already the limit that exists in current legislation in REACH Annex XVII and thus this limit is easy for all stakeholders to rely to.Data has shown no linear correlation between content and migration (shown in the BD, section B), so it would not be possible to determine "a concentration limit for the restriction". It has to be as low as possible in order to protect the population. | **RAC:** The contribution of food to the total exposure considering the recent legislation on FCM and validity of the studies on exposure via food and indoor environment were carefully reviewed and new risk characterisation calculations were revised in line with the recommendations of RAC. Due to the lack of data there are however a number of remaining uncertainties that could not be eliminated. For further information see our response in Table 2 H10.The suggestion to model the estimated exposure after the restriction/remaining exposure from articles not in the scope is no longer relevant as we are not in favour of a restriction.This conclusion was reached on the basis of the estimated risk for the current situation. Projected volumes in 2020 for the baseline which suggest a decrease in volume of four phthalates on the EU market by 69-85% as compared to the volume in 2007. As a result of the continuous substitution taking also the need for authorisation from 2015 into account the anticipated decrease in volume, the exposure to the four phthalates will further decrease. Following from this it would seem that the effects of ongoing substitution, existing restriction are already capable of limit the risk, to an acceptable low level.  |
| The justification of the proposal would in our view gain from more biomonitoring data. There are some ongoing projects regarding biomonitoring of phthalates, e.g. EU project DEMOCOPHES which will produce new data during summer 2012 on the present baseline levels of phthalates in the gen-eral population in Europe based on mother-child pairs. Biomonitoring data on situations described in exposure scenarios (eg. mouthing erasers and/or wearing sandals), if possible, would be useful for comparison of the real exposure and exposure estimates. Moreover, braces and other dental devices that are placed in the mouth can contain significant amounts of phthalates. Even though these medical devices are not in the scope of the restriction, it would be informative to have biomonitoring data on patients using these dental devices compared to the general public, or if not possible, at least modeling the exposure from dental devises for comparison. This kind of information on biomonitoring would help to estimate the impact of the proposed restriction to human health. | We agree, but there are no data available for the time being - and we are of the opinion that human experiments are not considered appropriate. Regarding dental devices we agree but data are not published as far as we know.  | **RAC**: RAC is aware of the ongoing projects, however none of the projects could be considered as results are not yet available.  |
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| Comment to the chapter ”Widespread use” on page 7. ECHA definition for wide-spread use is ”uses occurring at numerous locations, which do not result in significant release”, should be considered ”widespread” but not as ”wide-dispersive”. Therefore, it would seem more pertinent to head this paragraph as ”Wide-dispersive uses”, which refers to ”many small point sources or diffuse release by for instance the public at large or sources like traffic and can relate to both indoor and outdoor use&quot. | Editorial comment that do not change the conclusion - has been done.  | **RAC:** No further comment**.** |
| The remaining comments are addressed in Table II H 05 and 10. |  |  |
| **164** | Belgium / International NGO / European Environmental Bureau  | As a general point, we query why the fast track procedure of Article 68(2) has not been used in this case, given that the substances concerned are Reprotox Category 1B. The decision not to use A68(2) seems inefficient and not in line with the intentions of REACH for that particular category of substances “in articles that could be used by consumers”. A great deal of the time and effort that has gone into preparation of the dossier and its evaluation by the Committees could have been avoided had Article 68(2) been applied. | The dossier is based on the combined effects of the four phthalates and since this is the first time that such an approach is used a discussion in the appropriate scientific bodies is good. | **RAC and SEAC:** No further comment. |
| EEB would in this respect like to stress as a general point that a Socio-economic assessment is NOT mandatory in order to assess the validity and completeness of the restriction proposal. According to Section 3 of Annex XV on SEA, the “socio-economic impacts of the proposed restriction MAY be analysed with reference to Annex XVI”.[ own emphasis added]. Annex VI on SEA also specifies that “This Annex outlines the information that MAY be addressed […] in connection with a proposed restriction […] [own emphasis added]. However we find the information generation exercise useful, in particular to provide useful supporting elements for those parties that see potential concerns in terms of negative (economic) impacts in regards to the restriction. EEB’s contribution should be seen as a response to addressing some of these perceived concerns. | We agree. | **SEAC:** We fully agree and thank you for the submitted information which has been taken into consideration. Please see further table H11. |
| Remaining comments are addressed in Table II, H 07; 09 and 11. |
| **161** | Belgium / Industry or trade association / Test & Measurement Coalition  | Test and measurement equipmentThe proposed restrictions are not supported by an adequate risk assessment and, at least to the extent that they apply to phthalates-containing parts or components of test and measurement equipment and/or to the equipment itself, are disproportionate. | It is the combined exposure from all articles that forms the basis for the proposal and therefore single uses should be seen in this context. However, other arguments have been raised for exempting these articles from the restriction and this has been done. | **RAC and SEAC:** No further comments. |
| Remaining comments are addressed in Table II, H 01; 06; 07 and 11. |
| **160** |  / / Sweden MSCA | Sweden agrees that a proper functioning of the internal market necessitates action on a Community wide basis and that a restriction is an appropriate action. Although three of the four phthalates (DEHP, BBP and DBP) are included in Annex XIV the import of articles containing the three phthalates will not be affected since the authorization process does not cover imported articles.  | We agree. | **RAC and SEAC:** We agree with the basic principles but cannot support this restriction proposal at hand as it did not provide sufficient justification for a health risk to be addressed.  |
| BaselineA clearer definition and identification of the baseline is needed in order to fully answer the question “what will be the outcome without implementing any further action”. The description of the baseline also needs to consider eventual outcome of an authorisation for one of or several of the phthalates in question and what this will mean in terms of risk reduction. The baseline scenario also needs to take a longer time perspective into account.  | The baseline chapter has been totally revised in the BD and we thus refer to the new version. | **RAC and SEAC:** We agree and also refer to the updated discussion in appendix 2 of the BD. |
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| Remaining comments are addressed in Table II, H 07; 10 and 11. |
| **158** | / / Individual | Will Denmark respect common EU REACH regulations or will it continue to have national laws exceeding REACH for toys such as law :- Statutory Order 855 of 05/09/2009 which has limits of 0.05% for certain phthalates as opposed to the 0.1% limit in REACH which is applied by all the rest of EU ?  | We consider this a political statement that has nothing to do with the proposed restriction and thus is not relevant to react upon | **RAC and SEAC:** No comment. |
| Does Denmark respect the REACH regulation process by adding it's own natiuonal legislation which has different limits to REACH regulation and does the EU allow member states to make their own legislation which is different to REACH and a barrier to trade or is it unable to effectively manage the single market | The comment is not relevant for the proposed restriction.  | **RAC and SEAC:** No comment. |
| **153** | / / Ireland MSCA | The IE CA supports the principle of substituting hazardous substance with less hazardous substances. However, based on the evidence presented in the dossier further data and evaluation is required to support the principle that a permanent EU restriction on phthalates should be introduced, to address the risk to human health associated with imported articles containing phthalates at &gt; 0.1%.  |  |  |
| We would therefore welcome the consideration of information on the volumes, uses, exposures and risk management measures of these phthalates in articles arising from (i) registration dossiers, (ii) substances in articles notifications and (iii) future applications for authorisation, given that 3 of the 4 phthalates are listed on Annex XIV and all four phthalates are included onto the Candidate List of SVHCs.  | Information from the registration dossiers have been used in the dossier; only total volumes have been used as there is no information on use in single types of articles. The information received through the notification process (long time after the original dossier was submitted) has also been included in the revised BD in the list of articles either proposed to be within or out of the scope of the restriction. No applications for authorisation have yet been submitted.  | **RAC and SEAC:** No further comments. |
| A further assessment of the impact of the recent changes to parallel legislation (e.g. food contact materials; Toy Safety Directive, etc.) would be useful to in order to gain an appreciation of how other legal instruments are possibly reducing the use of these 4 phthalates generally | This has been done to the extent possible in the BD throughout section B. | **RAC:** No further comments. |
| Identification of potential alternative substances and techniques: We note that alternatives appear to be available for each of the four phthalates, but the nature of the substitution is dependent on the final article. However, even if substitution occurs, it appears that the four phthalates in question may be present as impurities at &gt; 0.1% in the alternative substances, which would still lead to a breach of the restriction. This presents great difficulties for the current proposal.  | We don't believe that there is a concern about impurities as the proposed limits are the same for the restriction already in place in REACH Annex XVII where in many cases DINP/DIDP are used as alternatives - and no other comments received during public consultation (incl. those from industrial organisations) has pointed to this as a problem. | **RAC and SEAC:** No further comments. |
| D. Justification for action on a Community-wide basisTaking the wide scope of the current proposal into account, we find the evidence in the current dossier, insufficient to demonstrate the need for such broad action on a Community-wide basis. Therefore, we would find it difficult to support the restriction without additional information to sufficiently demonstrate the risk. We suggest that a further assessment of the impact of the recent changes to parallel legislation needs to be undertaken. In addition we would welcome additional information and a further examination of information from the registration dossiers and substances in articles notifications. | Please see above. | **RAC and SEAC:** We agree. |
| Assessment of risk management options: On the basis of the data provided in the dossier, we find it difficult to support the restriction proposal in its current form. If evidence of the need for action at community-wide level can be more clearly demonstrated by the Dossier Submitter, then at that time, the IECA could agree that Restriction is the most appropriate risk management measure. |  | **RAC and SEAC:** We agree. |
| We note that the four phthalates are included on the Candidate List and as such, once imported in articles in quantities over one tonne/yr and present in concentrations greater than 0.1% w/w, the presence of these substances in articles must be notified to ECHA. Such notifications under article 7(2) may bring further information on the presence of these phthalates in imported articles. Moreover, since BBP, DEHP and DBP are included on Annex XIV; future applications for authorisation may provide further clarity on the uses of these phthalates and provide possibilities to control the risks.  | Please see above. | **RAC:** We agree**.** Information from notifications have been taken into account, their numbers indicated that at least for DEHP a high number of articles contain concentrations of 0.1% or higher.However no additional information on concentrations and in particular on migration rates is available from notifications. |
| The submitted registration dossiers should contain further information on the uses of the four phthalates in articles. | **We agree, but unfortunately this is not the case.** |  |
| Remaining comments are addressed in Table II, H 06; 07; 10 and 11. |
| **149** | United States / Industry or trade association / RESILIENT FLOOR COVERING INSTITUTE  | The proposal also assumes that restrictions imposed on these four phthalates under the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) will not to significantly reduce the import of products containing substances subject to REACH authorization. | This seems to be a misunderstanding. All articles whether produced or imported to the EU would be affected by a restriction. | **SEAC**: The proposal assumes that the authorisation requirement, which will only apply to EU-manufactured products, does not have a significant direct effect on imports, whereas restrictions directly affect both, imported and EU-manufactured products. |
| Given the speculative nature of the effects the Danish proposal purports to address, the potential for the precedent established by the proposal to dramatically alter the European approach to regulation, and the nascent status of the REACH authorization process, it is inappropriate to consider approval of the proposal. | We do not agree. The hazard assessments of the four phthalates are based on the conclusions from the EU RAR and other accepted literature. | **RAC:** The most relevant endpoint to base the combined assessment on has been extensively discussed in RAC. Decreased testosterone levels, testes toxicity and other indications of anti-androgen effects (such as decreased ano-genital distance) were consistently found for the four phthalates and have been used in the final risk assessment to account for the combined risks . |
| Remaining comments are addressed in Table II, H 04; 05; 06; 10; 12 and 15. |
| **148** | United Kingdom / International NGO / ClientEarth | A relatively large number of studies of the effects of DEHP on reproduction and reproductive development are included in its dossier. One key study, Christiansen et al (2010), is not described in the dossier for this compound since the studies it reports do not conform to Good Laboratory Practice (GLP) guidelines. It is, however, considered acceptable by the authors of the report and supports earlier findings. It contains key information about the effects of DEHP on nipple retention and anogenital distance in rats, and gives a lower lowest observed adverse effect level (LOAEL) than the studies used by the EU in the determination of its LOAEL. In terms of how the compound is classified and labelled, its effects via lactation are conclusive but there are insufficient data for classification | This study has now been included in the BD. Please see part B.5.5.  | **RAC**: No further comments. |
| The remaining comments are addressed in Table II H 05 and 06. |
| **142** | Netherlands / International NGO / Health Care Without Harm | We think it is important that findings of human epidemiologic studies, become part of the record. In the past few years, studies conducted in the US, Sweden, and India have examined the relationship between phthalate exposures and various measures of semen quality. Duty S, Silva M, Barr D, Brock J, et al. Phthalate exposure and human semen parameters. Epidemiology 2003a; 4, 269–277. Duty S, Singh N, Silva M, Barr D, et al | This study should be reviewed and included in the BDif relevant. | RAC: The study does not focus on developmental effects on the reproductive system. Authors found an association of the urinary level of the metabolite MEP (a metabolite of diethylphthate) with loss of DNA integrity in a COMET assay, but no associations with urinary level of other phthalate metabolites (including those from the restriction proposal) in semen of adult men. The study would have no impact on the outcome of the risk assessment (no effects on relevant metabolites from phthalates of the restriction proposal, relevant concern not addressed, co-exposure to other sperm toxicants not considered, limited numbers of individuals, single urine sample examined, no information of sampling time).  |
| The remaining comments are addressed in Table II H 13.  |
| **139** | / / Germany | Information on hazard and risk (B)Studies discussed in the registrations should also be referred to in the restriction. This is true for DEHP and the study of Noriega N, Howdeshell KL, and Furr J (2009). | This study is included in the BD (part B.5.3.) but not used due to doses higher than the LOAEL. | **RAC**: No further comments. |
| The remaining comments are addresed in Table II H 07; 09; 10; 11; 14 and 15. |
| **138** | Japan / Company / J-Plus.Co.,Ltd | Endocrine disruptionAlso for “endocrine disruption,” no scientific assessment method is in place.However, its risk assessment method is being discussed in the EU. Therefore, the problem of endocrine disruption should be reexamined at least after the discussion is completed. | Although the criteria for endocrine disruptors are under discussion, risk assessment based on alterations in reproductive end-points as performed in the present restriction proposal is a valid and well established procedure.  | **RAC**: No further comments. |
| Remaining comments are addressed in Table II, H 05; 10 and 15. |
| **136** | / / United Kingdom | P. 7; “Widespread use” – It is not clear if the applications described under this heading are current uses for the 4 phthalates that are the subject of this proposal or relate to phthalates in a more general sense. On p. 12 it is stated that “the phthalates are only used as plasticisers” but the text on page 7 implies additional uses. P. 8/9; We agree with the groups selected for exposure assessment (2 yrs, 6-7 yrs, adult) and that the risk characterisation should be based on the concept of dose addition.P. 10; “OCs and RMMs not under control” – Since there are not enough data to assess the impact of existing measures on exposure, the basis for the conclusion that the regulatory measures taken so far in REACH and other existing legal requirements are not sufficient to reduce the total exposure to DEHP, BBP, DBP and DIHP to a safe level is not clear. | We thank you for the very helpful and detailed comments that have spotted some mistakes/errors. DS to update this response, in particular P7. | RAC: Regarding P. 10 we agree that due to uncertainty in the risk characterisation (related both to hazard and exposure) it is difficult to conclude that present OCs and RMMs are not sufficient. This has been taken into account in the opinion. |
| B.7 Environmental hazard assessmentWe note that in the dossier the statement “not relevant” has been inserted in this section however, information on the environmental hazards of the 4 phthalates summarised from the EU risk assessment reports is presented in section C.14. We have made comments here.The environmental hazard assessment of the four phthalates has been conducted adequately based on the available data. BBP and DBP are both classified for the environment based on high acute toxicity to aquatic organisms; additionally BBP is classified based on chronic toxicity. DEHP, which constitutes the greatest use of the four, showed no effects in tests, although observed effects in chronic daphnia studies may be open to interpretation.The section (p.236 – 241) might be improved by using a Klimisch-type scoring approach. The issues hang around the observance of possible effects around the substance’s limit of water solubility. It could be similarly argued that the number of substances showing effects but with equivocal evidence for physical fouling could lead to the conclusion that “conventional” toxic effects are occurring around the water solubility limit (as proposed in the second bullet on page 240). This alternative conclusion might have implications for environmental classification.Other comments on the environmental assessment of the 4 phthalates; | As a consequence of the targeting of the dossier environmental risks were not considered relevant for part B. They were however found to be relevant for the comparison of substances to be banned with possible alternatives. DS to respond to the following detailed comments.Environmental effects have been addressed in a proper way given the available data and existing classification; this is not a classification dossier – and the cmments given below are very detailed and do not change anything in the conclusions – and since the requests from ARC/SEAC have been very comprehensive we have chosen to use our working hours for the important issues; but if we find time before the finalisation of the BD, we will include these minor adjustments of the text. | **SEAC:** Thank you for your detailed comment. The restriction proposal is targeted on human health effects. However, when assessing alternatives all aspects (human and environmental hazards) need to be taken into account to assess the suitability of an alternative (please see our response in Table 2 section H 09).We agree with the DS that for this purpose the environmental hazards of the four phthalates and the alternatives have been adequately presented in the BD. |
|  |  | p.232, first paragraph. Please consider rephrasing the sentence referring to potential inclusion of MEHP in the measured BCF (based on total radioactivity) – “…these data are assumed to be valid” is not quite the right meaning. Suggest “However, since the main metabolism product of DEHP is the reprotoxic MEHP, its inclusion in the measured BCF is appropriate.” |  |  |
| p.232, first sentence of second paragraph: please delete as the BCF decreasing at concentrations higher than 5 micro g/l is most likely an artefact of the quantity in water versus the bioavailable (truly dissolved) fraction. |  |  |
| p.252, “exposure via sludge” second paragraph: the solubility in sludge mixtures will not be higher than in distilled water. Presumably this should be the bioavailability of DEHP in sludge mixtures may be higher… |  |  |
| p.258, title to table is incorrect: should refer to DEHP. Plus small table below C.14.2 should be removed – shouldn’t appear here. |  |  |
|  |  | p. 275, first paragraph under table on bioaccumulationThe BCF test is not meant to allow a direct conclusion on biomagnification potential. Please change to “…that BBP is not considered to bioaccumulate” (i.e. it’s very unlike to biomagnify with such a low BCF).p.276, algae paragraph. It is stated that the 0.20 mg/l ErC10 is used to derive the PNEC aq. This seems wrong as the Daphnia NOEC is used to derive the PNEC aq. |  |  |
| The remaining comments are addressed in Table II H 05; 06; 07; 08; 09; 10; 11; 14 and 17. |
| **133** | Czech Republic / National authority / Ministry of Industry and Trade of the Czech Republic | When introducing the proposed restrictions it should be also considered if the derogations for medical devices covered under Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC and for articles intended to come into contact with food covered by Regulation (EC) No 1935/2004 are fully justified. We believe that restrictions should be general and always the same in all areas of their use (particularly in the field of medical devices). Otherwise the proposal fails to fulfil its main purpose, i.e. the protection of human health. | The existing legislation is already discussed in the BD and it is up to the dossier submitter to target the proposal, and in this case the dossier submitter finds that the (existing) legislation on food contact materials, medical devices etc. are the right place to regulate these materials/devices. | **RAC and SEAC**: No further comments. |
| The remaining comments are addressed in Table II H 01. |
| **131** | / / NorwayMSCA | Based on information from the Norwegian Product register the use of the 4 phthalates as substances or in mixtures is decreasing in Norway. As shown below, both the tonnage and the number of substances/mixtures.(products) have to a great extent decreased between 2002 and 2010. The main use areas are in paint, glues, jointing paste, and as a softener. Phthalate use in 2002 (tons/no. of prod); use in 2010 (tons/no. of prod).BBP: (14/73);(0/2)DBP: (43/97);(2,6/5)DIDP: (18/21);(5/5)DEHP: (138/47);(0,1/2).This information suggests that alternatives are available for most purposes. However, we do not know much about imported products. Analyses of products on the Norwegian market show some findings of phthalates. In 2009 mittens for children were taken off the market due to findings of DEHP (13, 21 %). Preliminary results for analyses done in 2011, as of yet unpublished, show that 3 out 31 products contained phthalates.See attachment for details and more data. | Thank you for this information. The data presented are in line with the argumentation in the BD. | **RAC and SEAC**: No further comments. |
| The remaining comments are addressed in Table II H 07; 10 and 17. |
| **124** | Belgium / Industry or trade association / DIGITALEUROPE  | The report suggests a transitional period of 12 months from entry into force of the ban. DIGITALEUROPE requests that the timeline for these restrictions be aligned with that for the authorization of these substances. Any restriction should not be effective before the authorization sunset date (e.g. 21. February 2015 for DEHP, BBP, DBP). | We will look into this and consider if this could apply for at least some of the articles. | **RAC and SEAC**: As the restriction proposal is not supported by the Committees this issue has limited relevance. |
| The remaining comments are addressed in Table II H 07. |
| **122** | Japan / Industry or trade association / I.F.A | Although the production volume for EU is not substantial amount, approximately more than 100,000 sqm/year, we have produced 60 million sqm/year of vinyl floor covering.Needless to say, the consumption of DEHP is substantial amount.The concentration of DEHP in the article is approximately 30%. | Floors are produced in the EU and elsewhere without DEHP as described in detail in the dossier. | **RAC and SEAC**: Thank you for the information. |
| The remaining comments are addressed in Table II H 11. |