RAC/M/29/2014
Final
11 September 2014

Minutes of the 29th Meeting of the Committee for Risk Assessment (RAC-29) 2 – 6 June 2014

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 29th meeting of the Committee for Risk Assessment (RAC). Apologies were received from five members. The participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed once no longer needed. The Chairman noted that the minutes would be published on the ECHA website and would include a full list of participants as given in Part II of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting.

The Final Draft Agenda (RAC/A/29/2014) was adopted. The agenda and the list of all meeting documents, including conclusions and action points are attached to these minutes as Annexes I and II, respectively.

3. Declarations of conflicts of interests to the Agenda

The Chairman requested all participants to declare any potential conflicts of interest to any of the agenda items. Seven members and one invited expert declared new potential conflicts of interest, each to specific agenda items. In addition, a number of members had declared potential conflicts of interest during previous RAC meetings, on items which were also in the agenda for RAC-29 meeting. In the event of a vote, these meeting participants were requested to refrain from voting on the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

At its March meeting, the Management Board approved a revised ECHA Procedure for Prevention and Management of potential Conflicts of Interest, including a slightly revised Annex, i.e. the declarations of interest form. The revisions in the Declaration of Interest form need to be integrated into the Rules of Procedure of each Committee and the Forum. The Secretariat briefly presented the Revised DoI form for the information of members and explained its potential implications.

The Chairman informed the Committee about the outcome and recommendations of the Management Board, Conflicts of Interest Advisory Committee (CoIAC) in relation to the practice of members declaring a potential conflict of interest when the dossier is submitted by a Member State Competent Authority (MSCA) or executing agency by which the member is employed and where they had not been involved in its preparation.

The CoIAC acknowledged that although RAC and SEAC members were independent, concurrent employment in a MSCA or executing agency could create a perception of conflict or potential conflict of interest as observed in the minutes of RAC and SEAC. Therefore the current practice is in line with the existing legal and policy framework. The CoIAC further recommended maintaining the current practice – i.e. allowing those members with a potential conflict of interest to participate in the opinion forming debate like any other member. In this regard, the Chairman explained the rules for voting as contained in REACH and the RAC Rules of procedure. The only practical implication from the declaration in this specific situation is that the member cannot vote or issue a

minority opinion, as stipulated in the legal text; their position could however be reflected in the minutes of the meeting; the Commission could be informed as appropriate.

The Chairman confirmed that in accordance with the CoIAC recommendations, the Secretariat would streamline the various CoI documents.

4. Report from other ECHA bodies and activities

a) Report on RAC-28 action points, written procedures and other ECHA bodies

The Chairman informed the Committee that all action points of RAC-28 had been completed, or were on-going; noting that the publication of some adopted opinions had been delayed but that these would be finalised and uploaded to the ECHA website as soon as possible. The summary of all consultations, calls for expression of interest in (co-)rapporteurship and written procedures is available in a meeting document on CIRCABC (see Annex IV). He also informed the Committee that the final minutes of RAC-28 had been adopted via written procedure and were uploaded to CIRCABC and on the ECHA website on 29 May, and thanked those members who had provided comments on the draft.

b) RAC work plan for all processes

The Chairman presented the updated RAC work-plan for 2014 and Q1/2015, covering the three processes of restriction, authorisation and harmonised classification and labelling of substances. He informed the meeting that the ongoing analysis of the workload for the Committees for 2014 indicated a rise from 40 opinions in 2013 to more than 70 in 2014 (ca. 50 CLH, six restrictions and 12 applications for authorisations with multiple uses). The Chairman confirmed that the RAC-31 meeting scheduled for the last week of November 2014 would be a two week meeting, as indicated on the Committee web page. He also noted that the Secretariat was exploring options for enhanced efficiency of plenary discussions (see AP. 5.3a).

5. Harmonised classification and labelling (CLH)

5.1 CLH dossiers

a) Bupirimate (ISO) (remaining health hazards)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that the pesticide active substance bupirimate (ISO) was being tabled for a second plenary discussion. Bupirimate (ISO) currently has no harmonised classification in Annex VI to CLP. The dossier submitter (DS; the Netherlands) proposed classification as: Carc. 2, Skin Sens. 1B; Aquatic Chronic 1 (M=1). At RAC-28, the members had agreed to classify bupirimate (ISO) as Skin Sens. 1B and Aquatic Chronic 1 (M=1).

The Chairman informed that the discussion should focus on carcinogenicity and other remaining health hazards and reported that during the evaluation of carcinogenicity, the Rapporteur had asked for additional information on historical control data from the DS, which had subsequently been provided. In view of a potential STOT RE classification, the latter had also submitted a clarification in relation to effects on the thymus.

The Chairman invited the Rapporteur to present the outstanding parts of the evaluation of the dossier. During the subsequent discussion, the RAC members agreed to the DS's proposal not to classify the substance for STOT RE, mutagenicity and reproductive

toxicity. As to carcinogenicity, the debate focussed on the two types of tumours observed, namely thyroid follicular adenoma and subcutaneous fibroma, while a range of clarifications, i.a. on the metabolite ethirimol, was provided by the ECPA expert.

With regard to the thyroid follicular adenoma, it was recognised that low-potency dose response and some evidence for a perturbation of the HPT axis was reported, thus classification was not warranted. However, in relation to subcutaneous fibroma, RAC agreed on a classification into Carc. 2 (H351) as a treatment-related increase of (benign) tumours was observed in both female and male rats, and because the high-dose incidences in females (12.5%) were well beyond relevant HCD incidences (about 3%).

Finally RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for their presentation of the arguments, the Committee for their participation in the discussion.

b) 1-methyl-2-pyrrolidone (NMP)

The Chairman reported that the DS (the Netherlands) had indicated that NMP has a wide variety of industrial uses (the manufacture of coatings, in particular for wire, as a cleaning agent, in functional fluids, laboratories, agrochemicals and pharmaceutical manufacture). The substance currently has a harmonised classification in Annex VI of the CLP Regulation including a Repr. 1B classification for developmental toxicity with specific concentration limits (SCL) of 5%. The SCL was originally set based on an older method no longer recommended anymore in the ECHA guidance. The DS proposed to remove the SCL for the Repr. 1B endpoint in line with current Guidance. There were seven comments received during the Public Consultation from six Member States and one European Economic Area country. All comments received supported the removal of the specific concentration limits for the reproductive toxicity endpoint. The Rapporteur supported the DS proposal. During the RAC Consultation (26 March – 23 April) seven RAC members provided their comments. All of the received comments supported the proposal.

RAC agrees that the data for setting SCL for developmental toxicity for NMP clearly shows that NMP corresponds to the medium potency group (i.e. boundaries: 4 mg/kg bw/day < ED_{10} value < 400 mg/kg bw/day, CLP Guidance table 3.7.2-d) and according to CLP Guidance table 3.7.2-e the GCL of 0.3% should be applied for NMP. Based on the available data, RAC considered that no modifying factors were applicable which could affect the assessment of the potency of NMP. RAC therefore considers that the current SCL of 5% should be removed and the GCL should be applied for NMP.

The Committee agreed by consensus to remove the specific concentration limit, in which case, the general concentration limit of 0.3% would apply. The Chairman thanked the Rapporteur for presenting the case.

c) Propylene oxide

The Chairman welcomed the Rapporteur and the ECHA's Secretariat support team for this dossier.

The substance currently has a harmonised classification in Annex VI of the CLP Regulation. The Chairman informed members that the DS's (the Netherlands) proposal was to replace in the current entry Acute Tox. 4* (H302) with Acute Tox. 4 (H302), Acute Tox. 4* (H332) with Acute Tox. 3 (H331), and Acute Tox. 4* (H312) with Acute Tox. 3 (H311). In addition, it was proposed to delete Skin Irrit. 2 (H315).

The Rapporteur presented the draft opinion. RAC members expressed their agreement with the assessment of the Rapporteur and the opinion was adopted by consensus.

In conclusion, the Chairman thanked the Rapporteur for presenting the case.

d) Glutaraldehyde

The Chairman reported that glutaraldehyde is a biocidal active substance in disinfection and in product and process preservation. It already has a harmonised classification in Annex VI to the CLP Regulation as Acute Tox. 3* (for oral and inhalation routes), Skin Corr. 1B with specific concentration limits, Skin Sens. 1 (with SCL), Resp. Sens. 1 and Aquatic Acute 1. The legal deadline for the adoption of the opinion is 24 March 2015.

The DS (Finland) proposed to add an M-factor to Aquatic Acute classification, to additionally classify as Aquatic Chronic 2, to remove the minimum classification for acute toxicity via the oral route and to increase the inhalation classification to Acute Tox. 1, to revise the Skin Sensitisation classification to subcategory 1A and to add classification for STOT SE 3 and the label EUH071.

The Committee supported the proposal for classification for acute toxicity via oral route, as well as sub-categorisation into Skin Sens. 1A and the addition of STOT SE 3 as proposed by the DS. In addition, the Committee supported the proposed addition of supplemental labelling as 'corrosive to the respiratory tract' (EUH071).

The discussion then focused on acute toxicity via inhalation route, in particular whether the cut-off points for vapours or for dusts/mists should be used when comparing the LC50 value from dynamic inhalation studies with the criteria. In the absence of more detailed information on the form of the substance the test animals were exposed to, the Committee decided not to support the DS proposal and instead proposed classification as Acute Tox. 2 for the inhalation route.

The Committee agreed with the DS proposal to remove specific concentration limits for skin sensitisation to align with the sub-categorisation into a higher category, but did not agree to the DS proposal to lower the SCL for STOT SE 3 from 0.5% to 0.00005%. As no evidence for maintaining the SCLs for corrosion was included in the CLH report, the Committee proposed to remove these.

With regard to the environmental classification, the Committee agreed to classify glutaraldehyde as toxic to aquatic life with long lasting effects (Aquatic Chronic 2). RAC did not agree to assign an M-factor of 10 to the acute aquatic classification, but proposed an M-factor of 1 instead.

The Committee adopted the opinion on glutaraldehyde by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee for their participation in the discussion.

e) Tinuvin 123

The Chairman reported that this was an industry proposal submitted by Germany in accordance with Art. 37(6) CLP and that Tinuvin 123 is used as a heat and light stabiliser. It already has a harmonised classification in Annex VI to CLP as a substance which may cause long lasting harmful effects to aquatic life (Aquatic Chronic 4; H413).

Based on the result of a study on aquatic bioaccumulation in fish according to OECD Guideline 305 which revealed a measured BCF (bio-concentration factor) below 500 and did not therefore fulfil the classification criteria for Aquatic Chronic 4, the DS proposed to

declassify the substance for environmental hazards. The Committee agreed to the proposal and adopted the opinion on Tinuvin 123 by consensus. The Chairman thanked the Rapporteur for the presentation.

f) Flumioxazin (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer, noting that the pesticide active substance flumioxazin (ISO) was being tabled for a second plenary discussion. He explained that the substance had also been under peer-review in EFSA, the aim being the renewal of the approval of the active substance, and that the CLH opinion should be adopted by RAC as soon as possible and preferably at this meeting.

The Chairman reported that the CLH proposal reviews the current entry in Annex VI to CLP where it is listed as Repr. 1B, Aquatic Acute 1 (M = 1000) and Aquatic Chronic 1. The DS (Czech Republic) had proposed to declassify the substance for reproductive toxicity and to assign in addition a separate M-factor = 1000 to the chronic aquatic classification. The latter was already agreed by RAC at the RAC-28 plenary meeting.

The Chairman noted that, the discussion on reproductive toxicity that could not be finalised at RAC-28 should be continued. He stated that the clarifying information on the link between the possible induction of anaemia in the rat embryo and the proposed mechanism that was requested from the dossier submitter at the last RAC meeting had been provided and been reviewed by the Rapporteur. The applicant in the EFSA process (Sumitomo, Japan) had also commissioned an expert to submit comments on the plausibility of the mode of action and the relevance to humans of the developmental toxicity of flumioxazin, which had been provided to ECHA and circulated to RAC.

The Chairman reported that during the most recent RAC consultation, support was equally expressed for Repr. 1B and Repr. 2 while no RAC member had supported declassification as proposed by the DS. He invited the Rapporteur to present the case.

The Rapporteur then summarised the data on reproductive toxicity and mechanistic studies in her presentation. She reported that while the current classification into Repr. 1B was based on rat data, the DS proposed that the mode of action (MoA) causing the effects in rats are not relevant for humans. The subsequent discussion focused on three questions: plausibility of the proposed MoA, relevance of this MoA for humans and the resulting classification. It was concluded that the MoA was plausible but not convincingly demonstrated (e.g. the mode of action had not been explored at the dose where effects were observed) while other mechanisms could not be excluded, based on the data presented. It was further concluded that relevance for humans could not be excluded, although there may be quantitative differences between rats and humans. Throughout the debate, the ECPA expert provided further clarifications as to the data available in the dossier.

Whereas the DS proposed removal of the Repr. 1B classification based on non-relevance to humans, RAC did not agree that non-relevance was sufficiently shown. On the other hand it was recognised that the CLP Regulation allowed the use of category 2 if there were doubts about the relevance of the mode of action to humans. However, the RAC members concluded that the doubts in this case were not sufficient to warrant classification as Repr. 2. RAC therefore agreed to retain the current classification of Repr. 1B (H360D).

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for their presentation of the arguments, the Committee for their participation in the discussion.

g) 1,2 dichloropropane (DCP)

The Chairman reported that the substance is used as an intermediate in the production of perchloroethylene and other chlorinated chemicals; it already has a harmonised classification in Annex VI to the CLP Regulation as highly flammable liquid and vapour and as harmful if swallowed and if inhaled (minimum classifications). The legal deadline for the adoption of the opinion is 7 May 2015.

The DS (IND) proposed to add harmonised classification and labelling for carcinogenicity, Carc. 2; H351 based on an inhalation carcinogenicity study in the rat (Umeda et al, 2010).

Based on this rat study and on a new inhalation carcinogenicity study in mice which was made available during the public consultation (Matsumoto et al, 2013) the Rapporteur proposed category 1B; H350. The proposal was based on the evidence in inhalation studies in animals (increase in bronchio-alveolar adenomas/carcinomas in both sexes in mice, increase in nasal papillomas in both sexes in rat and a small increase of rare esthesioneuroepitheliomas in male rats), and further supported by cancer cases in humans (Japanese Ministry of Health, Labour and Welfare (2013)). Although tumours seen in animal studies are possibly point-of-contact tumours, secondary to irritation, a genotoxic mechanism could not be excluded.

The Committee supported the Rapporteur's conclusion and agreed that the additional animal data (Matsumoto, 2013) would be sufficient for classification in category 1B on its own. The human data were considered insufficient for classification in category 1A but as supporting evidence for classification in 1B.

The Committee adopted the opinion on 1,2 dichloropropane (DCP) by consensus. The Chairman thanked the Rapporteur and her adviser for the presentation of the arguments and the Committee for their participation in the discussion.

5.2 Appointment of RAC (Co-)Rapporteurs for CLH dossiers

The Secretariat collected the names of volunteers for the CLH dossiers listed in the room document and the Committee agreed upon the proposed appointments of the (Co-) Rapporteurs for the intentions and/or newly submitted CLH dossiers.

5.3 General and procedural CLH issues

a) New procedures for agreement seeking

The Chairman presented a proposal to improve the flow of CLH opinions and reduce debating time in plenary meetings. The main principle of the *fast track agreement* for adoption of opinions is to separate the hazard classes for agreement without further discussion in the plenary (so-called A-points) and thus to allow more debating time for complex dossiers / hazard classes. The proposal received broad support from RAC members, the Commission observer and the stakeholders.

In the discussion, some members pointed out that the pre-selection of A-points should be the responsibility of the Rapporteurs and the Secretariat. Members expressed reservations regarding a suggested rota system requesting comments from members

during the RAC consultation, noting that fewer comments to some of the proposed hazard classes should not prevent the use of the fast track route. On the other hand, it was pointed out by one member that some hazard classes (such as CMR or respiratory sensitisers) would always need to be discussed in the plenary.

Stakeholder observers appreciated that the proposed differentiation would improve the quality of discussions in the Committee, however, they pointed out that the ultimate gain of the debating time might be limited. In addition, they underlined that a substantial scrutiny of the fast-tracked hazard classes had to be ensured and industry needed to be encouraged to provide comments during the public consultation. Another stakeholder observer mentioned the potential difficulties in assessing downstream consequences of a proposed harmonised classification.

The Secretariat was requested to revise the document based on the discussion, send it for agreement to the Committee by written procedure and implement the fast track approach in time for RAC 30. The Chairman thanked the Committee for the constructive discussion and for their support.

6. Restriction

6.1 General restriction issues

a) Review of the restriction process:

Update from Task Force

Note: this item was removed from the agenda; it will be presented at the September plenary.

6.2 Restriction Annex XV dossiers

a) Opinion development

1) Nonylphenol – 4th version of the draft opinion

The Chairman welcomed the DS representatives (Sweden) and the SEAC Rapporteurs, who followed the discussion remotely via WebEx. He reminded the Committee that the restriction dossier on Nonylphenol (NP) and Nonylphenol ethoxylates (NPE) had been submitted to ECHA in August 2013 and that the 4th version of the RAC draft opinion and the related documents had been provided to the Committee on 8 May 2014. The Chairman informed about an ad-hoc meeting organised on the evening of 2 June with the Rapporteurs and interested RAC members and as a result, a modified 4th version of the RAC draft opinion was produced and distributed to members as a room document.

The Rapporteurs then presented the modified 4th version of the RAC draft opinion. They highlighted the major changes compared to the 3rd and 4th version of the RAC draft opinion. Further elaboration of PNEC derived from traditional apical endpoints and its relation to endocrine disruption had been made, including effects reported at "low" concentration primarily in fish developmental studies. It was emphasised that the resulting RCRs represent a "minimum" risk. The monitoring data provided during the public consultation had also been included as well as information on NP levels in textiles. In addition, entirely new sections on practicality and monitorability had been included with an explanation of recommended changes to the original proposed restriction

wording (removal of NP from the scope, textile definition and clarification of which textiles are considered subject to washing, the second hand market, etc.).

One RAC member expressed appreciation for the approach used by the Rapporteurs in relation to the wording of the restriction (that only elements of the restriction have been presented in the opinion, and the exact wording has been left to be decided by the Commission). This member suggested using the same approach for all future dossiers.

The Commission representative was interested to hear whether the Rapporteurs had considered a derogation for the new textile articles that have been washed prior to putting on the market (e.g. faded jeans). The Rapporteurs responded that if such products are manufactured within the EU, the current NP/NPE restriction does not allow the use of NP and NPE in textiles. If they are imported into the EU, it means they have been washed outside the Europe. The Commission representative also asked whether the Rapporteurs had considered the impact of exclusion of NP from the scope of the restriction in terms of risk reduction. The Rapporteurs replied that based on available information there does not seem to be a need to retain NP in the scope, however, they suggested that some study could be commissioned in the future to analyse NP content in textiles.

RAC adopted its opinion by consensus.

It was agreed that the Rapporteurs, together with the Secretariat, would make the final editorial changes to the opinion as presented at RAC-29. The Rapporteurs and the Secretariat should also ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. The Secretariat will forward the RAC opinion and its supporting documentation to SEAC, as well as publish it on the ECHA website and on CIRCABC.

2) 1-Methylpyrrolidin-2-one (NMP) – 4th version of the draft opinion

The Chairman welcomed the DS representative (Netherlands) and the SEAC Rapporteur, both of whom followed the discussion remotely via WebEx. He noted that the restriction dossier on 1-Methyl-2-pyrrolidone (NMP) had been submitted to ECHA in August 2013 and that the 4th version of the RAC draft opinion and the related documents had been provided to the Committee on 5 May 2014. The Chairman reminded the Committee that at RAC-28 the Rapporteurs had proposed an alternative risk management option (RMO), based on application of the DNELs for inhalation and dermal exposure. This option, along with an analysis of those proposed by the DS, was presented for RAC consideration in the 3rd version of the draft opinion. The Chairman informed the participants that the Rapporteurs had introduced some further amendments to the 4th version of the RAC draft opinion, which had been distributed to the participants as a room document.

The Rapporteur then presented the modified 4th version of the RAC draft opinion. He introduced the conditions of the restriction proposed by RAC and also informed the Committee that the Forum had proposed some further modifications to these conditions in their final advice. In the view of the Rapporteurs these changes would make the text of the restriction more complicated and therefore they proposed not to add these modifications. Instead, the final Forum advice will be forwarded to the Commission together with the opinions and the Commission could then decide on the exact final wording.

The Rapporteur was interested in the view of other Committee members whether the comparison between the DNEL and the IOEL should be kept in the opinion. Some members preferred to keep it, while others suggested moving it to the Background

Document (BD). It was concluded that this comparison should be kept in the opinion as it makes the difference between the IOEL and the RAC DNEL clear.

The Rapporteur highlighted that SEAC's support for the modified restriction may depend upon possibilities to include derogations (e.g., for the wire-coating sector). However, in his view, RAC should not support a 15 year derogation. One RAC member recommended to point out in the opinion that for some industry sectors the implementation of the proposed restriction might be more critical than for others and that SEAC might want to consider this in their opinion. Some other members, however, felt that RAC does not need to mention it in their opinion and the Committee agreed to this view.

The Rapporteur was also interested whether substance evaluation should be discussed in the RAC opinion. Some members were of the view that the text proposed to be added by the Rapporteurs should not be included in the opinion, as this restriction should trigger better risk management in the companies, and not the substance evaluation. Several other members, however, considered the proposed text to be softly formulated and not demanding anything. It was finally agreed to include this text in the opinion, but to delete the last sentence.

RAC adopted its opinion by consensus with the modifications agreed at RAC-29.

The Rapporteurs, together with the Secretariat, were tasked to make the final editorial changes to the opinion as presented at RAC-29. The Rapporteurs and the Secretariat should also ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. The Secretariat will forward the RAC opinion and its supporting documentation to SEAC, as well as publish it on the ECHA website and on CIRCABC.

3) Cadmium and its compounds in paints – 2nd version of the draft opinion

The Chairman informed that the first version of the cadmium in paints opinion was opened for written commenting round by RAC in March 2014. Following the written comments received, the RAC Rapporteurs prepared the second version of the RAC opinion in May 2014. The public consultation on this dossier will finish on 17 June 2014.

The Chairman asked the RAC Rapporteur to present the second version of the RAC opinion and the update on the public consultation comments received so far. Subject to remaining public consultation comments, the RAC was invited to agree on the main elements presented by the RAC Rapporteurs.

One member asked what to do with the public consultation comments addressed to the other public consultation (on Cd in artist's paints) but submitted via the cadmium in paints public consultation. The Secretariat responded these would be forwarded and taken into account in the correct public consultation.

The Chairman concluded that RAC agreed on the main elements presented by the RAC Rapporteurs. The Secretariat may launch a written procedure for the adoption of the RAC opinion following the end of the public consultation, or depending on the last comments received, may conclude matters at RAC 30.

4) Cadmium and its compounds in artist paints – first plenary discussions on the key issues document

The Chairman introduced the topic by informing the Committee of the hundreds of comments already received in the public consultation, many from artists against the proposed restriction but many also in support. He then asked the RAC Rapporteurs to present their key issues document. Their presentation focused on the proposal that RAC

would base its opinion on the EFSA assessments (2009, 2012), they provided clarifications on the scope of the restriction and provided explanations on the role of the Gustafsson study (2013). The exposure scenario described by the DS was briefly discussed and questioned by RAC, such as how the paints are used and what is actually disposed of to waste water treatment. The uncertainties in the assumptions were acknowledged by RAC and it was concluded these should be reflected clearly in the opinion. Members expressed concerns at the minute impact this restriction appeared to have on dietary intake of Cd in general and questioned whether given the wide uncertainties in the proposal this could possibly be significant.

Industry informed the Committee that in their view, the uncertainties of the predicted effects of the minute quantities over the very long period are too large to be of statistical significance. The time-scale for the transformation-dissolution of the Cd in the artist's paints allows the assumption that this compound will be comparable as soluble Cd compounds as referred to in the Gustafsson study and Industry offered to provide further evidence on this aspect. Industry noted, however, that the dossier refers to equal bioavailability of Cd in soil from sludge as that from other sources. There is a so-called sludge protective effect to consider, i.e. cadmium added via sludge is about two-fold less available than that from other sources.

While there was some support for using the EFSA report as the basis of the opinion, i.e. using the principle that any further exposure to Cd should be avoided, some members pointed out that caution should be taken when translating exposure to risks and that it was the risks that the Committee should ultimately assess. There was further discussion on using the kidney effects rather than the breast cancer or bone breakages. The Chairman requested the RAC (co-)Rapporteurs to take the discussions into account in their first version of the RAC draft opinion, which is due by 1 August 2014. Following the new working procedure on the opinion development, the RAC members were invited to come forward to support the Rapporteurs in the opinion development.

5) Chrysotile - first plenary discussions on the key issues document

The Chairman informed the Committee of the state of play regarding the opinion development on the amendment of a derogation to an existing restriction. The RAC Rapporteurs then presented the key issues document to RAC, expressing their support for the proposed risk management option (i.e. derogation with a fixed end date).

One stakeholder representative called for an immediate end to the derogation to the ban on existing uses of Chrysotile. He claimed that an extension of the derogation is not necessary since the industry has already imported enough Chrysotile fibres to permit over 10 years functioning of its diaphragms. Furthermore, according to his opinion there are already technically and economically feasible alternatives currently available on the market. In response to this, the Chairman recommended the stakeholder representative to submit such information also via the public consultation in order to be evaluated by the Committee. In addition, the stakeholder representative asked the companies to provide more monitoring data to be presented to the Committee with regard to the worker protection.

Some of the RAC members supported the Rapporteurs based on the available information that the exposure is controlled and risks are low. Some members however considered it necessary to have more data to evaluate whether the risks are indeed adequately dealt with, for example in relation to the monitoring data in order to be able to make a rigorous assessment on the preferred risk management options.

Another stakeholder representative stated that a better developed authorisation option could have been presented in the dossier and furthermore called on RAC to take into consideration the whole life cycle of the substance in its risk evaluation, including the mining phase of Chrysotile. The Secretariat responded however that RAC the assessment would only be able to take into account the aspects covered within the EU regulation and presented in the dossier.

The expert supporting the CEFIC stakeholder informed the Committee that the owner of the German plant still using Chrysotile filters had made a commitment to the German state that asbestos would not be imported after 2017.

A Commission representative welcomed the fixed end date, stating that the exact timing could be discussed, noting as well that the member states may add additional conditions to the restriction. Regarding the confirmation stated by the industry representative that asbestos would not be imported after 2017; the Commission representative suggested this could be also reflected in the restriction.

The Chairman gave then the floor to the CEFIC expert to answer detailed questions addressed to him by members and to provide RAC with general information on the procedures for maintaining and replacing filters as well as the disposal of the filter material and use of alternatives in its operations.

Finally, the Chairman concluded that the RAC (co-)Rapporteurs would take the discussions into account in their first version of the RAC draft opinion, which is due by 1 August 2014.

b) Conformity check

1) Isopropylidenediphenol (bisphenol A) - outcome of conformity check

The Chairman welcomed the DS representative (France) and reminded the Committee that they had agreed on non-conformity at the March plenary meeting. A revised dossier was resubmitted to ECHA by France on 6 May.

The Chairman invited the representative of the DS to present the main revisions to the restriction proposal. The Rapporteur then presented the outcome of the conformity check, concluding that the dossier was now in conformity.

After a short discussion, the Chairman concluded that RAC agreed that the bisphenol A dossier conforms to the requirements of Annex XV. In addition the Chairman reminded the participants of the meeting that if they wish to contribute information relevant to the proposal, it should be submitted via the Public Consultation.

The Chairman then informed the participants that following the conclusion of SEAC on conformity, the Secretariat would communicate the results of the conformity check and the recommendations to the DS.

2) Ammonium salts - outcome of conformity check

The Chairman welcomed the DS representative (France) and the SEAC Rapporteur, who followed the discussion remotely via WebEx. He informed the participants that the restriction dossier on inorganic ammonium salts had been resubmitted by France on 8 May 2014 following the decisions made by RAC and SEAC in March that the dossier originally submitted by France was not in conformity. The Chairman reminded the Committee that this dossier has been submitted within Article 129 of the REACH Regulation (safeguard clause).

The RAC commenting round finished on 26 May with comments received from one RAC member. The representative of the DS provided a presentation on the main changes introduced in the revised dossier. The RAC Rapporteur then informed the Committee that following improvement of certain aspects (e.g. update of DNEL, more concrete presentation of exposure estimation, insertion of RCR values, improved presentation and analysis of RMOs), the dossier is now in conformity from the RAC point of view.

The Committee agreed and the Chairman informed that SEAC will conclude on the conformity of this dossier at SEAC-23 next week. If the dossier will be considered in conformity by both Committees, the public consultation on the dossier will be launched on 18 June.

6.3 Appointment of (co-) Rapporteurs for restriction dossiers

The Secretariat presented the recommendation of the Chairman for the appointment of (co-)Rapporteurs for the restriction dossiers Bis(pentabromophenyl) either (**DecaBDE**) (to be submitted by ECHA), **methanol** (to be submitted jointly by Poland and Finland), and Perfluorooctanoic acid (**PFOA**) (to be submitted jointly by Germany and Norway) as outlined in the meeting document RAC/29/2014/05 RESTRICTED. RAC agreed on the appointment for (co-)Rapporteurs as proposed in the recommendation.

7. Authorisation

In a session on common approach to the applications for authorisation there was an opportunity for members to discuss the possibilities for RAC to recommend additional conditions, monitoring arrangements, or the length of the review period in the appropriate context (and when it would be advisable not to). Additionally, a short presentation on evaluating PBTs in the context of AfA provided a prelude to the conformity on an application for the PBT flame retardant HBCDD.

7.1 Authorisation applications

The Chairman announced that the discussion of application for authorisations would take place in observed sessions, i.e. with stakeholder observers present. However, in the unlikely event that confidential business information needed to be discussed, he would close the session as a precaution. He reminded the participants, including stakeholder observers of the need to keep the discussions on the applications confidential.

RAC was to discuss and where indicated agree on the draft (or outline) versions of the draft opinions of the six applications for authorisation for a total of 12 uses of DEHP and DBP, three applications for authorisation for a total of four uses of diarsenic trioxide and one application for authorisation for the six uses of two lead chromate pigments.

Note: the sequence in the minutes may differ to that in which dossiers were handled and agreed in Committee, as several of the dossiers are related to each other.

a) Authorisation application on phthalates – 2nd version of the RAC draft opinions (applications submitted within the August 2013 submission window)

1. Two uses of DEHP submitted by ARKEMA FRANCE (DEHP 2a):

i. Formulation of DEHP in compounds, dry-blends and Plastisol formulations

ii. Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles

The Chairman welcomed the RAC Rapporteurs and the Authorisation Team. He invited the Rapporteurs to update the Committee on the developments since the last plenary discussion and to present the second version of the draft opinions for uses i and ii of this application. Due to their similarities, the uses i and ii of the DEHP2a, b and c applications were discussed under the same agenda point. For the same reasons, the DEHP2c use iii was discussed on a separate agenda point together with DBP2 use iii.

The co-Rapporteurs presented their assessment of the exposure data as well as the risks to workers and the general public. Following the presentation, the Chairman opened the floor for discussion on the respective presented issues, asking the views and agreement from members.

The Chairman summarised the views of RAC as follows:

RAC confirmed their previous considerations from RAC28, that adequate control for workers had not been demonstrated but that there is adequate control for the general population for use i exposure scenario (ES) 2 and use ii ES 3. In addition, RAC considered that for service-life scenarios (ES3 SLP1 and SLP2, SLC1) for professional and consumers the RCRs are <1. One member raised concern about the way the opinion was written regarding consumers and the use of the DEMOCOPHES data and proposed some rewording.

With regard to workers, RAC was of the view that the exposure assessment of the applicant was not considered to be adequate to describe the exposure situation at workplaces for the whole of Europe. However, it was shown by the exposure data that the exposures indeed were adequately controlled in several of the monitored workplaces. However, as the data indicate that this seems not to be the case for all affected workplaces, the remaining risk is therefore not reduced to as low as technically and practically possible for all industrial sectors, process technologies and workers' settings within each process category covered by the very broad use.

Moreover, RAC agreed not to propose additional conditions or monitoring arrangements, and considered that remaining risks were not minimized due to the same reasoning explained above. RAC also considered that due to the uncertainties in this specific case, the human health impacts cannot be adequately quantified and only a qualitative description might be possible. RAC was of the view that in general for authorisation cases where sufficient exposure data was presented by the applicant, quantification of the human health impacts (e.g., in terms of infertility cases) should be considered.

With regard to alternatives, RAC considered that they appear to constitute a lower risk to consumers and workers; however, the risks are not adequately described. RAC was of the view that, unless SEAC indicates that technical and economically feasible alternatives exist, then the RAC evaluation in the 2nd draft opinion would be sufficient.

Considering the general weaknesses of the exposure assessment and the lack of adequate control, RAC recommended a short review period, in case SEAC would have grounds to recommend granting the authorisation.

The Rapporteurs will prepare the third version of the draft opinions by 20 August, which will be discussed for agreement at the next plenary meeting or adopted via written procedure.

The Chairman thanked the Rapporteurs for their work and the Committee for their participation in the discussion.

2. Two uses of DEHP submitted by Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna (DEHP 2b):

   i. Formulation of DEHP in compounds, dry-blends and Plastisol formulations
   ii. Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles

Due to their similarities, the uses i and ii of the DEHP2b application were discussed under the same agenda point with uses i, and ii of DEHP2a and c. For a description of the discussion see point 7.1.a)1 of the minutes.

3. Three uses of DEHP submitted by DEZA a.s. (DEHP 2c):

   i. Formulation of DEHP in compounds, dry-blends and Plastisol formulations
   ii. Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles
   iii. Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

Uses 1 and 2: Due to their similarities, the uses i and ii of the DEHP2c application were discussed under the same agenda point DEHP2a and b. For a description of the discussion see point 7.1.a)1 of the minutes.

Use 3: Due to their extensive similarities, DEHP2c use 3 was discussed together with DBP2 use 3 of the same applicant, DEZA a.s. The Chairman invited the Rapporteurs to update the Committee on the developments on DEHP2c use iii since the last plenary.

The Rapporteurs explained that important new information that was not contained in the original application had been received from the applicants at the request of RAC. For DEHP2c the new information only concerned the lambda sensor scenario, for DBP2 both the lambda sensor and the capacitator scenario. Due to the submission of this information at a late stage in the process (April 2014), the opinion forming process on this use had been delayed.

The Rapporteurs were of the opinion that the information is sufficient to perform a reliable exposure assessment. The Rapporteurs noted that the applicant had assessed the risks for combined exposure to DEHP and DBP in the application for DEHP (as well as in the application for DBP). The Secretariat clarified that since this is the case, the opinions of RAC for these two applications should consider the risks from combined exposure to DBP and DEHP.

The Rapporteurs were asked to prepare the first version of the draft opinion by 25 June. After the RAC consultation and amendment of the document, RAC will be requested to adopt the draft opinion via written procedure, or at the next plenary.

The Chairman thanked the Rapporteurs for their work and the Committee for their participation in the discussion.

4. The third use of DBP and DEHP submitted by Roxel (UK Rocket Motors) Ltd (DEHP 3):

    i. Industrial use of DBP within a specialty paint in manufacture of motors for rockets and tactical missiles.

Use 3 (DBP)

The Chairman invited the RAC Rapporteurs to present the draft opinion. The Rapporteurs in their presentation shortly summarized conclusions presented at the last plenary meeting and additional clarifications submitted by the applicant as reply to RAC additional questions. The applicant confirmed the number of workers that could be exposed to DBP under the activities described, submitted graphical explanations of the processes (including pictures). Due to lack of measurements data for DBP the applicant provided information on the exposure to the volatile solvent (MEK). This information was not considered useful by the RAC for supporting modelling results for DBP. The applicant also submitted information on the volume of DBP used in the various Worker Contributing Scenarios (WCS) and information regarding the duration and frequency of the activities in the WCS. The Rapporteurs recommended to the RAC to conclude that the exposure assessment in the application demonstrated adequate control of risks from the use applied for (Combined RCR: 0.924 <1). The Rapporteurs do not propose additional conditions and monitoring arrangements or any advice to SEAC on the review period.

During a short discussion, the RAC members supported the Rapporteurs' recommendations and RAC agreed that the adequate control had been demonstrated by the applicant. Therefore, RAC agreed the text of the draft opinion on the application for authorisation, recommending granting of the authorisation.

The Chairman thanked the Rapporteurs for their work and the Committee for their participation in the discussion.

5. The second and the third uses of DBP submitted by DEZA a.s. (DBP 2):

    i. Use in propellants (DBP 2, Use 2)

The Chairman invited the RAC Rapporteurs to present the case and the draft opinion. The Rapporteurs informed the Committee on the new information provided by the applicant in the updated CSR. They pointed that new Worker Contributing Scenarios (WCS) are described in the updated CSR:

- 61 WCS for SS1 (8 in the previous version)
- 15 WCS for SS2 (14 in the previous version).

The Rapporteurs recommended to the RAC that Human Exposure via the environment is adequately described and risk of exposure of man via the environment is adequately controlled. The RAC supported this conclusion.

The Committee discussed the results of the worker exposure modelling for each sub scenario, in particular how the exposure values for different Worker Contributing Scenarios should be combined. The RAC also discussed if the adequate control of the risk should be assessed separately for two sites described in the SS1 or jointly. Moreover, the RAC discussed how to use the air monitoring data which are available only for one site, resulting in RCRs higher than the modelling. The Rapporteur explained that the measurements represented only 6 samples. All of them were above the detection limit

but below the quantification limit. To consider these open questions further, the Chairman invited interested RAC members to participate in an ad-hoc working group and to report their findings back to the plenary.

A group of five RAC members and several ECHA staff participated. The group proposed the following recommendations to RAC:

- to use the modelling data to assess adequate control of risk (for SS1 and SS2) and to consider the measurement data only as supporting information (for SS1);
- to assess adequate control for each site separately in SS1. The reason being that the applicant provided detailed scenarios which are described for each production site with different operating conditions. The operating conditions in the CSR become the conditions for authorisation and critical for the adequate control;
- to simply consider all the combined exposure scenarios presented by the applicant as plausible. All combined RCRs for each sub-scenario (and for each site separately) were below 1 (Combined RCR for SS1=0.548, Combined RCR for SS2=0.469).

The RAC agreed with all the above recommendations as proposed by the ad-hoc group and presented by the Rapporteurs. The Rapporteurs were then asked to prepare the next version of the draft opinion. After RAC consultation and necessary changes in the document the RAC will be requested to adopt the draft opinion via written procedure or at the next plenary.

The Chairman thanked the Rapporteurs for their work and the Committee for their participation in the discussion.

ii. Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements (DBP 2 Use 3)

Due to their extensive similarities, DBP2 use 3 was discussed together with DEHP2c use 3 of the same applicant, DEZA a.s.

The Chairman invited the RAC Rapporteurs to present the case for DBP2. The Rapporteurs informed the RAC about additional information submitted by the applicant after the trialogue in the form of updated chapters 9 (exposure assessment) and 10 (risk characterization related to combined exposure). She informed them that DBP used for Lambda sensors can be used in combination with DEHP as indicated in the revised chapter 10. The applicant provided detailed description of each production step, information about PPE and workers training, and information that workers do combined tasks during the 8h shifts.

The Rapporteurs then presented the exposure and risk assessment for all exposure scenarios and sub-scenarios.

Exposure scenario 1: "Use of DBP in the production of lambda sensors"

- Sub Scenario 1 :"Production of casted zirconia (solvent based) tapes"
- Sub scenario 2: "Production of Lambda sensors"

Concerning exposure of man via the environment, the Rapporteurs proposed that even using worst-case assumptions, no relevant emissions would be expected. As exposure is adequately described and the environmental RCRs are < 1, RAC considered that exposure and risk for man via the environment are considered to be negligible.

With regards to worker exposure, the Rapporteurs evaluated the applicant's information on which tasks were performed by the same workers and informed RAC about the

appropriate combination of RCRs for those tasks. The highest combined RCRs (inhalation and dermal route) were 0.63 for SS1 and 0.45 for SS2.

Exposure scenario 2: "Use of DBP in manufacture of Multi-Layer Ceramic Capacitors" (MLCC)

No environmental exposure scenario for this use was provided by the applicant. Therefore, the Rapporteurs proposed to consider ES1-ERC 4 for the manufacture of Lambda sensor elements as representative also for the production of capacitors (Similar processes as Exposure Scenario 1). The exposure and risk for man via the environment are considered to be negligible by the RAC.

For worker exposure the applicant and the Rapporteurs followed the same approach and assessed the combined exposure and risk for the tasks performed by the same workers. The highest combined RCRs (inhalation and dermal route) is 0.496. The Rapporteurs recommended that the tasks/activities and the exposure assessment are considered to be correctly described and that the RCRs for combined exposure are below 1.

Regarding the ES1, despite the fact that authorisation for DBP and DEHP had been applied for by the same applicant in separate applications, the applicant had decided to combine the risks for DBP and DEHP in their two applications. The Secretariat clarified that since this is the case, the opinions of RAC for these two applications should consider the risks of each application separately as well as the potential for combined exposure to DBP and DEHP.

The Rapporteurs were asked to prepare the next version of the draft opinion on the above basis. After RAC consultation and any necessary changes to the document, the RAC will be requested to adopt the draft opinion either via written procedure or at the next plenary.

The Chairman thanked the Rapporteurs for their work and the Committee for their participation in the discussion.

6. Two uses of DEHP submitted by VINYLOOP FERRARA S.p.A., Stena Recycling AB and Plastic Planet srl (DEHP 4):
    i. Formulation of recycled soft PVC containing DEHP in compounds and dryblends
    ii. Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles

The Chairman invited the RAC Rapporteur to present the case and the draft opinion. The Rapporteur informed the Committee about the information provided by the applicants in CSR and pointed to the similarities with the uses i and ii of the DEHP2a, b and c applications.

After the discussion the RAC concluded that no adequate control for workers is demonstrated by the applicant but that there is adequate control for the general population for use 1 and use 2 exposure scenario (ES1 and ES2). With regard to the service-life scenarios (ES2, SL-P and SL-C) for professionals and consumers: RAC considers that the RCRs are below one. The RAC supported the views of the Rapporteur not to propose additional conditions or monitoring arrangements and also agreed that the remaining risks are not minimised. The RAC considered that due to the uncertainties in this specific case, RAC cannot quantify the human health impacts. The Committee considered that quantification approaches should be still considered in the future cases.

After discussing the alternatives, the RAC agreed that alternatives relate to different processing options of the same substance and the Committee was not able to assess whether the exposure and the risks could be reduced when using the alternatives.

Considering the foregoing, the RAC recommended a short review period to SEAC because of the general weaknesses of the exposure assessment provided by the applicants and the lack of adequate control, in case SEAC would have grounds to recommend granting the authorisation. The Rapporteur requested ECHA to reconsider certain parts of the standard opinion text in the introduction to the opinion and to inform the Rapporteur whether certain parts of the Annex could be moved to the justification document to increase clarity. The Secretariat agreed to look into these matters. After receipt of the third RAC draft opinion, the Secretariat will launch the written procedure for adoption of the RAC draft opinion by the Committee, or alternatively, it can be concluded at RAC 30.

The Chairman thanked the Rapporteur and the Authorisation team for their work on the application for authorisation.

b) Authorisation application – 1st outline RAC draft opinions (applications submitted within the November 2013 submission window)

1. The use of diarsenic trioxide submitted by Boliden Kokkola Oy (Diarsenic trioxide 1):
    i. Use of diarsenic trioxide in the purification of metal impurities from the leaching solution in the zinc electrowinning process

2. The use of diarsenic trioxide submitted by Nordenhamer Zinkhütte GmbH (Diarsenic trioxide 2):
    i. Industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electrowinning process

Due to similarities in the applications for Diarsenic trioxide 1 (Boliden Kokkola Oy) and 2 (Nordenhamer Zinkhütte GmbH), the cases were presented and discussed together. The Chairman invited the RAC Rapporteurs to present the cases and main conclusions of the first outline of the draft opinions.

The discussions were mainly on the appropriateness of the exposure estimates, both for the workers and for the general public via environment. On the worker exposure, the Rapporteurs provided information on the latest clarification by the applicants' about measured exposure values in the work place that are used for the quantification of the cancer cases. Some of the members had concerns on these values, and the RAC Rapporteurs will further check if they are appropriate. The Rapporteurs will also add some information about background exposure to the arsenic. The RAC asked the Rapporteurs to prepare summary table of exposure data for each exposure scenario with data about PPE/RPE.

With regard to exposure of man via environment, the members recognised that the modelling tool used is generally very conservative and may overestimate the exposure. The result depends largely on the input parameters used by the applicant, i.e. the octanol-water partitioning coefficient log K_{ow}. The ECHA Secretariat agreed to check the input parameters and the model.

The Rapporteurs were requested to consider the advice given in the plenary discussion and to prepare the first version of the RAC draft opinion.

The Chairman thanked the Rapporteurs for their work and the Committee for their participation in the discussion.

3. Two uses of diarsenic trioxide submitted by Linxens France (Diarsenic trioxide 3):
    i. Formulation of diarsenic trioxide into a mixture
    ii. Industrial use of diarsenic trioxide as processing aid in gold electroplating

The Chairman invited the RAC Rapporteurs to present the case and the first draft opinions. For the two uses, the Rapporteurs presented the calculations of the exposure values and lifetime cancer risks as well as an estimate of the additional cancer cases per annum.

The Rapporteurs and the Secretariat clarified that the applicant had modelled dermal exposure, but did not calculate excess cancer risk resulting from this exposure. Therefore the RAC Rapporteurs had provided this calculation. Several RAC members found the calculated excess cancer risk via the dermal route as rather high and recommended to check the exposure modelling. In their opinion this value is an overestimated as the applicant had stated that in use 1 the activity is only carried out twice per week. One of the members expressed concerns about the calculation of the annual number of the cancer cases and asked for a clarification for the use of 11.5 years (as opposed to a working lifetime) in the calculations. Some RAC members pointed out that the Committee should aim for a reasonable worst case and not the extreme worst case in evaluating the risks. Other members questioned if it is necessary for RAC to discuss the acceptability of the risk level. In their opinion RAC should estimate the number of excess cancer cases and leave it to SEAC to compare the costs.

RAC proposed to reformulate the presentation on the number of cancer cases, as the estimated excess risk level indicates that there should be no additional cancer cases due to the use of the substance.

The Chairman concluded that there is need for further scrutiny concerning the risk estimates via dermal exposure. The Rapporteurs and the Secretariat proposed to refer the issue back to the applicant and request the applicant for further clarifications on the duration of activities and for recalculations concerning dermal exposure to provide the RAC with a more realistic estimate.

The Chairman thanked the Rapporteurs for their work and the Committee for their participation in the discussion.

4. Six uses of lead sulfochromate yellow (C.I. pigment yellow 34) and lead chromate molybdate sulphate red (C.I. pigment red 104) submitted by DCC Maastricht B. V. OR (Lead chromate pigments 2):

    i. Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use
    ii. Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)

iii. Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking

iv. Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use

v. Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use

vi. Professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hotmelt road marking

The Chairman invited the RAC Rapporteurs to present the case and the first outline RAC draft opinion.

After the discussion RAC agreed that the use of the adjustment factor for solubility is not justified. RAC also agreed that the applicant did not provide sufficient justification for deviating from the reference excess lifetime lung cancer risk estimates for workers exposed via the inhalation and oral routes as agreed earlier by RAC in its note "Application for Authorisation: Establishing a Reference Dose Response Relationship for carcinogenicity of Hexavalent Chromium" (RAC/27/2013 06 Rev.1). RAC instructed the Secretariat to request the applicant to respond to the questions raised by the RAC members during the plenary discussion and any further questions posed by the co-Rapporteurs and to submit recalculated values for the worker exposure estimates via inhalatory and oral routes, using the dose-response reference values previously agreed by RAC in its note.

The Secretariat will send to the applicant additional questions prepared by the Rapporteurs in accordance with the discussion at the RAC plenary.

The Chairman thanked the Rapporteurs and the Authorisation team for their work on the application for authorisation.

c) Authorisation application - outcome of the conformity check

A short presentation was given by the Secretariat on which risks needed to be assessed when RAC evaluates a PBT substance. It was generally concluded that in evaluating an application for authorisation of a PBT substance, it is important to assess whether risk management measures to appropriately reduce the emissions have been adequately implemented. This discussion was then continued in the context of HBCDD (see below).

1. HBCDD 1

The Chairman welcomed the RAC co-Rapporteurs, the ECHA's Secretariat authorisation team, as well as the SEAC Rapporteurs (following via WebEx). He informed the Committee that the aim of this session was to agree on the outcome of the conformity check of the HBCDD1 application for authorisation, which was submitted in the May submission window by 13 applicants applying for 1 substance and 2 uses. He continued by informing the Committee that a public consultation for the application has been launched on 14 May 2014 and will end on 09 July 2014. In addition, RAC and SEAC Consultations on the application have been launched on 07 May 2014 and will end 02 July 2014.

The Chairman reminded the Committee that the purpose of the conformity check was to determine if the information required under Article 62 had been provided. Any possible quality and/or other deficiencies could be addressed at a later stage and reflected in the opinion.

The Chairman then asked the Rapporteurs to present the conformity case. The Rapporteurs gave some brief information on the application, presented the outcome of their draft conformity check and closed the presentation with general remarks on key issues that would need to be examined for this application.

Members asked the Secretariat whether the human (worker) exposure would need to be assessed or not by the Committee. The Secretariat confirmed that they would provide further information at a later date following consultation with the Commission.

Asked by members, the Secretariat informed the Committee that the Commission had confirmed that any connection to the Stockholm Convention on Persistent Organic Pollutants provisions and developments thereunder are not issues for conformity. The Secretariat will follow this issue and will inform the Committee on the expected decision of the Commission on this topic.

The Committee agreed by consensus that the application is in conformity. However, given the uncertainty with regard to the inclusion or not of human exposure in a substance listed as PBT on Annex XIV (and where the reason for assigning the T of PBT by MSC was ecotoxicity), RAC requested the Secretariat to add a specific clause under point 4.b of the Conformity Check report, stating the following:

> "*At the stage of the Conformity Check [of HBCDD] by RAC it is unclear if a human exposure assessment has to be provided and taken into consideration by RAC in the context of this application for authorisation. This issue was not considered to constitute a failure of conformity. However, pending clarification on this issue, further information related to human exposure may be requested from the applicants and taken into consideration at a later stage in the opinion-making on this application for authorisation*".

The Chairman summarised the agreement of the Committee on the possible need of further information by the applicant.

The Chairman wished the co-Rapporteurs a productive (ad)venture in the development of the first outline draft opinion, which should be received by the Secretariat by 25 August 2014. A Rapporteurs' dialogue and a Trialogue discussion with the applicants will take place in late July.

7.2 Appointment of (co-)Rapporteurs for authorisation applications (closed session)

RAC agreed on the renewed pool of Rapporteurs for the applications for authorisation process without discussion.

8. AOB

Update on Guidance activities

The Chairman informed the Committee that an update on Guidance activities was made available to the members via CIRCABC.

In closing the meeting, the Chairman thanked all the participants and the Secretariat for their patience and dedication during this week-long meeting, noting the progress made on all three processes, i.e. CLH, Restrictions and Authorisations and wishing all a pleasant summer break.

Part II. List of Attendees of the RAC-29 meeting 2-6 June 2014

RAC members	ECHA staff
BARANSKI Bogusław	ATLASON Palmi
BARRON Thomasina	BERGES Markus
BIRO Anna	BLAINEY Mark
BJORGE Christine	BOWMER Tim, Chairman
BRANISTEANU Radu	BROECKAERT Fabrice
CARVALHO João	DVORAKOVA Dana
Di PROSPERO FANGHELLA Paola	JOVER BUSTILLO Vanessa
DUNAUSKIENĖ Lina	KANELLOPOULOU Athanasia
DUNGEY Stephen	KIOKIAS Sotirios
GRUIZ Katalin	KIVELÄ Kalle
GUSTAFSON Anne-Lee	KLAUK Anja
HAKKERT Betty	KOKKOLA Leila
ILIE Mihaela	KOSK-BIENKO Joanna
JENSEN Frank	LAPENNA Silvia
KADIĶIS Normunds	LOGTMEIJER Christiaan
KAPELARI Sonja	LUDBORŽS Arnis
KORATI Safia	LUSCHÜTZKY Evita
LEINONEN Riitta	MAGGIORE Angelo
LUND Bert-Ove	MARQUEZ-CAMACHO Mercedes
MENARD Anja	MAZZOLINI Anna
PARIS Pietro	MERKOURAKIS Spyros
PASQUIER Elodie	MOSSINK Jos
PRONK Marja	MOTTET Denis
RUCKI Marian	NICOT Thierry
RUPPRICH Norbert	NYGREN Jonas
SCHLÜTER Urs	ORISPÄÄ Katja
SCHULTE Agnes	PELTOLA Jukka
SMITH Andrew	PELTOLA-THIES Johanna
SOGORB Miguel	PERAZZOLA Chiara
SOERENSEN Peter	RODRÍGUEZ IGLESIAS Pilar
STASKO Jolanta	ROGGEMAN Maarten
STOLZENBERG Hans-Christian	SADAM Diana
TADEO José Luis	SOSNOWSKI Piotr
UZOMECKAS Zilvinas	STOYANOVA Evgenia

Van der HAGEN Marianne	VAINIO Matti
VARNAI Veda Marija	VAN HAELST Anniek
VIVIER Stephanie	
	Remote participants
Invited experts	**SEAC members (Afa and restriction):**
SANTONEN Tiina	FANKHAUSER Simone
	FIORE Karine
Advisers to the RAC members	FOCK Lars
ALESSANDRELLI Maria (adviser to Paola di Prospero Fanghella)	FURLAN Janez
ESPOSITO Dania (adviser to Pietro Paris)	PALOTAI Zoltan
MURRAY Brendan (adviser to Thomasina Barron and CLH adviser for flumioxazin))	
NEUMANN Michael (adviser to Hans-Christian Stolzenberg)	**Advisers:**
NIEMELÄ Helena (adviser to Riitta Leinonen)	HERINGA Minne (adviser to Betty Hakkert)
PAPPONEN Hinni (adviser to Riitta Leinonen)	Ter BURG Wouter (adviser to Betty Hakkert)
PRUTNER Wiebke (adviser to Norbert Rupprich and CLH adviser for bupirimate)	
RISSANEN Eeva (adviser to Riitta Leinonen)	**FR dossier submitters:**
TERENDIJ Carline (adviser to Elodie Pasquier, and the dossier submitter for BPA)	CAVALIERI Luisa (ammonium salts)
TIESJEMA Birgitte (adviser to Betty Hakkert, and CLH adviser for 1,2,dichloroppropane)	LECOQ Pierre (ammonium salts)
EU Commission observers	**NL dossier submitter:**
LEFEVRE Remi (DG ENV)	BEEKMAN Martijn (NMP)
MORRIS Alick DG EMPL, SCOEL	
SCAZZOLA Roberto (DG ENTR)	**SE dossier submitters:**
STRECK Georg (DG ENTR)	IVARSSON Jenny (cadmium in artist paints)
Stakeholders observers	LESTANDER Dag (nonylphenol, cadmium in artist paints)
ANNYS Erwin, CEFIC	
BARRY Frank, ETUC	**CZ dossier submitters:**
BUONSANTE Vito, ClientEarth	SKACEL Petr (flumioxazin)
ROHDE Arlean, CONCAWE	BOUSKOVA Eva (flumioxazin)
ROMANO Dolores, EEB	
ROWE Rocky, ECPA	**DE dossier submitters:**
VEROUGSTRAETE Violaine, Eurometaux	KASSNER Franziska (tinuvin)
	STAUDE Claudia (tinuvin)

Industry experts		
KAWAMURA Satoshi (Ecpa, flumioxazin)		**Commission observers:**
NETTERSHEIM Rolf (Cefic, Chrysotile)		FERNANDES-de BARROS Mariana
ROSSBACHER Roland (Cefic, glutaraldehyde)		GARCIA-JOHN Enrique
SMOLDERS Erik (Eurometaux, cadmium in artist paints)		LUVARA Giuseppina
STRUPP Christian (Ecpa, bupirimate)		ROZWADOWSKI Jacek
Dossier submitter		**EFSA :**
KARHI Kimmo (glutaraldehyde)		PARRA MORTE Juan Manuel
Excuses		
CZERCZAK Slawomir		
LOSERT Annemarie (maternity)		
MULLOOLY Yvonne		
SPETSERIS Nikolaos		
TSITSIMPIKOU Christina		
MUNARI Tomaso (EuCheMS)		
TAYLOR Katy (ECEAEA)		

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 29 2 – 6 June 2014

(Adopted at the meeting)

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/29/2014**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-29 minutes.
3. Declarations of conflicts of interests to the Agenda	
SECR informed the Committee on outcome and recommendation of the ECHA Management Board Conflicts of Interest Advisory Committee (CoIAC) on practice of declaring a potential conflict of interest with regards to concurrent employment by an MSCA.	**SECR** to inform the MB of the outcome of the RAC discussion **SECR** to improve the documentation concerning declarations of CoI in Committee in order to increase transparency
4. Report from other ECHA bodies and activities	
4.a) Report on other ECHA bodies **SECR** presented document **RAC/29/2014/01**and document **RAC/29/2014/02.**	**SECR** to upload the document to the CIRCABC non-confidential website.
4.b) RAC work plan for all processes SECR presented the update on the 2014 work plan for RAC covering the Classification and Labelling, Restriction and Authorisation processes.	**SECR** to upload the presentation to non-confidential folder of the RAC-29 meeting on CIRCABC.
5. Harmonised classification and labelling (CLH)	
5.1. **a) Bupirimate (ISO) (remaining health hazards)** **b) 1-methyl-2-pyrrolidone (NMP)** **c) Propylene oxide** **d) Glutaraldehyde** **e) Tinuvin 123** **f) Flumioxazin (ISO)** **g) 1,2-dichloropropane (PDC)**	
5.1.a) Bupirimate (ISO) (remaining health hazards)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [agreement on Skin Sens. 1B (H317); Aquatic	**Rapporteurs** to revise the opinion in accordance with the discussions at RAC-29 and to provide it to the SECR. **SECR** to make an editorial check of the

Chronic 1 (H410), M=1; Carc. 2 (H351)]	opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1.b) 1-methyl-2-pyrrolidone (NMP)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Removal of SCL for Repr. 1B; H360D]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC-29 and to provide it to the SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1. c) Propylene oxide	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Replace Acute Tox 4* (H302) with Acute Tox 4 (H302); replace Acute Tox 4* (H332) with Acute Tox 3 (H331); replace Acute Tox 4* (H312) with Acute Tox 3 (H311) and delete Skin Irrit. 2 (H315)]	**Rapporteur** to revise the opinion in accordance with the discussions in RAC. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1. d) Glutaraldehyde	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [agreement on Acute Tox. 2 (H330); removal of asterisk (*) from Acute Tox 3 (H301), Skin Sens. 1A (H317), STOT SE 3 (H335), Aquatic Chronic 2 (H411), M=1; addition of EUH071, removal of SCLs]	**Rapporteurs** to revise the opinion in accordance with the discussions in RAC. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1. e) Tinuvin 123	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Removal of current classification for Aquatic Chronic 4; (H413)]	**Rapporteur** to revise the opinion in accordance with the discussions in RAC. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1. f) Flumioxazin (ISO)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [agreement on M=1000 for Aquatic Chronic 1; Repr.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur.

1B (H360D)]	**SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1. g) 1,2-dichloropropane (PDC)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [agreement on Carc. 1B (H350)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.2 Appointment of RAC (co-)rapporteurs for CLH dossiers	
RAC appointed the new (co-)rapporteurs for CLH dossiers.	**SECR** to upload the list of appointed (co-)rapporteurs to CIRCA BC confidential.
5.3 General and procedural CLH issues	
5.3. a) New procedures for agreement seeking	**SECR** to revise the document in accordance with the discussion in RAC **SECR** to launch written procedure for the agreement of the document.
6. Restrictions	
6.2 Restriction Annex XV dossiers	
6.2.a) Opinion Development	
1. Nonylphenol – 4th version of the draft opinion Rapporteurs presented the modified 4th version of the RAC draft opinion. RAC discussed the main changes made to the draft opinion. RAC adopted the opinion on the proposed restriction by consensus.	**Rapporteurs,** together with SECR, to make final editorial changes to the opinion as presented at RAC-29. **Rapporteurs**, together with SECR, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and CIRCABC IG.
2. 1-Methyl-2-pyrrolidone (NMP) – 4th version of the draft opinion Rapporteurs presented the modified 4th version of	**Rapporteurs,** together with SECR, to make final editorial changes to the opinion as agreed at RAC-29.

the RAC draft opinion. RAC discussed the main changes made to the draft opinion. RAC adopted the opinion on the proposed restriction by consensus.	**Rapporteurs** to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and CIRCABC IG.
3. Cadmium and its compounds in paints – 2nd version of the draft opinion Rapporteurs presented the 2nd version of the RAC draft opinion.	**Rapporteurs** to take the RAC discussion as the remaining comments arriving from the public consultation into account in the final version of the draft opinion. **SECR** to open a written procedure on the adoption of the RAC opinion after the public consultation finishes (i.e. after 17 June 2014).
4. Cadmium and its compounds in artist paints – first plenary discussions on the key issues document Rapporteurs presented the key issues document for the RAC opinion.	**Rapporteurs** to take the RAC discussion into account in the 1st version of the draft opinion (by 1 August 2014). **RAC members** to volunteer to support the rapporteurs. **SECR** to open a written commenting round on the 1st version of the draft opinion.
5. Chrysotile - first plenary discussions on the key issues document Rapporteurs presented the key issues document for the RAC opinion.	**Rapporteurs** to take the RAC discussion into account in the 1st version of the draft opinion (by 1 August 2014). **SECR** to open a written commenting round on this version.
6.2.b) Conformity check	
1. Isopropylidenediphenol (bisphenol A) - outcome of conformity check RAC agreed that the dossier conforms to the Annex XV requirements and took note of the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload on CIRCA BC. **SECR** to inform the dossier submitter on the outcome of the conformity check.

2. Ammonium salts- outcome of conformity check RAC agreed that the dossier conforms to the Annex XV requirements and took note of the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload on CIRCABC. **SECR** to inform the dossier submitter on the outcome of the conformity check.
6.3 Appointment of (co-)rapporteurs for restriction dossiers RAC agreed on the appointment of proposed (co-)rapporteurs for the methanol, DecaBDE and PFOA restriction dossiers.	
7. Authorisation	
7.1 Authorisation applications	
7.1.a) Authorisation application on phthalates – 2nd version of the RAC draft opinions (applications submitted within the August 2013 submission window)	
7. Two uses of DEHP submitted by ARKEMA FRANCE (DEHP 2a):	**<u>Conclusions:</u>** No adequate control for workers but adequate control for general population for use 1 exposure scenario (ES) 2 and use 2 ES 3. Service-life scenarios (ES3 SLP1 and SLP2, SLC1) for professional and consumers: RAC considers that RCRs are <1. **RAC** does not propose additional conditions or monitoring arrangements. **RAC** considers that remaining risks are not minimised. **RAC** considers that due to the uncertainties in this specific case, RAC should not quantify the human health impacts. **RAC** considers that quantification approaches should be still considered in future cases. **RAC** considers that alternatives appear to constitute a lower risk to consumers and workers. **RAC** considers that risks of alternatives are not adequately described. **RAC** considers that its evaluation in the 2nd draft opinion is sufficient, unless SEAC indicates that technical and economical feasible alternatives exist. **RAC** recommends a short review period to SEAC -in case authorisation is granted- because risks are not demonstrated to be minimised and because of the general weaknesses of the exposure assessment.

	<u>Actions:</u> **RAC:** to express agreement on qualitative description of human health impacts as part of the opinion text. **Co-rapporteurs** to consider the plenary discussion and to prepare the third version of the RAC draft opinions by **20 August**. **SECR** to upload to CIRCABC the third version of the RAC draft opinion and RCOM table to CIRCABC.
8. Two uses of DEHP submitted by Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna (DEHP 2b):	**<u>Conclusions:</u>** No adequate control for workers but adequate control for general population for use 1 exposure scenario (ES) 2 and use 2 ES 3. Service-life scenarios (ES3 SLP1 and SLP2, SLC1) for professional and consumers: RAC considers that RCRs are <1. **RAC** does not propose additional conditions or monitoring arrangements. **RAC** considers that remaining risks are not minimised. **RAC** considers that due to the uncertainties in this specific case, RAC should not quantify the human health impacts. **RAC** considers that quantification approaches should be still considered in future cases. **RAC** considers that alternatives appear to constitute a lower risk to consumers and workers. **RAC** considers that risks of alternatives are not adequately described. **RAC** considers that its evaluation in the 2nd draft opinion is sufficient, unless SEAC indicates that technical and economical feasible alternatives exist. **RAC** recommends a short review period to SEAC -in case authorisation is granted- because risks are not demonstrated to be minimised and because of the general weaknesses of the exposure assessment. **<u>Actions:</u>** **RAC:** to express agreement on qualitative description of human health impacts as part of the opinion text. **Co-rapporteurs** to consider the plenary discussion and to prepare the third version of the RAC draft opinions

	by **20 August**. **SECR** to upload to CIRCABC the third version of the RAC draft opinion and RCOM table to CIRCABC.
9. Three uses of DEHP submitted by DEZA a.s. (DEHP 2c): The third use of DBP submitted by DEZA a.s. (DBP 2 use 3 ES1):	**DEHP2c Uses 1 and 2:** **Conclusions:** No adequate control for workers but adequate control for general population for use 1 exposure scenario (ES) 2 and use 2 ES 3. Service-life scenarios (ES3 SLP1 and SLP2, SLC1) for professional and consumers: RAC considers that RCRs are <1. **RAC** does not propose additional conditions or monitoring arrangements. **RAC** considers that remaining risks are not minimised. **RAC** considers that due to the uncertainties in this specific case, RAC should not quantify the human health impacts. **RAC** considers that quantification approaches should be still considered in future cases. **RAC** considers that alternatives appear to constitute a lower risk to consumers and workers. **RAC** considers that risks of alternatives are not adequately described. **RAC** considers that its evaluation in the 2nd draft opinion is sufficient, unless SEAC indicates that technical and economical feasible alternatives exist. **RAC** recommends a short review period to SEAC -in case authorisation is granted- because risks are not demonstrated to be minimised and because of the general weaknesses of the exposure assessment. **Actions:** **RAC:** to express agreement on qualitative description of human health impacts as part of the opinion text. **Co-rapporteurs** to consider the plenary discussion and to prepare the third version of the RAC draft opinions by **20 August**. **SECR** to upload to CIRCABC the third version of the RAC draft opinion and RCOM table to CIRCABC.

	DEHP2c Use 3 and DBP2 use 3 ES1: **Co-rapporteurs** to consider plenary discussion and to prepare the first version of the RAC draft opinions for use 3 by **25 June**. **SECR** to upload to CIRCA BC the first version of the RAC draft opinion and to launch 28 calendar days RAC consultation on the first draft version of the RAC draft opinion. **RAC** members to provide written comments on the first version of the RAC draft opinion by **31 July**. **Co-rapporteurs** to respond to comments received from other RAC members and to send the second version of the RAC draft opinion by **20 August**. **SECR** to upload to CIRCA BC the second version of the RAC draft opinion and RCOM table by **27 August**.
10. The third use of DBP and DEHP submitted by Roxel (UK Rocket Motors) Ltd (DEHP 3):	**Rapporteurs** presented the 2nd version of the RAC draft opinion. **RAC** adopted the opinion on the application for authorisation by consensus. **SECR** to inform SEAC about adoption of the Draft Opinion **SECR** to send the Applicant the Draft Opinion (after SEAC agreement) with a request to indicate his intention to submit comments on the Draft Opinion. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman to approve the Final Opinion on behalf of RAC. **SECR** to send the Opinion to the Commission, the Member States and the Applicant. **SECR** to publish the Opinion on the ECHA website. *Option 2:* Should the Applicant wish to comment, SECR to make the Applicant's comments available on CIRCABC and to inform RAC.

	SECR to invite the co-rapporteurs to provide their views on the comments. **Co-rapporteurs** to preview the Applicant's comments and to prepare a draft version of the Final Opinion taking into account the Applicant's comments, and to send it to SECR. **SECR** to organise written commenting in RAC. **Co-rapporteurs** to revise the draft Final Opinion. **SECR** to initiate the adoption of the Final Opinion at the RAC plenary meeting or via written procedure.
11. The second use of DBP submitted by DEZA a.s. (DBP 2):	**RAC** agreed: - Not to use air monitoring data (available only for production site 2) for assessment of the adequate control of risk but as supporting information - To assess adequate control of risk for each site separately - That the risk of use 2 is adequately controlled. - No proposal for additional monitoring conditions - No recommendation for review period **Co-rapporteurs** to consider plenary discussion and to prepare the third version of the RAC draft opinions for use 2 by **25 June**. **SECR** to upload to CIRCA BC the third version of the RAC draft opinion and to launch 28 calendar days RAC consultation on the first draft version of the RAC draft opinion. **RAC** members to provide written comments on the third versions of the RAC draft opinion by **31 July**. **Co-rapporteurs** to respond to comments received from other RAC members and to send the fourth draft version of the RAC draft opinion by **20 August**. **SECR** to launch a written procedure to adopt the draft opinion.
12. Two uses of DEHP submitted by VINYLOOP FERRARA S.p.A., Stena Recycling AB and Plastic Planet srl (DEHP 4):	**<u>Conclusions:</u>** No adequate control for workers but

	adequate control for general population for use 1 and use 2 exposure scenario (ES1 and ES2). Service-life scenarios (ES2, SL-P and SL-C) for professional and consumers: RAC considers that RCRs are <1. **RAC** does not propose additional conditions or monitoring arrangements. **RAC** considers that remaining risks are not minimised. **RAC** considers that due to the uncertainties in this specific case, RAC should not quantify the human health impacts. **RAC** considers that quantification approaches should be still considered in future cases. **RAC** considers that alternatives relate to different processing options of the same substances and RAC is not able to assess whether the exposure and risk are reduced when using the alternatives. **RAC** recommends a short review period to SEAC -in case authorisation is granted- because risks are not demonstrated to be minimised and because of the general weaknesses of the exposure assessment. **Action points:** The **Rapporteur** to consider plenary discussion and to prepare the third version of the RAC draft opinions for uses 1 and 2. **SECR** to upload to CIRCABC the third version of the RAC draft opinion.
7.1.b) Authorisation application – 1st outline RAC draft opinions (applications submitted within the November 2013 submission window)	
1. The use of diarsenic trioxide submitted by Boliden Kokkola Oy (Diarsenic trioxide 1):	**RAC** recommended to **the Co-rapporteurs** to summarise worker exposure data per ES. SECR to check (EUSES) input parameters of the models. **Co-rapporteurs** to consider plenary discussion and to prepare the first version of the RAC draft opinion by **25 June**. **SECR** to upload to CIRCA BC the first version of the RAC draft opinion and to launch 28 calendar days RAC consultation on the first draft version of

	the RAC draft opinion. **RAC** members to provide written comments on the first version of the RAC draft opinion by **31 July**. **Co-rapporteurs** to respond to comments received from other RAC members and to send the second version of the RAC draft opinion by **20 August**. **SECR** to upload to CIRCA BC the second version of the RAC draft opinion and RCOM table to CIRCABC by **27 August**.
2. The use of diarsenic trioxide submitted by Nordenhamer Zinkhütte GmbH (Diarsenic trioxide 2):	**RAC** recommended to **the Co-rapporteurs** to summarise worker exposure data per ES. SECR to check (EUSES) input parameters of the models. **Co-rapporteurs** to consider plenary discussion and to prepare the first version of the RAC draft opinion by **25 June**. **SECR** to upload to CIRCA BC the first version of the RAC draft opinion and to launch 28 calendar days RAC consultation on the first draft version of the RAC draft opinion. **RAC** members to provide written comments on the first version of the RAC draft opinion by **31 July**. **Co-rapporteurs** to respond to comments received from other RAC members and to send the second version of the RAC draft opinion by **20 August**. **SECR** to upload to CIRCA BC the second version of the RAC draft opinion and RCOM table to CIRCABC by **27 August**.
3. Two uses of diarsenic trioxide submitted by Linxens France (Diarsenic trioxide 3):	**SECR** to forward the RAC requests to the applicant to reconsider the dermal exposure in both uses. **Co-rapporteurs** to consider plenary discussion and any reply given by the applicant and to prepare the second version of the RAC draft opinions by **25 June**. **SECR** to upload to CIRCA BC the second version of the RAC draft opinion

	and to launch 28 calendar days RAC consultation on the first draft version of the RAC draft opinion. **RAC** members to provide written comments on the second version of the RAC draft opinion by **31 July**. **Co-rapporteurs** to respond to comments received from other RAC members and to send the third version of the RAC draft opinion by **20 August**. **SECR** to upload to CIRCA BC the third version of the RAC draft opinion and RCOM table to CIRCABC by **27 August**.
4. Six uses of lead sulfochromate yellow (C.I. pigment yellow 34) and lead chromate molybdate sulphate red (C.I. pigment red 104) submitted by DCC Maastricht B. V. OR (Lead chromate pigments 2):	**<u>Conclusions:</u>** RAC agreed that the use of the adjustment factor for solubility is not justified. RAC agreed that the applicant did not provide sufficient justification for deviating from the reference excess lifetime lung cancer risk estimates for workers exposed via the inhalation and oral routes agreed earlier by RAC in its note "Application for Authorisation: Establishing a Reference Dose Response Relationship for carcinogenicity of Hexavalent Chromium" (RAC/27/2013 06 Rev.1). Furthermore RAC requested that the calculation be carried out in a specific manner. RAC instructed the Secretariat to request the applicant to respond to the questions raised by the RAC members during the plenary discussion and any further questions posed by the co-rapporteurs and to submit recalculated values for the workers exposure estimates via inhalatory and oral routes, using the dose-response reference values previously agreed by RAC in its note "Application for Authorisation: Establishing a Reference Dose Response Relationship for carcinogenicity of Hexavalent Chromium" (RAC/27/2013 06 Rev.1). **<u>Action points:</u>** **Co-rapporteurs** to consider plenary discussion and to prepare set of the questions to the applicant by **13 June**. **SECR** to send co-rapporteurs'

	questions to the applicant. **Co-rapporteurs** to draft first version of the draft opinion, considering the discussion at the plenary meeting and the answers provided by the applicant by **21 July.** **SECR** to upload to CIRCABC the first versions of the RAC draft opinions and to launch 28 calendar days RAC consultation on the first draft versions of the RAC draft opinions.
7.1.c) Authorisation application - outcome of the conformity check	
1. HBCDD 1 RAC agreed on the conformity of the application	**Rapporteurs/SECR** to finalise conformity report, adding a statement that the relevance of human health exposure assessment with regard to this application was noted by the Committee but is unclear at the moment and will be further investigated. Pending clarifications on this issue, some questions related to human health exposure might be asked to the applicants and taken into consideration at a later stage in the opinion-making process. **SECR** to upload to CIRCA BC the adopted Conformity Report. **SECR** to inform SEAC about the outcome of the Conformity check. **SECR** to send the updated Conformity Report to the Applicant.
7.2 Appointment of (co-)rapporteurs for authorisation applications RAC agreed on the updated pool of Rapporteurs for the applications for authorisation.	**SECR** to upload the pool of Rapporteurs to CIRCABC restricted.
8. AOB	
9. Action points and main conclusions of RAC-29	**SECR** to upload the adopted action points to CIRCA BC.

Bupirimate (ISO); 5-butyl-2-ethylamino-6-methylpyrimidin-4-yl dimethylsulphamate

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	612-288-00-0	bupirimate(ISO); 5-butyl-2-ethylamino-6-methylpyrimidin-4-yl dimethylsulphamate	255-391-2	41483-43-6	**Add** Carc. 2 Skin Sens. 1B Aquatic Chronic 1	**Add** H351 H317 H410	**Add** GHS08 GHS07 GHS09 Wng	**Add** H351 H317 H410		M= 1	
RAC opinion					**Carc. 2** **Skin Sens. 1B** **Aquatic Chronic 1**	**H351** **H317** **H410**	**GHS08** **GHS07** **GHS09** **Wng**	**H351** **H317** **H410**		**M= 1**	
Resulting Annex VI entry if agreed by COM					Carc. 2 Skin Sens. 1B Aquatic Chronic 1	H351 H317 H410	GHS08 GHS07 GHS09 Wng	H351 H317 H410		M=1	

Flumioxazin (ISO); 2-[7-fluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Entry	613-166-00-x	flumioxazin (ISO); 2-[7-fluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione	-	103361-09-7	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360D*** H400 H410	GHS08 GHS09 Dgr	H360D*** H410		M=1000	
Dossier submitters proposal	613-166-00-x	flumioxazin (ISO); 2-[7-fluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione	-	103361-09-7	**Remove** Repr. 1B	**Remove** H360D***	**Remove** GHS08 **Modify:** Wng	**Remove** H360D***		**Add** M (chronic) = 1000	
RAC opinion					**Repr. 1B**	**H360D**	**GHS08** **Dgr**	**H360D**		**M (chronic) =1000**	
Resulting Annex VI entry if agreed by COM					Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360D	GHS08 GHS09 Dgr	H360D H410		M=1000 M=1000	

1,2-dichloropropane

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram ,Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Entry	602-020-00-0	1,2-dichloropropane; propylene dichloride	201-152-2	78-87-5	Flam. Liq. 2 Acute Tox. 4 * Acute Tox. 4 *	H225 H302 H332	GHS02 GHS07 Dgr	H225 H302 H332			
Dossier submitters proposal	602-020-00-0	1,2-dichloropropane; propylene dichloride	201-152-2	78-87-5	**Add** Carc. 2	**Add** H351	**Add** GHS08	**Add** H351			
RAC opinion					**Carc. 1B**	**H350**	**GHS08**	**H350**			
Resulting Annex VI entry if agreed by COM					Flam. Liq. 2 Carc. 1B Acute Tox. 4 * Acute Tox. 4 *	H225 H350 H302 H332	GHS02 GHS08 GHS07 Dgr	H225 H350 H302 H332			

Propylene oxide

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram,Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Entry	603-055-00-4	propylene oxide; 1,2-epoxypropane; methyloxirane	200-879-2	75-56-9	Flam. Liq. 1 Carc. 1B Muta. 1B Acute Tox. 4* Acute Tox. 4* Acute Tox. 4* STOT SE 3 Skin Irrit. 2 Eye Irrit. 2	H224 H350 H340 H302 H312 H332 H335 H315 H319	GHS02 GHS08 GHS07 Dgr	H224 H350 H340 H302 H312 H332 H335 H315 H319			
Dossier submitters proposal	603-055-00-4	propylene oxide; 1,2-epoxypropane; methyloxirane	200-879-2	75-56-9	**Remove** Skin Irrit. 2. **Modify** Acute Tox. 4 (oral) Acute Tox. 3 (dermal) Acute Tox. 3 (inhalation)	**Remove** H315 **Modify** H311 H331		**Remove** H315 **Modify** H311 H331			
RAC opinion					**Acute Tox. 4** (oral) **Acute Tox. 3** (dermal) **Acute Tox. 3** (inhalation) ~~Skin Irrit. 2~~	**H311** **H331** ~~H315~~		**H311** **H331** ~~H315~~			
Resulting Annex VI entry if agreed					Flam. Liq. 1 Carc. 1B Muta. 1B Acute Tox. 4	H224 H350 H340 H302		H224 H350 H340 H331			

by COM					Acute Tox. 3 Acute Tox. 3 STOT SE 3 Eye Irrit. 2	H311 H331 H335 H319		H311 H302 H335 H319			

Tinuvin 123; reaction mass of bis(2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-1,10-decanedioate and 1,8-bis[(2,2,6,6-tetramethyl-4-((2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-decan-1,10-dioyl)piperidin-1-yl)oxy]octane

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-331-00-5	reaction mass of bis(2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-1,10-decanedioate and 1,8-bis[(2,2,6,6-tetramethyl-4-((2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-decan-1,10-dioyl)piperidin-1-yl)oxy]octane	406-750-9	129757-67-1	Aquatic Chronic 4	H413		H413			
Dossier submitters proposal	607-331-00-5	reaction mass of bis(2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-1,10-decanedioate and 1,8-bis[(2,2,6,6-tetramethyl-4-((2,2,6,6-tetramethyl-1-octyloxypiperidin-4-yl)-decan-1,10-	406-750-9	129757-67-1	**Remove** Aquatic Chronic 4	**Remove** H413		**Remove** H413			
RAC opinion					~~Aquatic Chronic 4~~	~~H413~~		~~H413~~			
Resulting Annex VI entry if agreed by COM					-	-	-	-	-	-	-

		dioyl)piperidin-1-yl)oxy]octane									

Glutaraldehyde; 1,5-pentanedial

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	605-022-00-X	glutaral; glutaraldehyde; 1,5-pentanedial	203-856-5	111-30-8	Acute Tox. 3 * Acute Tox. 3 * Skin Corr. 1B Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1	H301 H331 H314 H334 H317 H400	GHS06 GHS05 GHS08 GHS09 Dgr	H301 H331 H314 H334 H317 H400		* Skin Corr. 1B; H314: C ≥ 10% Skin Irrit. 2; H315: 0,5% ≤ C < 10% Eye Dam. 1; H318: 2% ≤ C < 10% Eye Irrit. 2; H319: 0,5% ≤ C < 2% STOT SE 3; H335: C ≥ 0,5% Skin Sens. 1; H317: C ≥ 0,5%	
Dossier submitters proposal	605-022-00-X	glutaral; glutaraldehyde; 1,5-pentanedial	203-856-5	111-30-8	**Add** STOT SE 3 Aquatic Chronic 2 **Modify**	**Add** H335 H411 **Modify**		**Remove** H400 **Add** H335	**Add** EUH071	**Add** M(acute) = 10 **Remove** Skin Sens.	

					Acute Tox. 3 (oral) Acute Tox. 1 (inhalation) Skin Sens. 1A	H330		H410 **Modify** H330		1; H317: C ≥ 0,5% **Modify** STOT SE 3; H335: C ≥ 0,00005%	
RAC opinion					**Acute Tox. 3 (oral)** **Acute Tox. 2 (inhalation)** **Skin Sens. 1A** **STOT SE 3** **Aquatic Chronic 2**	**H330** **H335** **H411**		~~H400~~ **H330** **H335** **H410**	**EUH071**	**STOT SE 3; H335: C ≥ 0,5%** **M(acute) = 1** ~~Skin Sens. 1; H317: C ≥ 0,5%~~ ~~Skin Corr. 1B; H314: C ≥ 10%~~ ~~Skin Irrit. 2; H315: 0,5% ≤ C < 10%~~ ~~Eye Dam. ; H318: 2% ≤ C < 10%~~ ~~Eye Irrit. 2; H319: 0,5% ≤ C < 2%~~	
Resulting Annex VI entry if agreed by COM					Acute Tox. 3 Acute Tox. 2 Skin Corr. 1B Resp. Sens. 1 Skin Sens. 1A STOT SE 3 Aquatic Acute 1	H301 H330 H314 H334 H317 H335 H400	GHS06 GHS05 GHS08 GHS09 Dgr	H301 H330 H314 H334 H317 H335 H410	EUH071	STOT SE 3; H335: C ≥ 0,5% M=1	

					Aquatic Chronic 2	H411					

1-methyl-2-pyrrolidone (NMP)

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	606-021-00-7	*N*-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	212-828-1	872-50-4	Repr. 1B STOT SE 3 Skin Irrit. 2 Eye Irrit. 2	H360D*** H335 H315 H319	GHS08 GHS07 Dgr	H360D*** H335 H315 H319		Repr. 1B; H360D: C ≥ 5% STOT SE 3; H335: C ≥ 10%	
Dossier submitters proposal	606-021-00-7	*N*-methyl-2-pyrrolidone; 1-methyl-2-pyrrolidone	212-828-1	872-50-4	**Remove** SCL for Repr. 1B (H360D)					**Remove** SCL for Repr. 1B; H360D	
RAC opinion										~~Repr. 1B; H360D: C ≥ 5%~~	
Resulting Annex VI entry if agreed by COM					Repr. 1B STOT SE 3 Skin Irrit. 2 Eye Irrit. 2	H360D*** H335 H315 H319	GHS08 GHS07 Dgr	H360D*** H335 H315 H319		STOT SE 3; H335: C ≥ 10%	

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-29 meeting

ANNEX II List of documents submitted to the members of the Committee for Risk Assessment for the RAC-29 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-29 meeting

ANNEX IV Administrative issues and information items

ANNEX I (RAC-29)

2 June 2014
RAC/A/29/2014

Final Agenda
29th meeting of the Committee for Risk Assessment

2-6 June 2014

ECHA Conference Centre (Annankatu 18, Helsinki)

2 June: starts at 9:00
6 June: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/29/2014
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Report from other ECHA bodies and activities

a) Report on RAC 28 action points, written procedures and other ECHA bodies

RAC/29/2014/01
RAC/29/2014/02 (room document)
For information

b) RAC workplan for all processes

For information

Item 5 – Harmonised classification and labelling (CLH)

5.1 CLH dossiers

h) Bupirimate (ISO) (remaining health hazards)

i) 1-methyl-2-pyrrolidone (NMP)

j) Propylene oxide

k) Glutaraldehyde

l) Tinuvin 123

m) Flumioxazin (ISO)

n) 1,2,dichloropropane (PDC)

For discussion/adoption

5.2 Appointment of RAC (co-)rapporteurs for CLH dossiers

RAC/29/2014/03 (restricted room document)
For agreement

5.3 General and procedural CLH issues

a) New procedures for agreement seeking

RAC/29/2014/04
For information/agreement

Item 6 – Restrictions

6.1 General restriction issues

a) Review of the restriction process:
Update from Task Force

For information

6.2 Restriction Annex XV dossiers

a) Opinion development

1) Nonylphenol – 4th version of the draft opinion

For adoption

2) 1-Methyl-2-pyrrolidone (NMP) – 4th version of the draft opinion

For adoption

3) Cadmium and its compounds in paints – 2nd version of the draft opinion

For discussion

4) Cadmium and its compounds in artist paints – first plenary discussions on the key issues document

For discussion

5) Chrysotile - first plenary discussions on the key issues document

For discussion

b) Conformity check

1) Isopropylidenediphenol (Bisphenol A) – outcome of conformity check

For agreement

2) Ammonium salts - outcome of the conformity check

For agreement

6.3 Appointment of (co-)rapporteurs for restriction dossiers

RAC/29/2014/05 (restricted document)
For agreement

Item 7 – Authorisation

7.1 Authorisation applications

a) Authorisation application on phthalates – 2nd version of the RAC draft opinions (applications submitted within the August 2013 submission window)

1. Two uses of DEHP submitted by ARKEMA FRANCE (DEHP 2a):

iii. Formulation of DEHP in compounds, dry-blends and Plastisol formulations

iv. Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles

For discussion/agreement

2. Two uses of DEHP submitted by Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna (DEHP 2b):

iii. Formulation of DEHP in compounds, dry-blends and Plastisol formulations

iv. Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles

For discussion/agreement

3. Three uses of DEHP submitted by DEZA a.s. (DEHP 2c):

   iv. Formulation of DEHP in compounds, dry-blends and Plastisol formulations

   v. Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles

   vi. Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

   For discussion/agreement

4. The third use of DBP and DEHP submitted by Roxel (UK Rocket Motors) Ltd (DEHP 3):

   ii. Industrial use of DBP within a specialty paint in manufacture of motors for rockets and tactical missiles

   For discussion/agreement

5. The second and the third uses of DBP submitted by DEZA a.s. (DBP 2):

   iii. Use in propellants

   iv. Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

   For discussion/agreement

6. Two uses of DEHP submitted by VINYLOOP FERRARA S.p.A., Stena Recycling AB and Plastic Planet srl (DEHP 4):

   iii. Formulation of recycled soft PVC containing DEHP in compounds and dryblends

   iv. Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles

   For discussion/agreement

b) Authorisation application – 1st outline RAC draft opinions (applications submitted within the November 2013 submission window)

1. The use of diarsenic trioxide submitted by Boliden Kokkola Oy (Diarsenic trioxide 1):

   i. Use of diarsenic trioxide in the purification of metal impurities from the leaching solution in the zinc electrowinning process

   For discussion

2. The use of diarsenic trioxide submitted by Nordenhamer Zinkhütte GmbH (Diarsenic trioxide 2):

   i. Industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electrowinning process

   For discussion

3. Two uses of diarsenic trioxide submitted by Linxens France (Diarsenic trioxide 3):

    i. Formulation of diarsenic trioxide into a mixture
    ii. Industrial use of diarsenic trioxide as processing aid in gold electroplating

For discussion/agreement

4. Six uses of lead sulfochromate yellow (C.I. pigment yellow 34) and lead chromate molybdate sulphate red (C.I. pigment red 104) submitted by DCC Maastricht B. V. OR (Lead chromate pigments 2):

    i. Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use
    ii. Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)
    iii. Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking
    iv. Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use
    v. Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use
    vi. Professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hotmelt road marking

For discussion

c) Authorisation application - outcome of the conformity check

1. HBCDD 1

For agreement

7.2 Appointment of (co-)rapporteurs for authorisation applications (closed session)

RAC/29/2014/06 (restricted room document)
For agreement

Item 8 – AOB

Item 9 – Action points and main conclusions of RAC-29

Table with Conclusions and Action points from RAC-29

For adoption

ANNEX II (RAC-29)

Documents submitted to the members of the Committee for Risk Assessment for the RAC-29 meeting.

Document number	**Title**
RAC/A/29/2014	Final Draft Agenda
RAC/29/2014/01	Report from other ECHA bodies and activities
RAC/29/2014/02 Room document	Administrative document
RAC/29/2014/03 Room document Restricted	Appointment of RAC (co-) Rapporteurs for CLH dossiers
RAC/29/2014/04	New procedures for agreement seeking
RAC/29/2014/05 Room document Restricted	Appointment of (co-) Rapporteurs for restriction dossiers
RAC/29/2014/06 Room document Restricted	Appointment of (co-) Rapporteurs for authorisation applications

ANNEX III (RAC-29)

The following participants declared potential conflicts of interest with the agenda items (according to Art 9 (2) of RAC RoPs)

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
ALREADY DECLARED AT RAC 27 and/or 28		
CLH: Bupirimate (ISO) (NL)	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Marja PRONK	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Flumioxazin (ISO) (CZ)	Marian RUCKI	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR: Nonylphenol (SE)	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Anne-Lee GUSTAFSSON	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR: 1-Methyl-2-pyrrolidone (NMP) (NL)	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Marja PRONK	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR: Cadmium in Artist paints (SE)	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Anne-Lee GUSTAFSSON	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

New dossiers

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
NEW		
CLH: 1-methyl-2-pyrrolidone (NMP) (NL)	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Marja PRONK	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Propylene oxide (NL)	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Marja PRONK	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Glutaraldehyde (FI)	Riitta LEINONEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR: Ammonium salts (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR: Bisphenol A (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

RAC invited expert

AP/Dossier / DS	RAC member adviser	Reason for potential CoI / Working for
RESTR: Bisphenol A	Tiina SANTONEN	Being involved in a study on BPA performed by her employer

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