EUROPEAN CHEMICALS AGENCY

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DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For 4,4'-isopropylidenediphenol (Bisphenol A), CAS No 80-05-7 (EC No 201-245-8)

Addressees: Registrants of 4,4'-isopropylidenediphenol (Bisphenol A) (concerned registrants)

Based on an evaluation by the Federal Institute for Occupational Safety and Health (BAUA) as the Competent Authority of Germany (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision does not take into account any updates of the registrations of the concerned registrants after 1 August 2013, the date upon which the draft decision was circulated to the other Competent Authorities of the Member States and ECHA pursuant to Article 52(1) of the REACH Regulation.

This decision does not imply that the information provided by the concerned registrants in the registrations is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossiers of the concerned registrants at a later stage, nor does it prevent a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Germany has initiated substance evaluation for 4,4'-isopropylidenediphenol (Bisphenol A), CAS No 80-05-7 (EC No 201-245-8) based on registration dossiers submitted by the concerned registrants and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to suspected endocrine disruption towards the ecosystem, exposure/wide dispersive use, consumer use and high aggregated tonnage Bisphenol A was included in the Community rolling action plan (CoRAP) for substance evaluation pursuant to Article 44(2) of the REACH Regulation to be evaluated in 2012. The CoRAP was published on the ECHA website on 29 February 2012. The Competent Authority of Germany was appointed to carry out the evaluation.

The evaluating MSCA did not evaluate ED properties related to human health in the Substance Evaluation in detail, yet acknowledged the information currently available with respect to this endpoint. The evaluating MSCA took note of further ongoing studies (NIEHS/NTP/FDA rodent study consortium (CLARITY-BPA; see Schug *et al.* 2013[1])), which are currently performed by American laboratories. Therefore, the need for further data requirements was not assessed at this stage. Any need for further testing may depend on the results from these studies and on other relevant new information which might become

[1]Schug TT, Heindel JJ, Camacho L, Delclos KB, Howard P, Johnson AF, Aungst J, Keefe D, Newbold R, Walker NJ, Zoeller RT, Bucher JR (2013) A new approach to synergize academic and guideline-compliant research: the CLARITY-BPA research program. *Reprod Toxicol*; **40**:35-40. doi: 10.1016/j.reprotox.2013.05.010.

available. Hence, endocrine disruption for human health may be considered at a later stage. The registrants are reminded that they have the obligation to include the results of any new relevant information in the considerations for the risk characterisation and to update the CSR accordingly once such results become available.

The evaluating MSCA did evaluate possible risks for consumers due to other endpoints (*e.g.* effects on body weight gain in repeated dose toxicity studies) and considers robust information on dermal absorption necessary to allow final conclusion on certain risks (uses of larger PVC articles and toys). The evaluating MSCA did not assess the risk for workers handling thermal paper.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 28 February 2013.

On 4 April 2013 ECHA sent the draft decision to the concerned registrants and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 6 May 2013 ECHA received comments from concerned registrants of which it informed the evaluating MSCA without delay.

The MSCA considered the registrants' comments received and did not amend Section II of the draft decision. The comments were reflected in Annex I of the draft decision. Due to the comments Section III of the draft decision (Statement of Reasons) was modified.

In accordance with Article 52(1) of the REACH Regulation, on 1 August 2013 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

Subsequently, four Competent Authorities of the Member States and ECHA submitted proposals for amendment to the draft decision.

On 6 September 2013 ECHA notified the Registrants of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA has reviewed the proposals for amendment received and amended the draft decision.

On 16 September 2013 ECHA referred the draft decision to the Member State Committee.

By 10 October 2013 the Registrants provided comments on the proposed amendments. The Member State Committee took the comments of the Registrants into account.

After discussion in the Member State Committee meeting on 4-8 November 2013, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 6 November 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall submit

the following information using the indicated test method and the registered substance subject to the present decision:

1. Skin absorption: *In vitro* method (Test method EU B.45; OECD 428) with specifications and with additional modifications as specified in Section III, in particular:

   The study shall be performed using well characterised viable human skin from appropriate locations of the human body, an appropriate solvent and doses which are representative of relevant human exposure situations.
   - The study shall be designed such that a minimum of 8 skin samples from at least four donors can be evaluated. The study shall be in line with the Scientific Committee on Consumer Safety (SCCS) basic criteria for the *in vitro* assessment of dermal absorption of cosmetic ingredients (SCCS/1358/10).
   - Additionally, the study shall investigate metabolites of Bisphenol A in the relevant compartments of the skin.

Pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall also submit the following information in the chemical safety report of the registered substance subject to the present decision:

2. Further information on emission pathways of Bisphenol A to the environment in the lead and joint registration dossiers.
   a) Exposure assessment for the terrestrial compartment (soil and groundwater);
   b) Exposure assessment for life cycle steps missing in the dossiers;
   c) Exposure assessment for industrial manufacturing of Bisphenol A and industrial use of Bisphenol A for manufacturing of polycarbonate;
   d) Industrial, professional and consumer use of articles made of polycarbonate;
   e) Industrial and professional repackaging of Bisphenol A;
   f) Industrial Use of Bisphenol A for manufacture of epoxy resins;
   g) Industrial, professional and consumer use of articles made of epoxy resin;
   h) Use of Bisphenol A for the manufacture of epoxy resin hardeners, Use of Bisphenol A in epoxy resin hardeners;
   i) Industrial use of Bisphenol A for manufacturing of thermal paper (including recycling of thermal paper and use of recycled paper);
   j) Industrial and professional use of Bisphenol A as anti-oxidant for processing and use of PVC;
   k) Professional and consumer use of articles made of PVC;
   l) Industrial use of Bisphenol A for manufacturing of polymers and industrial, professional and consumer use of polymers;
   m) Industrial use of Bisphenol A for manufacturing of coating material and industrial, professional and consumer use coating materials.

Furthermore, pursuant to Article 46(1) of the REACH Regulation the concerned registrants shall submit full study reports for the information required under point 1 of this Section II, because of the specifications and modifications with which testing is charged, which might not be sufficiently reflected in a robust study summary.

Pursuant to Article 46(2) of the REACH Regulation, the concerned registrants shall submit to ECHA by 20 December 2015 an update of the registration dossiers containing the information required by this decision.

III. Statement of reasons

Based on the evaluation of all relevant information submitted on Bisphenol A and other relevant and available information, ECHA concludes that further information is required in order to enable the evaluating MSCA to complete the evaluation of whether the substance

constitutes a risk to human health or the environment.

1. Skin absorption: *In vitro* method (Test method EU B.45; OECD 428) with specifications and with additional modifications

Various studies on the dermal absorption of Bisphenol A exist. Dermal absorption percentages range between approximately 10 and 50 %. Some of the dermal absorption studies were not performed according to accepted guidelines and / or exhibited methodological shortcomings which were expressed in the respective studies. Other studies, which were performed according to accepted guidelines, also exhibited methodological shortcomings.

In conclusion, the data available presented contradictory results. The evaluating MSCA used a value of 50 % dermal absorption, which might be regarded as a worst case for DNEL derivation. A dermal DNEL was derived based on effects on body weight and body weight gain from a dietary three-generation study performed in the rat (Tyl *et al.* 2002[2]) and a 50% absorption. Using this DNEL a risk characterisation ratio above 1 was identified for consumer use of PVC articles. Dermal absorption impacts strongly the outcome of this risk characterization. Therefore, in order to allow final conclusion on certain risks for consumers (uses of larger PVC articles and toys) more reliable data on dermal absorption of Bisphenol A is requested. The registrants shall perform the study using well-described viable human skin from appropriate locations of the human body, an appropriate solvent and with doses which are representative of relevant human exposure situations in a manner that at least 8 skin samples from at least four donors can be taken for evaluation.

As the respective guidelines (EC B.45; OECD 428) describe the investigation of dermal absorption from a rather broad and unspecific perspective, the dermal absorption study has to be in line with the Scientific Committee on Consumer Safety (SCCS) basic criteria for the *in vitro* assessment of dermal absorption of cosmetic ingredients[3], which addresses in more detail important points to consider in order to obtain scientifically valid results.

In these relatively complex *in vitro* studies, there are a number of points that require special attention that shall be considered by the registrant:

1) The design of the diffusion cell (technicalities and choice between static and flow through system);
2) The choice of the receptor fluid (physiological pH, solubility and stability of chemical in receptor fluid should be demonstrated, no interference with skin/membrane integrity, analytical method, *etc.*);
3) Skin integrity is of key importance and should be verified;
4) Skin temperature has to be ascertained at normal human skin temperature;
5) The test substance has to be rigorously characterised;
6) Dose (several small dosages shall be used) and vehicle (aqueous solution)/formulation should be representative for the in-use conditions;
7) Dose, volume and contact time with the skin have to mimic in-use conditions. The duration has to be at least 24 hours. For measurements and calculation of the percentage of absorption the low end of the anticipated exposure should be tested. For measuring the metabolism also the highest exposure should be included;
8) Regular sampling is required over the whole exposure period;
9) Appropriate analytical techniques should be used. Their validity, sensitivity and detection limits should be documented in the report;

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[2]Tyl RW, Myers CB, Marr MC, Thomas BF, Keimowitz AR, Brine DR, Veselica MM, Fail PA, Chang TY, Seely JC, Joiner RL, Butala JH, Dimond SS, Cagen SZ, Shiotsuka RN, Stropp GD, and Waechter JM (2002) Three-generation reproductive toxicity study of dietary bisphenol A in CD Sprague-Dawley rats. *Toxicol Sci*, **68**:121-46.
[3]Scientific Committee on Consumer Safety (2010) Basic criteria for the *in vitro* assessment of dermal absorption of cosmetic ingredients. SCCS/1358/10.
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_002.pdf

10) The test compound is to be determined in all relevant compartments:
    - product excess on the skin surface (dislodgeable dose),
    - stratum corneum (*e.g.* adhesive tape strips),
    - living epidermis (without stratum corneum),
    - dermis,
    - receptor fluid;
11) Mass balance analysis and recovery data are to be provided. The overall recovery of test substance (including metabolites) should be within the range of 85-115%; and
12) 8 skin samples from at least 4 donors shall be used. Variability / validity / reproducibility of the method shall be demonstrated and discussed.

The amounts measured in the dermis, epidermis (with stratum corneum) and the receptor fluid will be considered as dermally absorbed and taken into account for further calculations.

Additionally, the study shall investigate metabolites of Bisphenol A in the relevant compartments of the skin since at least the Zalko study[4] gave evidence for a significant formation of Bisphenol A metabolites in the skin.

Several registrants claimed a time period of two years for the conduct and analysis of data from the skin adsorption study and requested finally a timeframe of at least three years from the date of the decision to conduct research and report the data. The arguments brought up by the registrants have been refused by the evaluating MSCA because the metabolism of Bisphenol A has been well investigated and analytical methods for the quantification of Bisphenol A and Bisphenol A metabolites have already been established.

Generally, the evaluating MSCA is of the opinion that it is possible to perform a skin absorption study in less than 6 months. Including 3 months for the preparation and coordination according to Article 53 of the REACH Regulation and additional 3 months for reporting, the study report could be finalised within 12 months. However, the evaluating MSCA and ECHA acknowledged the additional efforts necessary for the metabolism study part. Therefore, the deadline was finally extended to 24 months.

Taking into account a proposal for amendment questioning the need of this request due to available studies, the evaluating MSCA confirmed that all studies referred to in the proposal for amendment were evaluated by the evaluating MSCA during the substance evaluation. After considerations of the proposal for amendment the evaluating MSCA is still of the opinion that the requested information is necessary to come to a conclusion on the concern evaluated by the evaluating MSCA (use of PVC large articles and toys) because the absorption rate will impact the risk characterization on the evaluated concerns. Thus, a study is considered necessary which generates robust and reliable data for concluding on the concern of the use of larger PVC articles and toys and for further risk characterisation and risk management measures.

2. Further information on emission pathways of Bisphenol A to the environment in the lead and joint registration dossiers

In the registrants' comments on the Proposals for Amendment, the registrants indicated that they believe that the 'amended Draft Decision does not specify the basis on which it relies to question the registrants' conclusions in the CSR that environmental concerns raised by the manufacture and use of Bisphenol A in the EU are negligible'. In response to this comment, the evaluating MSCA highlights that the legal basis for the information requests, *i.e.* Articles 46(1), 51 and 52 of the REACH Regulation, is clearly indicated in the decision. As is clear from Article 46, substance evaluation decisions are being issued in order to clarify a concern. Such decisions can either require further information on the intrinsic properties of substances or on the exposure towards the substance. In the present case, at

[4]Zalko, D., Jacques, C., Duplan, H., Bruel, S., and Perdu, E. (2011) Viable skin efficiently absorbs and metabolizes bisphenol A. *Chemosphere* **82**(3), 424-430.

this stage no further information is required on hazards for the ecosystem as the evaluating MSCA has sufficient information in this respect. However, further information is required in order to enable the evaluating MSCA to draw appropriate conclusions from the substance evaluation; specifically the evaluating MSCA needs to identify the relevant pathways of Bisphenol A to the environment.

To fully consider the concern that the registered substance poses for the environment, ECHA can, pursuant to Article 46(1), require further information. Information requests in substance evaluation can go beyond minimum registration requirements and information requested under Section II.2. cover standard requirements pursuant to Annex I of the REACH Regulation. Taking into account that the Registrants claim that requests are 'vague and do not guide', ECHA refers the registrants to the fact that the information requests are sufficiently clear and that applicable guidance can be consulted.

a) Exposure assessment for the terrestrial compartment (soil and groundwater)

Both exposure pathways for emissions to soil and groundwater – the application of sewage sludge and the deposition of Bisphenol A from air (except for the manufacture of Bisphenol A) – were not considered in the registration dossiers. For most identified uses registrants stated, that there is no application of sewage sludge to soil, sewage sludge is either incinerated or land filled at dedicated sites. A plausible confirmation that the incineration technique is installed for all uses or an assessment of emissions form landfill sites respectively is missing. Furthermore, atmospheric deposition cannot be completely excluded based only on short atmospheric half live. Due to this implausibility in the assessment and in the argumentation, the exposure assessment for the terrestrial compartment is not sufficient to conclude on the concern. The little number of available monitoring data is not seen as representative to negate the risk for the terrestrial compartment. For all exposure scenarios considered in the registration dossiers the registrants are requested to fully detail their calculations and input parameters for the exposure assessment for the terrestrial compartment.

b) Exposure assessment for life cycle steps missing in the registration dossiers

The registrants identified 21 uses of Bisphenol A in the update of the dossiers from December 2012. Some of these identified uses have subsequent life cycle steps including service life or waste stage. A lot of these subsequent life cycles steps for the identified uses are missing in the registration dossiers. Due to this lack of information it is not possible to sufficiently conclude on the concern. The concerned registrants are requested to develop exposure scenarios for the following life cycle steps:

- All subsequent life cycle steps following the manufacturing of chemicals
- All subsequent life cycle steps following the manufacturing of laboratory reagents
- Waste life cycle steps for all uses identified in the registration dossiers.

c) Exposure assessment for industrial manufacturing of Bisphenol A and industrial use of Bisphenol A for manufacturing of polycarbonate

For the industrial manufacturing of Bisphenol A the tonnage utilised for the calculation of the PECs is not clear and should be specified. There are two aspects to be clarified by the registrant. First, the registrants did not consider the manufacturing site with the highest emissions without providing a justification for this approach. The registrants are requested to fully justify why the site with the highest emissions has not been considered.

Second, in the registrations there are contradictory indications of tonnages for the

production of polycarbonate. In order to prove the save use of the substance, the registrants stated in the CSR that the manufacture of polycarbonate only takes place at a small number of listed sites that manufacture Bisphenol A. Therefore the production of polycarbonate has to be seen as own use of the registrants. In the CSR the registrants stated in the section "identified uses" a certain amount of the substance being used for the production of polycarbonate. There is a discrepancy of more than 100,000 tonnes between the total tonnage stated as own use of the registrants in the registration dossiers and the tonnage identified for the production of polycarbonate. If the missing tonnage is not an own use, the CSR fails to explain at what site the polycarbonate is produced. If polycarbonate is produced from the tonnage indicated as own use, the CSR fails to explain how the total tonnage of Bisphenol A produced in Europe is used. The discrepancy in tonnage should be explained. The concerned registrants are requested to revise the exposure assessment for the industrial use of Bisphenol A for the manufacturing of polycarbonate for all environmental compartments. The concerned registrants shall provide full justification for the input parameters used in the exposure scenarios.In its proposal for amendment ECHA suggested to rephrase the statement of reasons of the request. The evaluating MSCA agrees with the clarification in the phrasing proposed by ECHA and modified the text including some clarifying additions.

d) Industrial, professional and consumer use of articles made of polycarbonate

Under this scenario mentioned in the registration dossiers only consumer use of articles made of polycarbonate is considered. The data for this scenario are extracted from the EU RAR (2003)[5]. The consumption of Bisphenol A for the production of polycarbonate has doubled since the calculation presented in the EU RAR (2003). The data available on emissions to the environment from the residual monomer content is not sufficiently reliable to allow an assessment of the substance with regard to the concern. Distribution of the global polycarbonate production to the different application areas show that several uses are outdoor uses (industrial, professional or consumer). These uses and the conditions during the service life of these uses, weathering effects for example, could lead to direct emissions of the residual monomer content to the environment. These emissions are not considered in the registration dossiers. Emissions to the water compartment from outdoor uses could occur as emissions to waste water treatment plants and subsequent surface water and direct emissions to the environment from outdoor uses of polycarbonate. The registrants provided no sufficient data to conclude on the residual monomer content. In the comments on proposals for amendment the registrants claimed low concentration of residual Bisphenol Acontent, but again did not demonstrate that this is indeed the case. Furthermore, the registrants provided no sufficient data to conclude that coating of polycarbonate articles reduces emissions to environment to a negligible degree. Bisphenol A can regularly be found in sewage sludge from sewage treatment plants. It is likely that emissions to soil can result from application of sludge. Due to the high amount of Bisphenol A used to produce polycarbonate even low releases could contribute to relevant emissions to the environment. The data are not sufficient to conclude on the concern for the environment. The registrants are requested to develop exposure scenarios for industrial, professional, and consumer use of articles made of polycarbonate including the service life and waste stage for indoor and outdoor uses. The concerned registrants shall provide full justification for the input parameters used in the exposure scenarios.

In its proposal for amendment ECHA suggested editorial changes of the statement of the heading and the statement of reasons of the request. The evaluating MSCA agreed with the clarification in the phrasing and the heading proposed by ECHA and modified the heading and the text accordingly.

e) Industrial and professional repackaging of Bisphenol A

[5]EC (2003). European Union Risk Assessment Report 4,4'-ISOPROPYLIDENEDIPHENOL (BISPHENOL-A), Luxembourg: Office for Official Publications of the European Communities.

It is not plausible that the PEC value for air is reported to be zero for these uses. Repackaging is assumed to take place in open processes with a high probability of emissions to air. Furthermore, the assumptions for the repackaging processes are in contradiction to the assumptions for the manufacturing of Bisphenol A were the same RMM is applicable but emissions to air are considered. Additionally, the occurrence of dust emissions has been taken into account for the calculation of inhalation exposure for workers. The registrants have not claimed that waste air incineration is installed at all repackaging sites even more at professional sites than at industrial sites. In addition, it can be assumed that emissions to air from repackaging processes are in form of particles. Degradation time in air could be lower because of the particle form. Emission to soil and subsequent groundwater can arise from deposition of Bisphenol A dust. As these exposure routes are not considered in the CSR it is not possible to conclude on the concern. The registrants are requested to fully detail their calculations and input parameters for the exposure assessment for air and the terrestrial compartment and explain the reason for not consideration of dust deposition in the assessment.

f) Industrial Use of Bisphenol A for manufacture of epoxy resins

For sites where Bisphenol A production and manufacturing of epoxy resins take place, the releases of Bisphenol A have been assumed to be already covered by releases from Bisphenol A production sites. For sites carrying out epoxy resin production only release estimations from the EU RAR (2003) are provided in the CSR. According to information from the EU RAR (2010)[6], the amount of Bisphenol A used for production of epoxy resins already increased by 11 % until 2010 but there was no updating of the assessment in the registration dossiers. Furthermore, not all sites and probably not the worst case scenario are represented by the calculations because small-volume sales (approximately 20 customers with the amount sold being in the range of 200-800-tonnes/year per site according to the EU RAR (2003)), which are not considered in the assessment, account for approximately 10 % EU RAR (2010) of the production of epoxy resin. The exposure of the environment and subsequent the risk for environmental compartments could be underestimated. The information is not sufficient to conclude on the concern. The registrants are requested to update their calculations as the numbers for the assessment seem to be outdated and input parameters for the exposure assessment for all environmental compartments.

g) Industrial, professional and consumer use of articles made of epoxy resin

In the CSRs it is stated that potential release of Bisphenol A from consumer use of articles made of epoxy resin is low. The exposure is likely to be negligible in many cases as the residual Bisphenol A content in epoxy resin is about 10 ppm. Therefore an environmental exposure assessment was not performed for that use. Industrial and professional use of epoxy resin or articles made of epoxy resin is not assessed in the registration dossiers. Given the fact, that almost 200.000 tonnes of Bisphenol A are used to produce a number of different epoxy resins with different residual monomer content even low releases could lead to relevant emissions to the environment. One major professional use of epoxy resin is the application of epoxy resin to rehabilitate water pipes. But epoxy resin is not only used to repair existing pipes, but also for the production of new pipes. Depending on the hardening process and the corresponding curing quality, the concentration of Bisphenol A monomers in the cured epoxy resin can vary. The water temperature has a strong influence onto the leachability of Bisphenol A from epoxy resin into water. However, the leakage of Bisphenol A from epoxy resin into water depends also on other parameters, such as the resin surface (including diameter and length of coated pipe) to water volume ratio, and resin quality. Further variables influencing the permeation of piping materials are stated by the US EPA to be: Solute properties (composition, phase), Medium properties (composition, pore

[6]EC (2010). European Union Risk Assessment Report 4,4-ISOPROPYLENEDIPHENOL (Bisphenol-A) complete risk assessment in one document, Luxembourg: Office for Official Publications of the European Communities.

structure, swollenness), Solute-Medium interaction (equilibrium partitioning, diffuse coefficient), Pipe flow hydrodynamics (Reynold number), Transfer geometry (medium thickness) and environmental conditions (temperature). The German Federal Environment Agency (UBA) has performed several measurements of Bisphenol A contaminations in water pipes. As such complex data as described above is not available; the performed measurements can only indicate maximum Bisphenol A concentration for different applications (central heating, centralised warm water supply, continuous flow water heater, apartment boiler). Bisphenol A levels of nearly 10 µg/l can be found in warm water pipes. However, even this concentration can be exceeded in case of low quality rehabilitation as concentrations of 280 µg/l have also already been detected. According to industry information, use of epoxy resins for lining of water pipes has increased during the last years and is assumed to grow in future. Information on residual monomer content of different epoxy resins, uses and processes where epoxy resin is used with respective OC, RMM, and emission factors for the environment are not provided with the registration dossiers. Thus information is not sufficient to conclude on the concern. The registrants are requested to provide exposure scenarios for industrial and professional use of articles made of epoxy resin including the service life and waste stage concerning the unreacted Bisphenol A (*i.e.* remaining monomer). The concerned registrants shall provide full justification for the input parameters used in the exposure scenarios. Furthermore, in these exposure scenarios the boundary to the exposure scenarios for manufacture of coating material is to be defined. Moreover, the registrants are requested to specify reasons for not considering consumer use in their dossiers.

In its proposal for amendment ECHA suggested editorial changes of the heading and the statement of reasons of the request. The evaluating MSCA agrees with the clarification in the phrasing and the heading proposed by ECHA and modified the heading and the text accordingly.

h) Use of Bisphenol A for the manufacture of epoxy resin hardeners, Use of Bisphenol A in epoxy resin hardeners

The manufacture, industrial use and professional use of epoxy resin hardeners are all reported in the registration dossiers to be uses without exposure to the environment. This assumption is not plausible in the light that PROCs reported for manufacture, industrial and professional use including open processes with potential for releases. Furthermore, there is a big discrepancy between the tonnages stated by the registrants for the manufacture of epoxy resin hardeners and the both uses (industrial and professional use), perhaps because consumer use has not been considered in the CSR. The tonnages indicated for the manufacture of epoxy resin hardeners is not plausible. Nevertheless, against the background that most registrants have indicated in their individual dossiers epoxy resin hardeners as form in the supply chain the amounts of Bisphenol A indicated for industrial and professional use is not plausible. The provided information is not sufficient to conclude on the concern for the environment. Consumer use of epoxy resin hardeners is expected to happen but not considered in the CSR. In this case it is expected that no RMMs preventing release to the environment are implemented which might result in emissions. The registrants are requested to fully detail their calculations and input parameters for the industrial and professional use of Bisphenol A in epoxy resin hardeners. The registrants are requested to provide exposure scenarios for the consumer use of Bisphenol A in epoxy resin hardeners.

i) Industrial use of Bisphenol A for manufacturing of thermal paper (including recycling of thermal paper and use of recycled paper)

According to the registration dossier of the lead registrant of the joint submission for the registered substance three different uses are summarised under the scenario "industrial use of Bisphenol A for manufacturing thermal paper": manufacturing of thermal paper, recycling

of thermal paper and use of recycled paper. It is not clearly described in the CSR which input data are used for the environmental exposure assessment (e. g. emission factor, efficiency of RMM, OC, tonnage of paper for recycling, content of Bisphenol A in waste paper feed for recycling) as it is not clear, which data are extracted from the EU RAR (2003) and EU RAR (2008)[7] and which data are updated based on data from European Thermal Paper Association (ETPA, 2012).

The exposure of the environment and subsequent the risk for environmental compartments could be underestimated. The provided data are not sufficient to conclude on the concern. The registrants are requested to fully detail their calculations and input parameters for the exposure assessment for industrial use of Bisphenol A for manufacturing of thermal paper (including recycling of thermal paper and use of recycled paper) for all environmental compartments. While updating the dossiers, the registrants shall take into account any new information publicly available.

In its proposal for amendment ECHA and one MSCA suggested editorial changes of the statement of reasons of the request. The evaluating MSCA agrees with the clarification and additions in the phrasing proposed by ECHA and a MSCA and modified the text accordingly.

j) Industrial and professional use of Bisphenol A as anti-oxidant for processing and use PVC

The identified uses under these two scenarios, i.e. industrial use of Bisphenol A as anti-oxidant for processing PVC and professional uses of Bisphenol A as anti-oxidant for processing PVC, each cover three different processes: a) the use as an anti-oxidant during the processing of PVC, b) the use for incorporation into an additive package for processing of PVC and c) the use as an anti-oxidant in the production of plasticisers used in PVC processing. In the EU RAR (2008) the reported releases for the three processes were different. It is not retraceable why the process anti-oxidant for processing PVC was chosen to be representative for all three processes. The tonnage used or OC for the different processes on site is not documented. The data are not sufficient to conclude on the concern for the environment. The registrants are requested to fully detail their calculations and input parameters for the exposure assessment for the industrial and professional use of Bisphenol A as anti-oxidant for processing PVC for all environmental compartments.

The registration dossiers only cover the assessment for the production of PVC using Bisphenol A as an anti-oxidant (a). The subsequent life cycle stages regarding the use of articles made of PVC (industrial use, service life and waste stage) are missing. Furthermore the assessment is missing for all life cycles steps following the use of Bisphenol A for the preparation of additive packages (b) and the use as anti-oxidant in plasticiser production (c). Emissions to the environment could be underestimated. The data are not sufficient to conclude on the concern for the environment. The registrants are requested to provide exposure scenarios for the missing life cycle stages.

In its proposal for amendment ECHA suggested editorial changes of the heading of the request. The evaluating MSCA agrees with the clarification in the heading proposed by ECHA and modified the heading accordingly.

k) Professional and consumer use of articles made of PVC

Against the background that high releases of Bisphenol A from articles made of PVC have been reported in the EU RAR (2010), it is questionable whether PECs are negligible. There is no description on professional or consumer uses and their respective OC and RMM given in

[7]EC (2008). Updated European Union Risk Assessment Report 4,4'-ISOPROPYLIDENEDIPHENOL (BISPHENOL-A), Luxembourg: Office for Official Publications of the European Communities.

the CSR and it stays unclear for which uses PVC articles are used or which downstream users are covered with this two scenarios. Therefore, it is not possible to conclude if emissions from the professional and consumer use of articles made of PVC are sufficiently addressed in the available CSRs. The registrants are requested either to fully justify or to revise the exposure assessment for Professional use of articles made of PVC and Consumer use of articles made of PVC, for all environmental compartments.

In its proposal for amendment ECHA suggested editorial changes of the heading of the request. The evaluating MSCA agrees with the clarification in the heading proposed by ECHA and modified the heading accordingly.

l) Industrial use of Bisphenol A for manufacturing of polymers and industrial, professional and consumer use of polymers

The exposure scenario for manufacturing polymers covers several uses of Bisphenol A: a) manufacturing unsaturated polyester resins, b) polyols / polyurethane, c) modified polyamide and d) phenoplast cast resins. Manufacture of polyols/polyurethane and modified polyamide take place at sites of Bisphenol A manufacture. Thus emissions from this uses are already covered under the exposure scenario for "industrial manufacturing of Bisphenol A". The manufacture of unsaturated polyester resin is a dry process according to the EU RAR (2010) and no emissions to water and air occur according to the CSR. In the CSR only the data for manufacture of phenoplast cast resins available in the EU RAR (2010) are used to elaborate this scenario. But no operational conditions, risk management measures and their efficacies are given in the CSR for the manufacturing of phenoplast cast resins and unsaturated polyester resins. Furthermore, subsequent life cycle steps following the manufacture of all four different polymers are missing in the dossiers. Therefore, data are not sufficient to conclude on the concern for the environment. The concerned registrants shall provide full justification for the input parameters used in the exposure scenarios for the manufacturing of phenoplast cast resins and unsaturated polyester resins for all environmental compartments and to develop exposure scenarios for the missing life cycle steps for unsaturated polyester resins, polyols / polyurethane, modified polyamide and phenoplast cast resins.

In its proposal for amendment ECHA suggested editorial changes of the heading and the statement of reasons of the request. The evaluating MSCA agrees with the clarification in the phrasing and the heading proposed by ECHA and modified the heading and the text including some additions in the text.

m) Industrial use of Bisphenol A for manufacturing of coating materials and industrial, professional and consumer use of coating materials

The scenario covers a) manufacture of powder coatings and b) manufacture of can coatings. However, as emissions from the manufacture of powder coatings have been considered to be negligible in the EU RAR (2010) the exposure estimation refers to the manufacture of can coatings (b) only. All PECs have been set to 0. This seems to be plausible as far as closed systems are used. However, there have been indicated PROCs including open operations like batch processes where emissions to air may occur. The registrants did not claim that the efficiency of the listed RMMs is high enough to conclude that emissions to the environment are negligible. Operational conditions or efficiencies of risk management measures are not described in the CSR. There is no justification that operational conditions and risk management measures used for calculation in 2003 are still applicable and are the same for manufacture of powder coatings and can coatings. The registrants are requested either to fully justify or to revise the exposure assessment for the use of Bisphenol A for manufacture of powder coatings and can coatings.

Furthermore, the registration dossiers separately list use of Bisphenol A for manufacture of epoxy resins and use of Bisphenol A for manufacture of coating materials without specifying in detail which products are covered by the term coating materials. According to the information available from the EU RAR (2010), can coating materials and powder coating materials are based on epoxy resins and data from industry publications indicate that 11% of produced epoxy resins is used for can and coil coatings and 18% of produced epoxy resin is used for powder coating. Taking into account a total volume of Bisphenol A used for production of epoxy resins of almost 200,000 tonnes per year, this would result in 56,550 tonnes of Bisphenol A (29 % of total production of epoxy resin) which are annually used for production of can coatings and powder coatings. It is therefore questionable whether the tonnage indicated for use of Bisphenol A in production of coating materials (5000 tonnes per year) in the exposure scenario is realistic. The registrants are requested to justify or revise the assessment of Bisphenol A for manufacturing of coating materials taking into account the assumptions in the exposure scenarios for the manufacture and use of epoxy resin.

In general, during use (industrial, professional and consumer uses) of epoxy resins for coating applications there is a potential for release via waste water or to air (*e.g.* cleaning of tools). The life cycle step service life (use of coated articles) is not addressed in the CSR. There are a lot of applications where surfaces coated with epoxy resins may contribute to emission of Bisphenol A to the environment either due to release of residual monomeric Bisphenol A and possibly also due to depolymerisation (*e.g.* weathering in outdoor applications like marine and protective coating of ships). These aspects might result in underestimation of emissions to the environment resulting from use of coated materials. The registrants are requested to provide exposure scenarios for the use of coating materials and the service life and waste stage of coated articles to conclude on the concern for the environment.

In its proposal for amendment ECHA suggested editorial changes of the heading of the request. The evaluating MSCA agrees with the clarification in the heading proposed by ECHA including some additions and modified the heading accordingly.

IV. Adequate identification of the composition of the tested material

The substance identity information submitted in the registration dossiers has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. In relation to the required test, the sample of substance used for the new study shall have a composition that is within the specifications of the substance composition that are given by all concerned registrants. It is the responsibility of all the concerned registrants to agree on the tested materials to be subjected to the test subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the study must be shared by the concerned registrants.

V. Avoidance of unnecessary testing by data- and cost- sharing

Avoidance of unnecessary testing and the duplication of tests is a general aim of the REACH Regulation (Article 25). The legal text foresees the sharing of information between registrants. Since several registrants of the same substance are required to provide the same information, they are obliged to make every effort to reach an agreement for every endpoint as to who is to carry out the test on behalf of the other concerned registrants and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation.

If ECHA is not informed of such agreement within 90 days, it shall designate one of the concerned registrants to perform the test on behalf of all of them. If a registrant performs a test on behalf of other registrants, they shall share the cost of that study equally and the registrant performing the test shall provide each of the others concerned with copies of the full study reports.

This information should be submitted to ECHA using the following form stating the decision number above at:

https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/datasharing_en.asp.

VI. General requirements regarding Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VII. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Jukka Malm
Director of Regulatory Affairs

Annex I: Discussion of Registrants' comments

General Registrant's comments

Several registrants commented that the draft decision would be too short to be sufficiently understandable and that the interim SEV report would be needed.

The German CA organized a meeting with the registrants. The meeting took place on 24th of April 2013.
The evaluating MSCA was always aware that the draft decision is a stand-alone document to be understandable without the SEV report. Therefore, the evaluating MSCA prepared a draft decision that was supposed to be submitted without the SEV report and is of the opinion that the draft decision is not too short to be sufficiently understandable.

Several registrants indicated that a completed EU Risk Assessment (2003) and an updated EU Risk Assessment (2008; called EU RAR 2010 in the present decision) of the substance are available. The German CA is aware of these reports, but since finalization of the reports further data has become available which has not been addressed in the registrations. Thorough evaluation of further data (already available but also from on-going studies) is necessary in order to decide whether Bisphenol A poses a risk to human health or not.

Furthermore several registrants stated that they are missing a clear rationale why the authorities require information on topics which they think they would be excluded from REACH. These are Waste, Polymers, Dangerous preparations, Food contact materials, unintended release and Potable water.

The German CA is of the opinion that the information which can be requested in the substance evaluation process is not limited by the standard information requirements for registration purpose. If needed to evaluate a possible risk and justified in an appropriate way, an evaluating MSCA may request information that is not part of a standard registration dossier.

The exclusions according to article 14 are exclusions of the CSR and not of the substance evaluation and therefore are not relevant for the present decision.
Polymers and preparations have not been evaluated. However, the risk of the substance resulting from its use in polymers or preparations is part of this evaluation and therefore information requests might cover such uses.
While REACH does not consider waste as a substance and therefore does not require a registration of waste, it is explicit in the legal text that the life-cycle of registered substances includes the waste stage (see *e.g.* Article 18(4)(a) and (e), Annex I, Sections 5.1.1. and 5.2.2., Annex II, Sct. 13., Annex VI, Sct. 3.6. and Annex XI, 3.2.
Therefore the evaluation of industrial chemicals must always also look at the waste stage. The overall goal of REACH is to look at chemicals at all of its life cycle.
Manufacturers or importers of a substance as such, in mixtures or in articles subject to registration under REACH are obliged to take the waste life-cycle stage of the substance into account, where relevant, according to Annex I, section 5.2.2 of REACH, when undertaking the appropriate assessments under Title II, REACH. (See Guidance on waste and recovered substances; 2010 [section 1.])

Regarding the suggested deadline several registrants commented that the requested test cannot be performed in the proposed 12 month timeframe. The registrants claimed that it would take 24 months to perform such a study and they asked for extension of the deadline from 12 months to 3 years to conduct the research and report the data. The arguments brought up by the registrant in order to extend the deadline to conduct research and report

the data are not fully comprehensible for the evaluating MSCA. Analytical methods to determine low amounts of Bisphenol A and Bisphenol A metabolites in various media have already been developed. Thus, there is no need for time consuming development of analytical methodologies which for most studies is the bottle neck when performing a study. Generally, the evaluating MSCA is of the opinon that it is possible to perform a skin absorption study in less than 6 months. Including 3 months for the preparation and coordination according to Article 53 of the REACH Regulation and additional 3 months for reporting, the study report could be finalised within 12 months. However, the evaluating MSCA acknowledges the additional efforts necessary for the metabolism study part. Therefore, a deadline of 18 months will be acceptable.

Since no convincing explanation was given the evaluating MSCA wants to maintain the requested timeframe.

Registrant's endpoint specific comments

1.1 Skin absorption: *In vitro* method (EC B45; OECD 428) under consideration of the Scientific Committee on Consumer Safety (SCCS) basic criteria for the *in vitro* assessment of dermal absorption of cosmetic ingredients

In their comments, several registrants stated that there would be enough data to conclude on the dermal absorption and that no additional testing would be needed.

The German CA has carefully evaluated and discussed all available studies mentioned by the registrants. All studies exhibit major deficits (such as low number of skin donors, use of organic solvents) and the dermal absorption values obtained from the studies indicate that dermal absorption of Bisphenol Amight be higher than concluded by the registrants. In order clarify the concern a properly conducted dermal absorption study should be performed.

Since no new information was presented by the registrants and no convincing explanation was given the evaluating MSCA wants to maintain the request.

2.1 Further information on emission pathways of Bisphenol A to the environment in the lead and joint registration dossier

a) Exposure assessment for the terrestrial compartment (soil and groundwater)

In the comments several registrants expressed that it is neither reasonable nor justified to question the soil risk assessment as performed in the registration dossiers. Arguments are that the incineration or deposition of sewage sludge at dedicated landfill sites is demanded in the dossier for each scenario concerned, that each user of the substance has to implement the risk management measures (RMM) / operational conditions (OC) as suggested by registrant, that the assessment of emissions from landfill sites are exempted from REACH and that emission into atmosphere is considered to be negligible based on application of efficient RMM / OC as considered in the EU RAR (2003, 2008) and that RMM / OC in operation at the time of the EU RAR are still in place.

Exposure of the terrestrial compartment (soil and groundwater) occurs via application of sewage sludge and deposition from air. Deposition from air can be expected at least for the following use: Industrial and professional repackaging of Bisphenol A. Emission to sewage treatment plant and subsequent application of sewage sludge can be expected at least for the following uses: Any use and service life of articles made of polycarbonate, other

polymers, epoxy resin, PVC. The argument that all sewage sludge is incinerated or disposed of at landfill sites is thus not valid at least for these uses.

According to literature the primary source of Bisphenol A in soils is the land-application of sewage sludge or biosolids. Reported levels of Bisphenol A in biosolids vary by many orders of magnitude, ranging from 0.10 to 3.2 x 10^7 mg/kg dry weight. Annually, an estimated 4 x 10^6 and 2.4 x 10^6 dry tons of biosolids are applied in the United States and Europe, respectively, primarily to agricultural fields. Given these rates, Bisphenol A inputs to terrestrial ecosystems may be substantial, despite potentially low Bisphenol A levels in biosolids.

Information in the registration dossiers for the terrestrial compartment is not sufficient to conclude on the concern since for example effectiveness of RMM are not given and for some uses RMM are in contradiction to PROCs.

The German CA is of the opinion that an exposure and risk assessment of the waste stage is within the obligations of the registrants under REACH. Regardless this fact the evaluating MSCA is of the opinion that further information necessary to conclude on the concern can be requested during substance evaluation even if it is outside the REACH registration obligations.

Since no new information was presented by the registrants and no convincing explanation was given the evaluating MSCA wants to maintain the request.

b) Exposure assessment for life cycle steps missing in the registration dossier

Several registrants commented that further scenarios would not be justified or reasonable.

In annex I chap. 5.2.2 of the REACH regulation is stated that "The emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses. The life-cycle stages resulting from the manufacture of the substance cover, where relevant, the waste stage. The life-cycle stages resulting from identified uses cover, where relevant, the service-life of articles and the waste stage."

To conclude on the concern for the environment the assessment of emissions from life cycle steps following the production of chemicals or laboratory reagents is necessary.

In each life cycle step waste occurs. Therefore, an assessment of the waste stage is necessary for all identified uses.

Since no convincing explanation was given the evaluating MSCA wants to maintain the request.

c) Exposure assessment for industrial manufacturing of Bisphenol A and industrial use of Bisphenol A for manufacturing of polycarbonate

Several registrants stated that the EU RAR approach and the PECs derived there are still valid and that the worst case emission site was considered in the registrations. Furthermore, the tonnages provided in the dossier are confirmed to be still valid and the discrepancy could not be verified.

Based on the data provided in the registrations the evaluating MSCA is of the opinion, that not the worst case site was considered. Although, the releases to water of the site chosen by registrants and the site considered as worst case by evaluating MSCA are similar. But,

since the river flow volume of the worst case site is 10 times lower the evaluating MSCA expects higher concentration in the river.

Tonnages reported to be produced for the production of polycarbonate and tonnages reported by registrants to be used for the production of polycarbonate show a very high discrepancy. It is unclear whether this discrepancy results from wrong information in registration dossiers or additional production sites for polycarbonate have been built and emissions from that sites are not considered in the registrations. Thus, it is not possible to conclude on the concern.

Since no convincing explanation was given the evaluating MSCA wants to maintain the request.

d) Use of articles made of polycarbonate

Several registrants noted that emissions for polycarbonate articles would be low and not directed to sewage treatment plants.

Registrants presented a study that degradation of polycarbonate through different processes (hydrolyse, photo degradation) does not lead to the formation of Bisphenol A. However, a concern for the environment resulting from migration of Bisphenol A residuals in polycarbonate into the environment directly, via sewage treatment plants or via emission from landfill sites still exists. A study provided by registrants supports this concern.

Since no convincing explanation was given the evaluating MSCA wants to maintain the request. As result of the comments the statement of reasons was modified.

e) Industrial and professional repackaging of Bisphenol A

Several registrants stated that there are little to no emissions into the environment.

Registrants provided no sufficient data on OC and RMM. The contradiction between RMM and resulting emissions for this use and the manufacture of Bisphenol A remain. A discussion of the effect of emission in form of particles on the degradation is missing. The use is not described to that level of detail that it is possible to conclude on the concern.

Since no convincing explanation was given the evaluating MSCA wants to maintain the request.

f) Industrial use of Bisphenol A for manufacturing of epoxy resin

Several registrants stated that the Risk assessment (RA) in EU RAR 2003 and 2008 would be still valid and that no small-sale-volume site would exist anymore.

One the one hand the registrants stated that the RA in the EU RAR is still valid; on the other hand the registrants stated in their comments on the draft decision that Bisphenol A is not sold to small-sale-volume-site anymore. In the registration dossiers it is not mentioned that sale to small-sale-volume-sites is excluded from the scenario. Furthermore the tonnages of the small-sale-sites were not considered in the tonnages for the RA in the RAR. These sites with amounts sold between 200-800 t/y account for approximately 10% of Bisphenol A used for epoxy resin production. Furthermore, the increase in tonnage between 2003 and 2013 is not accounted for in the registrations. Emissions to environment could be underestimated.

Since no convincing explanation was given the evaluating MSCA wants to maintain the request.

g) Use of articles made of epoxy resin

Several registrants commented that exposure from articles would be low; because residual content of Bisphenol Athe registrants augmented that the use of epoxy resin for water pipes would be out of scope of REACH and there would be no potential for a risk resulting from this use.

The evaluating MSCA is of the opinion that all uses where exposure to environment occurs have to be considered to conclude on the concern. In the exposure scenarios the OC and RMM and the use need to be described to a level of detail that it is understandable for what purpose the substance is used, which processes are carried out with the substance and how these processes are operated that the release is limited to the release factor reported in the registrations. The evaluating MSCA is of the opinion that an assessment of emissions from rehabilitated or new water pipes is within the scope of REACH.

It is not clear for which uses epoxy resin is used and where exposure to environment occurs (*e.g.* the use to rehabilitate or produce water pipes is not mentioned in the registrations). Tonnages or emission factors of uses with exposure to the environment are not provided in the registrations. Furthermore the EU RAR 2003 states on page 16 that "there are a number of different epoxy resins, which vary depending upon the starting constituents. Residual monomer contents varying from 1 to 1,000 ppm are mentioned in the different documents (EU RAR 2003, 2008, CSRs of the registrants, registrants comments on draft decision). Hence it is not possible to conclude on the residual monomer content of epoxy resins for the different uses. Due to this number of uncertainties it is not possible to conclude on the concern.

Since no convincing explanation was given the evaluating MSCA wants to maintain the request. As result of the comments the statement of reasons was modified.

h) Use of Bisphenol A for the manufacture of epoxy resin hardeners, use of Bisphenol A in epoxy resin hardeners

Several registrants commented that all processes would take place indoor, that only negligible emission to the environment would be expected, that plants that manufacture or process epoxy resin have specific accreditation and stay close to the state of technology and that an industrial production plant produces more than industrial / professional user would consume.

In the EU RAR 2003 (page 305) is stated that epoxy resin hardeners are used for marine antifouling paints, wood varnish, wood fillers and adhesives. Some of these uses are outdoor uses and are consumer uses. The uses are not described to that level of detail that it is understandable for what purpose the substance is used, which processes are carried out with the substance and how these processes are operated that the release to the environment is limited to negligible. Furthermore, it is not clear if consumer uses and releases to the environment are addressed under these scenarios or under the scenario "use of articles made of epoxy resin". Thus, it is not possible to conclude on the concern for the environment.

As already stated under "General comments" the waste stage has to be considered.

Since no convincing explanation was given the evaluating MSCA wants to maintain the request. As result of the comments the statement of reasons was modified.

i) Industrial use of Bisphenol A for manufacturing of thermal paper (including

recycling of thermal paper and use of recycled paper)

Several registrants stated that RMM and OC would be described in EU RAR 2003 and 2008, that plants / sites would operate according to IED and following BREF documents, that no aggregation would be necessary as processes covered under this exposure estimation would not take place at one site, that amounts of Bisphenol A imported with thermal paper could not be considered in RA as it would be difficult to gather data and that registrants would not have to cover imported tonnages in their registrations if they have no data on it or importers are not among them.

According to the registration dossier the production of thermal paper and the recycling of thermal paper are summarized under that scenario. Within recycling of thermal paper there is a differentiation between the paper feed for the recycling process. The manufacture and recycling of thermal paper does not take place at the same site. It seems plausible that an aggregation on local scale is not necessary.

For data for the exposure assessment for the production and recycling of thermal paper the registrants refer to EU RAR 2003 / 2008 and mention update of data with information based on data from ETPA (2012). However, it is not clear, which data are updated since the 2003 and 2008 EU RAR. Relevant data for environmental exposure assessment (*e.g.* emission factor, efficiency of RMM, OC, and tonnage of paper for recycling, content of Bisphenol A in waste paper feed for recycling) cannot be extracted from the registrations.

Furthermore, there is a need to take into account the overall Bisphenol A content (also from imported thermal paper) in the paper recycling process. The registrants should provide assumptions on amounts of thermal paper as they know that import occurs.

Emissions form thermal paper manufacturing site, sites which use thermal paper broke as feed for recycling and sites which use mixed paper waste as feed for recycling are not presented in that detail that a conclusion on the concern is possible.

Since no convincing explanation was given the evaluating MSCA wants to maintain the request. As result of the comments the statement of reasons was modified.

j) Use of Bisphenol A as anti-oxidant for processing and use of PVC

Several registrants stated that the use as anti-oxidant during processing PVC would be the relevant one, that the ERC changed in updated registrations due to collection of experience in the use of ERCs, that exposure assessment is based on EU RAR ERCs are used only descriptive and not for exposure calculation, that the use of Bisphenol A as anti-oxidant for PVC processing would have declined to a maximum of 500 tonnes and only some few users remained and that described RMM and OC would be applicable for all three processes.

In the EU RAR 2008 all three uses covered with this scenario are mentioned and exposure for the environment is calculated separately. Registrants provided no explanation why the use as anti-oxidant during processing PVC is the relevant one.

Since no convincing explanation was given the evaluating MSCA wants to maintain the request. As result of the comments the statement of reasons was modified.

k) Professional use of articles made of PVC and consumer use of articles made of PVC

Several registrants stated that PECs are not zero but negligible, that no uses which are reported in the EU RAR and which are still being applied could result in significant exposure

and that the losses from solid material that are theoretically possible but that the EU RARs do not describe estimates on environmental releases for consumer use of articles made of PVC.

Since it is not clear which of the uses described in the RAR are still applied at presence it is unclear from which uses emissions were calculated in the registrations. Furthermore, since the EU RARs do not describe consumer uses it is unclear for what uses emissions were calculated or what has been the basis for the calculation of consumer uses in the registrations.

As valid for all exposure scenarios the OC and RMM and the use need to be described to a level of detail that it is understandable for what purpose the substance is used, which processes are carried out with the substance and how these processes are operated that the release is limited to the release factor reported in the registrations. If additional onsite waste water treatment or waste air treatment is needed to limit the release, the corresponding suitable treatment techniques are to be identified in the ES. It is not possible to conclude of a concern for the environment without that data

Since no convincing explanation was given the evaluating MSCA wants to maintain the request. As result of the comments the statement of reasons was modified.

l) Industrial use of Bisphenol A for manufacturing polymers

Several registrants commented that the RMM and OC described in this scenario would apply for all processes listed in the scenario. Therefore, the given RMM / OC would be complete and no data would be missing. If that data would not be unambiguously described registrants suggest to modify the registrations to make it more comprehensive. Some registrants stated that the life cycle of polymer would be exempted from REACH and that no data would indicate that there would be a relevant amount of residual monomer or depolymerised monomer.

The registrants provide neither data on residual monomer content in the different polymers nor a description or tonnages on the uses of the different polymers. The emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses. The life-cycle stages resulting from the manufacture of the substance cover, where relevant, the waste stage. The life-cycle stages resulting from identified uses cover, where relevant, the service-life of articles and the waste stage. As relevant data for the environmental exposure assessment are missing in the information provided by the registrants it is not possible to conclude on the concern.

Since no convincing explanation was given the evaluating MSCA wants to maintain the request.

m) Use of Bisphenol A for manufacturing and use of coating materials

Several registrants commented that all uses would occur indoors, that the RMM / OC described in the registrations ensure safe use for manufacturing and use of coating materials, that the RMM / OC would be true for all processes and that efficiencies could be expected to be in the worst case on the technical standard of the EU RAR (2010) report year. Efficiencies could be expected to be even higher as plants have to follow the status quo. Registants understood also from the meeting with the German CA that the registration was not providing this information in an unambiguous mode and suggest to update the registration to make it better understandable. Furthermore the registrants clarified some questions of the German CA and agreed to add this information to the registration.

As valid for all exposure scenarios the OC and RMM and the use need to be described to a level of detail that it is understandable for what purpose the substance is used, which processes are carried out with the substance and how these processes are operated that the release is limited to the release factor reported in the registrations. If additional onsite waste water treatment or waste air treatment is needed to limit the release, the corresponding suitable treatment techniques are to be identified in the ES. The emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses. The life-cycle stages resulting from the manufacture of the substance cover, where relevant, the waste stage. The life-cycle stages resulting from identified uses cover, where relevant, the service-life of articles and the waste stage.

The evaluating MSCA welcomes the fact that the registrants already recognised that relevant data for the environmental exposure assessment are not unambiguous understandable from the registrations. The evaluating MSCA is of the opinion that some data are missing in the registrations and it is therefore not possible for the evaluating MSCA to conclude on the concern.

Since no convincing explanation was given the evaluating MSCA wants to maintain the request.