RAC/M/42/2017
Final
27 November 2017

Minutes of the 42nd Meeting of the Committee for Risk Assessment (RAC 42)

18 September starting at 09.00
22 September ending at 13.00

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 42nd meeting of the Committee for Risk Assessment. Apologies were received from four Members.

He drew attention in his opening address to a report prepared by a consultant at the request of the Commission on the functioning of ECHA (Review of the European Chemicals Agency (ECHA) established under Regulation No. 1907/2006, Final Report[1]), which had been published earlier in 2017 and included some findings on the ECHA Committees. It referred, amongst other aspects, to the improved transparency and efficiency of the opinion forming process for Harmonised Classification and Labelling. The Commission, MSCAs and stakeholders consider overall that RAC is a well-functioning Committee delivering opinions of high scientific quality within the legal timelines. Stakeholders are also globally satisfied with the transparency and independence of RAC. The effectiveness and quality of RAC's opinions improved over the past years. However, the report considered that RAC would benefit from more diversification of expertise among its Members. Given the wide mandate of the Committee, on hazard evaluation and risk assessment including human health and environment in general, and worker protection more specifically through REACH Authorisations and more recently Occupational Exposure Limits, the Chairman considered that this comment was helpful and noted that it would be followed up by ECHA in due course.

The Chairman also informed that starting in March 2018, the Management Board of ECHA had requested the Chairmen of RAC and SEAC to provide an annual report on the state of the Committees, noting that previously this had been done on an ad hoc basis, e.g. when co-opting Members in 2015, or following requests on specific issues.

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. He added that the recordings from the 41st meeting had already been destroyed. 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 III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting (RAC/A/42/2017). The Committee agreed that the following items proposed by the Secretariat could be added to, or modified in the agenda:

- Presentation of EEB's recent report (under any other business)
- Agenda Item 8.2.B.1 on titanium dioxide

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. Eleven Members declared potential conflicts of interest, each to specific agenda items, the majority related to concurrent employment at agencies submitting dossiers

[1] http://ec.europa.eu/docsroom/documents/24301

to RAC but who had not been involved in the preparation. In the event of a vote, these Members were requested to refrain from voting on the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. Where Members declared that they had contributed to the preparation of a substance dossier for consideration by RAC, or similar potential conflict, they were asked to refrain from voting and the Chairman noted that he would consider additional mitigation measures. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

4. Appointment of (co-) rapporteurs

a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95 (3) requests and Article 77 (3) (c) requests (closed session).

The Secretariat collected the names of volunteers for rapporteurships as stated in the restricted room document RAC/42/2017/01.

The Committee agreed upon the proposed appointments of the Rapporteurs for the intentions and/or newly submitted CLH, as well as the forthcoming applications for Authorisation.

5. Report from other ECHA bodies and activities

a) Report on RAC-41 action points, written procedures and an update on other ECHA bodies

The Chairman informed the Committee that all action points from the previous meeting, RAC-41 had been completed. He explained that the usual report covering the developments in the ECHA Management Board, the Socio-Economic Assessment Committee, Member State Committee, the Forum and the Biocidal Products Committee had been compiled and distributed to RAC as a meeting document (RAC/42/2017/02). The summary of all consultations, calls for expression of interest in rapporteurships and written procedures (room document RAC/42/2017/03) is also available in the usual meeting document on S-CIRCABC (see Annex IV).

The Chairman also informed the Committee that the final minutes of RAC-41 had been adopted via written procedure and were uploaded to S-CIRCABC and are published on the ECHA website, and thanked those Members who had provided comments on the draft.

b) RAC workplan for all processes

The Chairman informed the meeting participants about the updated RAC work plan for Q4/2017 and Q1&2/2018, covering the four processes of Restriction, Authorisation, Harmonised Classification and Labelling of substances as well as the evaluation of Occupational Exposure Limits (Article 77(3)c requests). He informed Members that they could find the expected schedules for Restriction, Occupational Exposure dossiers, Authorisation dossiers in the work plan. In addition, the specific planning for each Harmonised Classification and Labelling (CLH) dossier is given in the relevant section.

c) Annual update of RAC accredited stakeholders' list

RAC discussed the Secretariat's proposal on the annual update of the Committee's list of accredited stakeholder organisations.

RAC decided to give regular stakeholder status to an occasional observer who had demonstrated continuing commitment to RAC's work, and to list one regular observer organisation as an occasional stakeholder considering that items of their interest are not discussed on a regular basis in the Committee. Two new organisations interested in the work of RAC were also added to the list as occasional observers.

The new stakeholders will be informed by the Secretariat about RAC's decision. The updated list of stakeholders was agreed by RAC. The list will be published on ECHA's website and be applied with immediate effect following the end of the RAC-42 plenary meeting.

This brings the number of Regular Stakeholders to 7 and the number of Occasional Stakeholders to 65; the status will be reviewed again in 2018.

6 Requests under Article 77 (3)(c)

The Chairman informed the Committee that following a request from the Commission, with the mandate on 12 May 2017, the Executive Director had requested the Agency to prepare proposals on the evaluation of the scientific relevance of occupational exposure limits (OELs) for **nickel and its compounds, for acrylonitrile and for benzene**, which RAC would then evaluate independently and develop opinions. The aim of these opinions is to provide scientific advice in support of the Commission action on the 4th Proposal to amend Directive 2004/37/EC on the protection of workers from the risk related to exposure to carcinogens and mutagens at work (CMD). This advice must include a recommendation to be given to the Advisory Committee on Safety and Health at Work (ACSH) in line with the relevant OSH legislative procedures and in the format used by SCOEL in drafting its opinion. The Chairman reminded the participants that the deadline for forwarding the RAC-opinions to the Commission is 26 March 2018.

He noted the progress made over the summer by ECHA staff in drafting the proposals and thanked them for their valuable contribution. He pointed out that at this meeting the Committee would be asked to adopt an interim working procedure to make the roles and responsibilities of ECHA and RAC clear as well as the procedural steps to complete the task (see next item).

6.1 General issues

a) Interim working procedure on the evaluation of occupational exposure limits and other values in support of CMD

The Chairman informed the meeting participants that in order to process the three requested CMD opinions on nickel and its compounds, acrylonitrile and benzene as efficiently as possible in Committee, the Secretariat had drafted an interim working procedure. Based largely on the RAC working procedure on evaluating restriction dossiers, this is intended to help Members and particularly the teams of Rapporteurs to anticipate the key events and milestones in the process. The Chairman mentioned that key aspects for Members to consider in the discussion are the separation between the responsibilities of the Secretariat in drafting the proposal and of RAC in evaluating it and forming its opinion, as well as the timing and extent of the Public Consultation.

With regards to terminology, the Chairman advised RAC to use the SCOEL definition of a **'practical threshold'**[2] based on mode-of-action considerations, rather than any other term, as it would be more easily understood by DG EMPL and its Committees in their decision-making. He noted that at the 23 August 2017 meeting of the ECHA/RAC – SCOEL Joint Task Force, it was

[2] Note by the Secretariat: The ECHA/RAC – SCOEL Joint Task Force has since recommended that the term "***mode of action- based threshold***" be used.

agreed that where practical thresholds were deemed appropriate based on the scientific data, then the residual risk and the uncertainties would need to be described.

RAC discussed and agreed with the interim working procedure with some suggested additions. The Secretariat will publish the agreed working procedure on the ECHA website.

6.2 Occupational exposure limits (OEL) - opinion development

The Chairman then introduced the three items on the evaluation of the scientific relevance of occupational exposure limits (OELs) for **nickel and its compounds, acrylonitrile and benzene**.

a) Nickel and its compounds

The Chairman welcomed the industry expert accompanying a regular stakeholder observer.

The ECHA drafting team had provided an early version of the ECHA proposal ('background document') for the Rapporteurs to work on. The first draft opinion prepared by the Rapporteurs on nickel and its compounds was made available to RAC Members on 31 August. A first commenting round was opened until 27 September. The ECHA proposal will be made publicly available at the start of the Public Consultation, scheduled for 10 October, 2017.

The Chairman informed the Committee that the request from the European Commission refers to all nickel compounds, incl. organic and inorganic substances. He invited the Secretariat to present the draft ECHA proposal and afterwards the Rapporteurs to present their first draft RAC-opinion, which included separate OEL proposals for the inhalable and the respirable particulate fraction. A respirable OEL of 0.005 mg/m^3 is proposed for all Ni compounds including Ni metal. For the inhalable fraction an OEL of 0.02 mg/m^3 is proposed only for Ni compounds, but not for Ni metal.

The Committee supported that nickel ion (2+) levels in the cells are the main determinant of carcinogenicity. The discussion focussed on the mechanism of carcinogenicity of nickel compounds and the roles and combination of different MoAs in carcinogenicity, e.g. indirect genotoxicity and possible genotoxic consequences of inflammatory reactions triggered by intrinsic cytotoxicity.

Members commented that if available, additional information on the exposure levels (doses) at which key genotoxic events occur would need to be added to the opinion.

The industry expert informed the meeting participants on tissue-specific gene expression analyses after exposure to different nickel compounds and that the affected pathways reflected toxicity responses such as inflammation, and also mentioned an additional study considering reprotoxic effects after oral exposure.

The Committee considered in principle that a health-based OEL with a practical threshold for the carcinogenic effects of nickel metal and Ni compounds can be considered as an option depending on clarification of the mechanism of genotoxicity and carcinogenicity.

The Chairman invited the RAC Members to submit further comments within the written consultation round by 27 September 2017. The Rapporteurs should develop the revised draft RAC-opinion, taking into account the RAC-42 discussions and the results of the RAC- written commenting round. In parallel, the Secretariat should complete the draft proposal. A public consultation on the revised draft proposal will be launched in October 2017.

b) Benzene

The Chairman welcomed the industry expert accompanying a regular stakeholder observer.

The ECHA Secretariat drafting team had provided an early version of the ECHA proposal ('background document') for the Rapporteurs to work on. The first draft opinion prepared by the

Rapporteurs on benzene was made available to RAC Members on 31 August. A first commenting round was opened until 27 September. The ECHA proposal will be made available at the start of the Public Consultation, scheduled for 10 October, 2017.

The Chairman invited the Secretariat to present the draft ECHA proposal and afterwards the Rapporteurs to present their first draft RAC-opinion.

The Rapporteurs mentioned that an extensive human data base is available. Epidemiological studies of populations occupationally exposed to benzene consistently demonstrate an excess leukaemia cancer risk (see chapter 7.7 of Annex I). Various studies show induction of genotoxic effects in benzene exposed workers, however co-exposure to other genotoxic chemicals hamper the drawing of clear conclusions. Benzene is metabolised to numerous metabolites and both have been shown to exhibit direct and indirect genotoxicity in vitro and/or in vivo in animals. The major and most sensitive target organs of benzene are the bone marrow and blood system and benzene has been shown to affect virtually all blood cell types.

In addition, the Rapporteurs mentioned that the major occupational and non-occupational exposure route for benzene is via inhalation due to its high volatility. The dermal route is assumed to make a substantial contribution to total body burden, hence, air monitoring can be complemented with urinary measurements of either benzene as such or the metabolites S-phenylmercapturic acid, or possibly, trans-,trans-muconic acid. Suitable and appropriate methods are available for monitoring exposure to benzene.

The Rapporteurs presented three approaches and related uncertainties for cancer risk assessment of benzene – linear risk extrapolation, sub-linear risk extrapolation and threshold model.

1. The linear risk extrapolation:

- Cancer risk proportional to dose,
- Contribution of direct genotoxicty without threshold (Benzene or its metabolites),
- No relevant contribution of thresholded effects / non-linear contributions to cancer risk, such as haematotoxicity or indirect genotoxicity.

The Rapporteurs concluded that the critical endpoint for establishing an OEL is carcinogenicity. However, benzene is considered to be a non-threshold genotoxic carcinogen with respect to risk characterisation and while a detailed consideration of the carcinogenic mode of action, indicates that some steps may be thresholded, this still in their view, contains significant uncertainties. On the other hand, a ´derived minimal effect level´ (DMEL), as defined according ECHA guidance R.8 for non-threshold endpoints, can be established for benzene carcinogenicity, representing exposure levels where the likelihood that effects are avoided is appropriately high and considered to be of low concern from workers´ health point of view. However, the practical use of such a level in occupational health and safety would need to be further considered.

2. The sub-linear risk extrapolation:

- Contribution of direct genotoxicity in the low exposure range (Benzene or its metabolites)
- Thresholded effects adding to carcinogenicity at higher dose levels (haematotoxicity) increasing the slope factor above the NOAEL.

The Rapporteurs concluded that based on the assumption that the carcinogenicity will be potentiated above exposure levels where the haematotoxicity is observed, a sub-linear ('hockey-stick') dose-response can be envisaged, with 0.1 ppm as a break-point.

3. The threshold model:

- Indirect genotoxicity (topoisomerase inhibition, ROS) with NOAEL important and (weak) direct genotoxicity considered unlikely to contribute.

The Rapporteurs concluded that although the scientific data would not allow concluding on a threshold, a pragmatic view of the database and background exposure levels could provide arguments for setting an OEL of 0.1 ppm.

Some RAC Members expressed reservations on the available evidence to support a causal correlation between haematological effects and carcinogenicity.

One RAC Member proposed to investigate whether a factor for exposure duration might be necessary because haematotoxicity is considered to reflect effects following recent exposure.

One RAC Member also suggested to explore another approach in the second draft opinion focusing on genotoxicity and this was agreed by RAC as an additional option. The human LOAEC for chromosomal aberrations and/or numerical genome aberrations can be considered a relevant starting point. Referring to evidence for thresholded genotoxicity a reference value for human genotoxicity might be derived based on a combination of the human LOAEC for genotoxicity (aneuploidy) with adequate extrapolation factors with respect to LOAEC to NOAEC extrapolation, remaining intraspecies differences, extrapolation factor for severity of effects, and whether a factor for duration of exposure is necessary.

The industry expert indicated that it is difficult to reliably determine low benzene concentrations in air and many of the studies quoted (e.g. Lan *et al*. 2004) raise questions about the methodology, especially when it comes to airborne benzene concentrations below ~ 0.3 ppm. He also informed the meeting participants on a recent publication by Kerzic and Irons (2017)[3] that gives strong evidence not only for a threshold, but also for a different mechanism than the topoisomerase II inhibition (suggested as the likely genotoxic mechanism by DECOS). He noted that a series of papers have just been published or are in press and will be discussed at an upcoming meeting of IARC on benzene (10-17 October 2017).

The Chairman invited the RAC Members to submit further comments within the written consultation round by 27 September 2017. The Rapporteurs should develop the revised draft RAC-opinion, taking into account the RAC-42 discussions and the results of the RAC- written commenting round. In parallel, the Secretariat should complete the draft proposal. A public consultation on the revised draft proposal will be launched in October 2017.

c) Acrylonitrile

The Chairman welcomed the industry expert accompanying a regular stakeholder observer and the ECHA contractors.

A proposal for acrylonitrile had been developed by the ECHA contractor and an early version provided to RAC for its consideration. The first draft opinion on acrylonitrile was made available to RAC Members on 5 September. A first commenting round will take place until 27 September. The first draft opinion and the draft proposal are restricted documents. The ECHA proposal will be made available at the start of the Public Consultation, scheduled in October.

The Chairman invited the ECHA contractor to present their report and afterwards the Rapporteurs to present their first draft RAC-opinion.

The Rapporteurs mentioned that acrylonitrile is acutely toxic and causes neurotoxicity, local irritation of skin, eyes and respiratory tract, and skin sensitisation. Acrylonitrile is also a carcinogen for which the mode of action (MoA) is not fully understood, with a harmonised classification as Carcinogen 1B under CLP. Three possible Modes of Action (MoA) were presented for brain tumours: direct genotoxicity (from the metabolite CEO), indirect genotoxicity (from oxidative stress) and non-genotoxicity (via loss of gap junction intercellular communication) with the most consistent evidence for the involvement of oxidative stress. The MoA was

[3] Kerzic and Irons, Environmental Toxicology and Pharmacology 55 (2017), 212-216.

considered to be complex and could include multiple mechanisms, each of which could predominate at different doses. One Member stressed that many questions on the interpretation of the in vivo genotoxicity data remain. RAC Members agreed and expressed the need for additional information on the various Modes of Action, where possible, including dose response data.

The Rapporteurs clarified that rather extensive epidemiology data are available; this includes several large studies using different occupational cohorts in several different countries, plus several meta-analyses. There is little to no evidence for a causal association between acrylonitrile exposure in workers and increased cancer at a particular site (including a.o. lung, brain, bladder and prostate). The risk to humans appears therefore low considering current and past exposures in the workplace. However, increases in very rare tumours, such as those of the brain, may not easily be observed in epidemiological studies. Members discussed the weight of evidence of the largely negative carcinogenicity epidemiological data in light of the positive evidence from experimental studies. Several RAC Members expressed the need for a concise overview of epidemiology in the ECHA draft proposal, taking into account new developments.

RAC discussed the three approaches for cancer risk assessment, linear and non-linear approach for cancer effects and threshold for non-cancer effects, as presented by the Rapporteurs.

Some RAC Members mentioned that as acrylonitrile may also cause non-carcinogenic effects, it is important to compare the cancer-based limit values with a limit derived based on those other toxic effects. The three approaches appear to converge in the range of 0.05 to 0.1 ppm. RAC agreed that a further discussion on the proposed approaches for limit values, including the appropriateness of limit values for risks from non-carcinogenic effects, would need to take place at RAC-43.

The Chairman invited the RAC Members to submit further comments within the written consultation round by 27 September 2017. The Rapporteurs should develop the revised draft RAC-opinion, taking into account the RAC-42 discussions and the results of the RAC- written commenting round. The Secretariat with the support of the ECHA-contractor to complete the revised draft ECHA proposal. A public consultation on the revised draft ECHA proposal will be launched in October 2017.

7. Requests under Article 95(3)

a) Methodology related to the exposure of chemicals at the workplace in relation to non-threshold substances

The Chairman updated the meeting participants that the ECHA/RAC –SCOEL Joint Task Force met on 14 June and 23 August 2017 to discuss Task 2 on threshold, practical threshold and non-threshold approaches to defining Occupational Exposure Limits. The Joint Task Force is due to meet on 26 October again, at which time their draft report is scheduled for finalisation; the final report will then be considered by RAC at RAC-43 (and in parallel by SCOEL in their plenary meeting) with a view to endorsement.

8. Harmonised classification and labelling (CLH)

8.1 General CLH issues

There were no general CLH issues on the RAC-42 agenda

8.2 CLH dossiers

A. Hazard classes for agreement without plenary debate[4] (see section B below for hazard classes form the same substances debated in plenary)

RAC reviewed an 'A-listing' of hazard classes for a range of substances and being informed by the Secretariat of the appropriate scrutiny by Rapporteurs and commenting RAC Members in each case, agreed these without plenary debate. The details for each substance are given below in section B.

B. Substances with hazard classes for agreement in plenary session

1. Titanium dioxide

The item was removed from the agenda since the opinion was adopted by written procedure on 14 September 2017.

2. ethylene oxide, oxirane

The Chairman welcomed the expert accompanying the Cefic stakeholder observer and reported that ethylene oxide (oxirane) is mainly used for polymer production, as an intermediate and as a laboratory agent. It has an existing Annex VI entry as Flam. Gas 1; H220, Press. Gas; H280, Acute Tox. 3*; H331 (minimum classification), Skin Irrit. 2; H315, Eye Irrit. 2; H319, Muta. 1B; H340, Carc. 1B; H350, STOT SE 3; H335. The legal deadline for the adoption of an opinion is 22 February 2018.

The Dossier Submitter (AT) proposed to confirm the acute inhalation toxicity classification, to replace the skin and eye irritation classification by Skin Corr. 1B; H314, Eye Dam. 1; H318 and to add the following hazard classes: Skin Sens. 1; H317, Acute Tox. 3; H301, STOT RE 1, H372; nervous system, and Repr. 2; H361fd. Resp. Sens. and STOT SE (nervous system) was also assessed in the CLH report although no classification for these hazard classes was proposed. These hazards were open for comments during the public consultation.

The Committee concurred with the DS proposal for oral acute toxicity (Acute Tox. 3; H301), inhalation acute toxicity (Acute Tox. 3; H331), serious eye damage (Eye Dam. 1; H318, without labelling) and no classification for respiratory sensitisation via fast track.

As to specific target organ toxicity following single dose exposure (STOT SE) the Rapporteur based her argumentation for STOT RE 3; H336 on the three available studies on human and two studies on rats indicating neurological effects after single exposure. She concluded that taking into account the human data from exposure to ethylene oxide in sterilizing units and supported by observations from animal acute inhalation toxicity and one acute neurotoxicity study, the criteria for classification for specific target organ toxicity, based on transient, narcotic effects, are fulfilled. Two RAC Members did not support the classification of the substance because the symptoms described were unspecific and light in their severity. Another RAC Member noted that neurological effects are seen at lower concentrations of 300 and 500 ppm than the levels at which intoxication or lethality are observed. It points towards a conclusion that the observed neurological effects are caused by the substance. RAC agreed to classify the substance as STOT SE 3; H336. At the same time, the existing classification of STOT SE 3; H335 was retained, as the DS did not discuss this existing classification in their proposal.

[4] Following adequate scrutiny by the Rapporteur and commenting Members and taking the comments from the Public Consultation into account, selected hazard classes are proposed for agreement through a list ('fast-track') without further debate in the Committee.

The Committee agreed to classify the substance as Skin Corr. 1; H314 without sub-categorisation.

The Committee also agreed that there is no evidence of skin sensitisation in the available human and animal studies. Hence no classification for the Skin Sens. hazard class.

The RAC also agreed to classify the substance as specific target organ toxic after repeated dose exposure STOT RE 1; H372 – nervous system based on human evidence together with data from experimental animals.

In addition the Committee agreed not to classify the substance as STOT RE due to observed haematological effects, which were considered insignificant.

Regarding toxicity for reproduction the Committee discussed the observed effects on fertility. At high dose levels (>200 ppm) glutathione depletion in rats may have an impact on toxicity of the substance. However, decreases in implantations, increases in post-implantation losses and effects on spermatogenesis, sperm numbers/motility have been seen already at levels (50-100 ppm), in which no clear glutathione depletion is observed. These findings were considered relevant to humans. Since ethylene oxide is a well-established mutagen, some effects observed in one-generation studies may be mediated by a genotoxic mechanism. Especially post-implantation losses observed after exposure during the pre-mating period may be due to dominant lethal effect. Genotoxic insult during the specific stages of spermatogenesis may also affect sperm quality. This mechanism is considered relevant to humans therefore classification in the category 1B was discussed. A representative of industry observed that implantation and post-implantation losses are considered to be genetic effects, which are covered by the existing classification of Muta. 1B. One RAC Member acknowledged that it is not possible to confirm that these effects are related to mutagenic action of the substance. Therefore Repr. 1B for the effects on fertility is appropriate. Another RAC Member noted that relevance of the observed effects to humans is not fully evident therefore Repr. 2 could be more appropriate.

During the discussion on developmental toxicity the Rapporteur summarised the available evidence. Two studies (Snellings et al., 1982 and Hackett et al., 1982) demonstrate small decreases in foetal weights at 100-150 ppm. In the second study no effects on maternal weight gain at these levels were observed. At higher doses more severe findings have been found. Single high dose exposures have caused eye disorders (according to Weller et al., 1999 and Rutledge et al., 1989) at levels showing slight to severe maternal toxicity. Mutagenicity provides a plausible mechanism for malformations at high levels. Glutathione depletion at high dose levels may play a role decreasing the concern for humans. One RAC member and a representative from industry questioned whether there was sufficient data to classify the substance for developmental toxicity. Other RAC Members supported classification for the developmental effects in category 2.

The Committee agreed to classify ethylene oxide as Repr. 1B; H360Fd.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

3. ethanol, 2,2’-iminobis-, N-(C13-15-branched and linear alkyl)derivatives

The Chairman welcomed the expert accompanying the Cefic stakeholder observer and reported that ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivatives is a UVCB substance used in the manufacture of plastic products, including compounding and conversion.

It has no existing Annex VI entry. The legal deadline for the adoption of an opinion is 19 February 2018.

The Dossier Submitter (NL) proposed to classify the substance for developmental toxicity (Repr. 1B; H360D) based on developmental effects observed in an oral (gavage) pre-natal dev. tox. study in the rat (OECD 414 and GLP compliant). For fertility the DS proposed no classification.

The Committee agreed to no classification for effects on fertility and lactation due to lack of data.

For developmental toxicity, the Committee supported the DS proposal to classify the substance in category 1B based on embryonic mortality, abnormalities of the cervical vertebrae and of cranial bones, eye defects as well as increased incidence of an altered structure of the cut surface of the eye lens. These developmental toxic effects were not considered to be secondary non-specific consequences of other maternally related effects i.e. decreased food consumption and corrected maternal body weight gain during gestation (38% lower corrected body weight gain in the high dose group as compared to controls (not statistically significant), but there was no correlation between corrected body weight gain reduction and embryo-lethality in individual maternal animals).

The Industry expert informed the meeting that the substance was already withdrawn from some of their applications and that Industry intends to update the REACH registration dossiers accordingly.

RAC agreed to classify the substance as Repro. Repr. 1B; H360D.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

4. Acid Black 210 Na

The Chairman reported that Acid Black 210 Na is used in water-based formulations mainly for industrial leather dyeing. Secondary uses can be with similar processes in textile and paper formulation.

It has an existing entry in Annex VI to the CLP Regulation for serious eye damage (Eye Dam. 1; H318) and for environmental hazards (Aquatic Chronic 3; H412).

The legal deadline for the adoption of an opinion is 10 April 2018.

The DS (IT) proposed to remove the existing classifications based on new information provided in the framework of the REACH Regulation.

The Committee supported the approach taken by the Dossier Submitter in using studies with Acid Black 210 potassium salt in the evaluation of effects on the eye and for environmental fate and aquatic toxicity evaluation. RAC agreed that based on the results of the key *in vivo* study, the substance is a mild irritant causing transient colouration of the nictitating membrane in rabbits. This is also supported by two other *in vivo* studies and an *in vitro* BCOP study. However, the effects were not sufficiently marked to be considered for classification. Furthermore, the colouration of the nictitating membrane does not meet the criteria for classification, because it is part of the conjunctiva (not the cornea) in rabbits and there is no equivalent structure in the eye of humans. RAC therefore agreed to the removal of the existing classification for eye damage.

RAC supported the removal of the existing environmental classification based on the results of a new study on *Lemna sp.* which showed no toxicity to aquatic organisms along with a lack of acute effects in fish, and no chronic toxicity to *Daphnia* or algae at or below 1 mg/L (the existing

classification was based on an acute algal toxicity result, prior to the introduction of the chronic aquatic hazard criteria).

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

6. cobalt metal

The Chairman welcomed the expert accompanying the Cefic stakeholder observer and reported that cobalt has many uses including use as an intermediate and for the production of magnets, varistors, batteries, alloys and catalysts.

The substance has an existing entry in Annex VI to the CLP Regulation for skin and respiratory sensitisation (Skin Sens. 1; H317, Resp. Sens. 1; H334) and for aquatic chronic toxicity (Aquatic Chronic 4; H413). The legal deadline for the adoption of an opinion is 14 June 2018.

The DS (NL) proposed to additionally classify cobalt for carcinogenicity (Carc. 1B; H350 with an SCL of 0.01%), mutagenicity (Muta 2; H341) and for toxicity to reproduction / effects on sexual function and fertility (Repr. 1B; H360F), with no classification for developmental toxicity.

RAC noted that there are no specific animal in vivo toxicokinetic studies on cobalt metal. However, the bioavailability of cobalt metal has been demonstrated in inhalation studies. RAC also recognised that although cobalt metal seemed to be poorly soluble in water and neutral fluids, its solubility at low pH conditions (e.g. lysosomal and gastric fluids) is comparable to that of cobalt salts. Thus, where needed, it is justified to read-across data from cobalt salts when assessing toxicity of cobalt metal.

The Committee discussed the DS proposal to classify cobalt metal in category 1B for effects on fertility observed in male animals (rats and mice) exposed orally or via inhalation to Co metal or soluble Co salts. The effects observed at dose levels without marked general toxicity included decreased testis weight and epididymis weight, decreased number of spermatids and sperm, decreased sperm motility, testis atrophy, histopathologic changes in testis and epididymis and decreased fertilisation rate. One RAC Member noted that the effects e.g. on sperm motility were quite small, although consistent and among studies. The expert from industry noted that the hypoxia caused by lung toxicity, sometimes with haematological effects, could be the cause of the testis effects observed in the inhalation studies with cobalt metal. Also, the relatively low severity of the effects was the reason for IND to self-classify cobalt metal in category 2 for fertility effects. Thus, they considered the testis effects as secondary to the effects on the lung and sometimes related to haematological effects. As the effects on sperm and testis were also observed at a lower dose than effects on haematological parameters, RAC members considered them not to be secondary to haematological effects. In further discussion, it was pointed out that the studies with mortalities should not be fully disregarded but the fertility effects observed could be taken as supporting evidence. RAC considered the effects on male fertility, primarily testis toxicity to be consistent and – as observed in two species and not regarded to be a secondary non-specific consequence of other toxicity – sufficient for the classification in category 1B, which was agreed.

RAC concurred with the DS that developmental effects were observed at doses without severe maternal toxicity in some non-guideline studies with significant limitations. Contradictive results were obtained in other non-guideline and two guideline studies. RAC agreed that no classification for effects on developmental toxicity was warranted, as the available evidence is not robust enough.

RAC considered that cobalt is not directly mutagenic in mammalian or bacterial cells based on negative response in in vitro tests. However, cobalt metal and soluble cobalt salts had

consistently shown chromosomal damage as evidenced by positive results in micronucleus (MN) tests supported by Comet assay results in somatic cells *in vitro*. In addition, in vivo genotoxicity studies with intraperitoneal (i.p.) administration of cobalt salts resulted in positive responses in e.g. MN tests whereas in vivo genotoxicity studies via oral and inhalational routes were largely negative for cobalt metal, cobalt oxide and its salts. Furthermore, in a carcinogenicity study, specific gene mutations were observed in the *K-ras* gene in the lung tumours induced by cobalt sulphate. The Committee noted that induction of reactive oxygen species (ROS) and oxidative stress and impairment of DNA repair were possible mechanisms for the genotoxicity caused by cobalt.

In the discussion, some RAC members pointed out that the recent in vivo data on cobalt metal or cobalt oxide showed in general negative responses after oral and inhalational exposure, which may outweigh the positive evidence after i.p. administrations, suggesting systemic genotoxicity only at high doses. Other members could not dismiss the positive results of the i.p. studies also considering the systemic availability of cobalt as evidenced by the effects on testis in fertility studies via oral and inhalation routes of cobalt metal or cobalt salts.

RAC concluded that in spite of the recent studies showing no systemic genotoxicity via inhalation/oral exposure, it is difficult to conclude on a total lack of genotoxicity via these physiological routes of exposure.

Thus, based on the chromosomal effects of cobalt metal and its salts in vitro, the genotoxic effects observed of cobalt salts in vivo i.p. studies, the local mutations observed in lung tumours caused by inhalation of cobalt, and consideration that the cobalt ion is the ultimate genotoxic species, RAC concluded that cobalt metal warrants classification as Muta 2.

RAC supported the DS proposal to classify cobalt metal in category 1B for carcinogenicity based on animal data (rats and mice) showing clear dose related increases in lung tumours (alveolar adenomas and carcinomas) in both species and in both sexes after inhalation of cobalt metal. There were no carcinogenicity data for other routes of exposure to cobalt or cobalt compounds. Considering that cobalt has been shown to be absorbed from the lungs and is likely also absorbed from the gastrointestinal tract and that systemic carcinogenicity (adrenal pheocromocytomas, and pancreatic islet tumours) were observed in rats after inhalation of cobalt metal, RAC concluded that carcinogenicity cannot be excluded after exposure via other routes and thus no specification of the route of exposure was justified.

After some discussion RAC supported the DS proposal for setting a specific concentration limit (SCL) of 0.01 % for carcinogenicity for cobalt metal by applying an estimated T25 value of 0.1 mg/kg bw/day, which is below the limit of 1 mg/kg bw/day for high potency carcinogens according to the guidance on the T25 method[5]. It was noted that the T25 value was not near the limit and no elements that could decrease the concern for high potency were found, also considering the available human data. According to the IND expert the T25 method5 was specifically developed for non-threshold carcinogens and that the database on which the model is based should be updated.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

6. metaldehyde

[5] Simplified carcinogenic potency index; (EC) 1999; Guidelines for setting specific concentration limits for carcinogens in Annex I of directive 67/548/EEC. Inclusion of potency considerations. Commission working group on the classification and labelling of dangerous substances

The Chairman welcomed the experts accompanying the ECPA stakeholder observer and reported that Metaldehyde (ISO) is a molluscicide for the control of slugs and snails. It has an existing Annex VI entry as Flam. Sol. 2 (H228) and Acute Tox. 4 (H302). The legal deadline for the adoption of an opinion is 15 December 2017.

The Dossier Submitter (AT) proposed to retain classification as Flam. Sol. 2 (H228), to modify acute oral toxicity to Acute Tox. 3 (H301) and to add specific target organ toxicity after repeated dose exposure as STOT RE 2; H373 oral. Other hazard classes were also assessed in the CLH report although no classification for them were proposed. All the hazard classes were open for comments during the public consultation. Following comments on the environmental hazards, the DS agreed that classification as Aquatic Chronic 3; H412 could be more appropriate than the originally proposed no classification.

The Committee concurred with the DS proposal for oral acute toxicity (Acute Tox. 3; H301) and no classification for dermal and inhalation acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT SE, germ cell mutagenicity and toxicity to reproduction – developmental toxicity via fast track.

As to toxicity reproduction – fertility, two RAC members acknowledged severity of the observed effects on testis in dogs. Another RAC member was of the view that interspecies differences should be considered and that the observed effects might be of no relevance to humans. This view was supported by the Rapporteur reminding the Committee that the non-metabolised part of metaldehyde in the urine of dogs is 80 %, while in mice it is 1 %. The RAC members concluded that metaldehyde-related testis toxicity in dogs was observed also at doses without systemic toxicity. The Committee agreed by consensus to classify the substance due to its observed effects on fertility observed in dogs as category 2 reproductive toxicant (Repr. 2; H361f).

Regarding specific target organ toxicity after repeated dose exposure the RAC Members agreed that the observed effects on testis were considered being the effects observed due to reprotoxicity of metaldehyde. The Committee agreed by consensus on no additional classification for STOT RE hazard class for the substance.

Regarding carcinogenicity the Rapporteur presented the following evidence: there was a slight increase of liver adenomas and of liver adenomas and carcinomas in female rats, a slight (not statistically significant) increase of liver carcinomas in male rats, a slight increase of liver adenomas in male mice, where the incidence was slightly higher at 300 ppm vs. 1,000 ppm, common tumour in male CD-1 mice; there was uncertainty as to whether the slight increases of liver adenomas in male mice were treatment-related; there was no progression to carcinomas, no pre-neoplastic lesions, and no indication on mutagenicity. This analysis had been supported by three RAC members during the RAC consultation prior to the RAC plenary meeting. In order to evaluate the relevance of findings in mice two RAC members suggested to examine historical control data. Historical control data from EFSA showed a rather limited data base of data about 120 mice males and 120 mice females. In 120 males 1 to 7 adenomas and 0 to 1 carcinoma had been identified. In 120 females 0 to 6 adenomas and 0 carcinomas had been identified. One RAC member suggested that this evidence does not provide certainty whether the observed effects were treatment-related, since the dose for male rats of 50 ppm is low. Another RAC Member questioned the reliability of the rat study (Gill and Wagner, 1992) due to substantial differences in initial liver histopathological examination vs. peer reviewed examination.

RAC agreed in the meeting by majority not to classify metaldehyde for the carcinogenicity hazard class. Three RAC members reserved their positions at that time depending on the final opinion text (see further below).

During the discussion on Aquatic Chronic toxicity hazard class the Secretariat informed the Committee that on 31 August 2017 the Secretariat received a letter from industry about a new

chronic toxicity fish study (23 December 2016) on metaldehyde. The Secretariat requested the full study report which was duly provided by Industry along with a non-confidential robust study summary. The study report was made available to RAC Members who considered the it to be reliable and suitable for inclusion in the dossier It was pointed out by the Secretariat that that it was not part of normal procedure to accept such late information. However, as the study was recent and valid, for the sake of completeness, it was on this occasion allowed into the process.

During the further discussion the RAC Rapporteurs proposed to consider a mollusc study using pond snails. The Committee provided the following argumentation:

- In the case of metaldehyde, acute toxicity tests have shown that molluscs – the target organisms for this pesticide - are next to fish the most sensitive taxonomic group based on an immobility endpoint. However, in this dossier, adequate chronic toxicity data for molluscs is absent.

- In the case of metaldehyde a weight of evidence approach was therefore taken in which all information in addition to the standard dataset is taken into account for a full description of the aquatic hazard of metaldehyde.

- Acute aquatic toxicity of metaldehyde in molluscs (Egeler *et al.*, 2007) should be taken into account for the chronic classification via the surrogate method.

- In agreement with comments made during the public consultation, RAC disagreed with the original conclusions of the Egeler *et al*. (2007) study with regards to the endpoint used and the result achieved. Subsequently, RAC reassessed the study and derived a 48h EC_{50} of 78.2 mg/L based on immobility.

- The surrogate approach, taking into account that the substance is not rapidly degradable and the pond snail 48 h EC_{50} (immobility) is 78.2 mg/L, results in a classification of the substance as Aquatic Chronic 3; H412.

Several RAC Members expressed support for the Rapporteurs' proposal to classify the substance as Aquatic Chronic 3; H412. One RAC Member acknowledged the validity of the study (Egeler *et al.*, 2007) but thought it should not be used for classification. It was pointed out that it was considered valid by the dossier submitter and also under the PPP Regulation. RAC agreed on the classification of the substance as Aquatic Chronic 3; H412.

The Chairman noted that once the revised draft opinion became available, the three members that reserved a position on the carcinogenicity hazard class would be invited to submit their minority positions in writing within a set deadline – should no written minority positions be received by the Secretariat by that deadline, then it would be assumed that they had withdrawn their reservations and the adoption would revert to 'by consensus'.

RAC then agreed the opinion by **majority[6],** pending the response of those with a declared minority position.

The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

7. halosulfuron-methyl (ISO)

[6] As no minority positions were received within the deadline set by the Secretariat, the opinion was adopted by **consensus**.

The Chairman reported that Halosulfuron-methyl (ISO) has currently no Annex VI entry. The legal deadline for the adoption of an opinion is 12 January 2018.

The Dossier Submitter (IT) proposed to add the following classifications: Aquatic Acute 1 (H400) Acute M-factor of 1000; Aquatic Chronic 1 (H410) Chronic M-factor of 1000. The Rapporteurs' proposal was to add Repr. 2; H361d concurring with EFSA's evaluation of this substance.

RAC agreed with the proposed classification for aquatic toxicity via a fast-track procedure, and with no classification for all human health endpoints except reproductive toxicity.

In the plenary, with regards to toxicity to reproduction, RAC discussed the three available studies on reproductive toxicity; a two-generation study in rats and a developmental toxicity study in rats and in rabbits. Committee agreed with the DS and Rapporteurs that the evidence did not meet the classification criteria for adverse effects on sexual function and fertility or for effects on or via lactation.

The Rapporteurs considered that there was sufficient evidence of a substance-mediated adverse effect on development and proposed classification in category 2 based on statistically significant reduction in rat foetal body weight as compared to controls, extensive and widespread increase in rat skeletal variations, evidence of increased rat external, skeletal and visceral malformations and rabbit skeletal malformations, increase in rat and rabbit early resorptions and post-implantation loss and reduction in rabbit live litter size. The developmental effects occurred only at the top dose at which the co-occurring maternal toxicity was considered minimal by the Rapporteurs. Some RAC Members supported the Rapporteurs' proposal for classification because the effects were observed at the top dose, there was co-occurring maternal toxicity and the incidences for developmental toxicity were considered low. IND commented that maternal toxicity was interacting with aspects of gestational physiology, and that it was significant at high doses as marked reduction of bodyweight gain during the period of early embryo implantation and early development in rats and Rabbits. This was observed also in the 28 day rat study. They considered the effect on fetal weight to be secondary to maternal toxicity. Regarding the malformations, IND observed that the forked/fused ribs were considered as minor abnormalities when these were found in isolation without vertebrae/spine anomalies and that when added together the findings on rib with or without vertebrae anomalies, the incidences were the same in the control and the highest dose groups. The IND also commented that the rat malformations were very low in incidences, some of them similar or lower than background control data as published in the paper by MARTA and MTA (1996). The Rapporteurs responded that there were no indications that the referenced background control data was from the same laboratory performing the rat developmental toxicity study on halosulfuron-methyl.

Several RAC Members commented that halosulfuron-methyl induced post-implantation losses in two species (rats and rabbits) and these incidences lay above the HCD, because although the observed malformations occurred at low incidences, they were severe effects and the incidences were higher than in concurrent controls and above the very low HCD, because halosulfuron-methyl induced statistically significant decreases in foetal weights in rats that were also associated with skeletal variations, because developmental toxicity occurred with minimal maternal toxicity and therefore the observed maternal toxicity should not influence the classification category for developmental toxicity, and because potency and the fact that the effects were observed at the top doses only should not be considered in categorisation for reproductive toxicity. After discussing these points RAC considered the evidence for adverse effects on development met the CLP criteria for category 1B rather than category. RAC therefore recommended to classify halosulfuron-methyl (ISO) as category 1B for development (Repr. 1B; H360D).

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

8. nickel (II) sulphide [1]; nickel sulphide [2]; millerite [3]

9. nickel bis(sulfamidate)

The Chairman welcomed the expert accompanying the Eurometaux stakeholder observer and the representative of the Dossier Submitters and reported that both nickel compounds (nickel sulphide and nickel bis(sulfamidate)) have existing Annex VI entries, including for their CMR properties. The legal deadline for the adoption of an opinion on nickel sulphide is 8 February 2018; for an opinion on nickel bis(sulfamidate) it is 9 May 2018.

The Dossier Submitters from industry (Talvivaara Sotkamo Ltd for nickel sulphide and Umicore NV/SA for nickel bis(sulfamidate)) proposed adding acute toxicity classifications (Acute Tox. 4; H332 for nickel sulfide and Acute Tox. 4; H332 and Acute Tox. 4; H302 for nickel bis(sulfamidate)).

The classification of nickel bis(sulfamidate) in category 4 for acute toxicity via oral route of exposure was supported by RAC based on the acute oral toxicity study with nickel bis(sulfamidate) tetrahydrate in female rats with a LD_{50} and an acute toxicity estimate (ATE) of 1,098 mg/kg bw. For the anhydate form, an ATE of 853 mg/kg bw was agreed as the existing Annex VI entry will cover both forms.

Contrary to the DS proposal, RAC did not support the classification of nickel sulphide and nickel bis(sulfamidate) for acute inhalation toxicity due to insufficient justification of the proposed read-across from nickel sulfate hexahydrate respectively nickel subsulfide (which does not have a harmonised classification for this endpoint) and nickel sulphate, respectively. The Committee found that the assumption that the acute inhalation toxicity of either of these compounds is caused by the release of Ni^{2+} and not by the particles themselves as not substantiated. In addition, it was not clear that the proposed source substances are the most relevant ones, e.g. in terms of particle size tested for applying read across to both nickel compounds under this proposal. In addition, RAC noted that no approved guidelines on the use of the bioelution methodology exist.

The DS representative admitted that details regarding bioelution testing methods were missing from the dossiers; in response to a question from a RAC member he informed that particles of 2-7 µm diameter were used in both the bioelution tests with Ni sulphide and Ni subsulphide.

The Eurometaux expert briefly recalled the background of the classification under the DSD of more than 100 nickel compounds: compounds were grouped using water solubility and classifications were read-across from only 4 source Ni substances. Assumptions used were: 1) the nickel ion is responsible for the toxicity of Ni-containing substances (systemic and local effects), 2) water solubility is sufficient to group and read across classifications for most health endpoints, and 3) bioaccessibility is considered as a refinement (i.e. collecting data in artificial biological fluid can help refine this grouping). The discussions of today highlights that some further discussions/guidance would be welcomed to clarify further how to use water solubility/ bioelution for grouping for endpoints like STOT-R, e.g. in the context of the RAAF.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

10. dodecyl methacrylate

The Chairman reported that the substance has an existing Annex VI entry as Skin Irrit. 2 (H315), Eye Irrit.2 (H319), STOT SE 3 (H335), Aquatic Acute 1 (H400) and Aquatic Chronic 1, (H410).

The Dossier Submitter (DE, based on an industry submission) proposed to delete all existing classifications. The legal deadline for the adoption of an opinion is 5 April 2018.

For human health, RAC supported the DS proposal to remove the existing classifications for Skin Irrit. 2; H315 and Eye Irrit. 2; H319 based on read across from longer- and shorter- chain length methacrylates except for STOT SE 3; H335, which was retained because no data on respiratory tract irritation was available and data for a read across to other shorter- or longer- chain methacrylate was not included by the DS in the proposal.

For the environment RAC supported the DS proposal to remove the existing classification, since the substance is rapidly degradable and the available data indicated a lack of relevant effects up to the water solubility limit for fish (acute only), *Daphnia* and algae.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

9. Restrictions

9.2 Restriction Annex XV dossiers

a) Opinion development

1) Diisocyanates

The Chairman welcomed the Dossier Submitter's representatives from Germany, the SEAC Rapporteurs (following via WebEx), an industry expert accompanying a regular stakeholder observer and an occasional stakeholder observer from EuPC, accompanied by their expert. He reminded the participants that this restriction proposal (submitted by Germany) limits the use of 18iisocyanates in industrial and professional applications to those cases where a combination of technical and organisational measures as well as a minimum standardised training package have been implemented. Information on how to gain access to this package is communicated throughout the supply chain. Exemptions are defined for cases where the content of 18iisocyanates in the substance or mixture placed on the market or used is less than 0.1% by weight, as well as for mixtures containing 18iisocyanates at higher levels than 0.1% by weight which fulfil criteria that show that the potential risks using such products are very low. The Rapporteurs had developed the second draft opinion on this dossier, taking into account the discussion held at RAC-41, which was made available to RAC on 6 September comments received from three RAC members. At this meeting, the Committee was invited to reach agreement on all the main components of the restriction, thus enabling the Rapporteurs to develop a final version of the opinion or identify where remaining work is needed.

The Rapporteurs explained that deficiencies in safe working practices still result in a significant number of OA cases and that technical improvements to reduce the exposure and other improvements to the general occupational hygiene practices are necessary in some companies dealing with diisocyanates throughout the EU. Particularly SMEs have difficulties in complying with OSH regulations due to more limited resources (e.g. financial, but also lower awareness and lack of directly available expertise). Several members expressed support for the conclusions of the Rapporteurs and RAC thus agreed that the RMMs and OCs currently implemented are not sufficient to control the risk. Furthermore, the Rapporteurs highlighted that based on the key principles of ensuring a consistent level of protection across the Union, any necessary action to address risks associated with the use of diisocyanates should be implemented in all MSs. As there is no MS in the EU, for which an occupational exposure to diisocyanates can definitely be

excluded, the Committee agreed with the Rapporteurs that action is required on an EU-wide basis.

With regard to the justification whether the restriction is the most appropriate measure, the Rapporteurs noted that due to the high number of uses and the relatively complex supply chain, the authorisation process might be impractical, whereas a restriction offers a straightforward approach to address all diisocyanates in one regulatory action. Several members expressed support for the conclusions of the Rapporteurs and RAC agreed that the restriction is the most appropriate measure in this case.

Dermal contact and peak exposures must be avoided as they can lead to sensitisation. Contrary to what has been proposed by the dossier submitter, the Rapporteurs explained that they do not support any exemptions for this restriction. In their view, the evaluation of substances or mixtures containing diisocyanates to determine whether they fulfil the conditions to be exempted from the restriction might significantly undermine its effectiveness uncertainties. The risk posed by exempted diisocyanates-containing substances or mixtures might be much lower, but how much lower is not known given the fact that no threshold can be set. Furthermore, every worker handling diisocyanates should have a sufficient knowledge on the hazards, risks and appropriate RMMs (including the correct use of appropriate PPE). Several members noted that although they tend to agree with the Rapporteurs from a scientific point of view, they would like exemptions to still be considered, as this restriction would apply to millions of workers and it is important that it is workable. Several other members, however, expressed support for the conclusions of the Rapporteurs and noted that it should be considered that peak exposures can occur, when several workers use these substances at the same time (e.g. on a construction site). An industry expert pointed out that if a company would like to benefit from an exemption, they would need to make and correctly document an assessment, which can at any point of time be checked by the enforcement. It was agreed that RAC will firm up its final view on the conditions of the restriction, including any exemptions at the next plenary meeting.

Finally, the Committee discussed the effectiveness of the proposed restriction in reducing the identified risks and agreed that training is effective in reducing the risks, however, that a number of elements in the training programme need to be further elaborated before the restriction can be implemented successfully.

The Chairman informed the Committee that the public consultation on this proposal finishes on 22 September 2017. The Rapporteurs should develop the third draft opinion, taking into account the RAC-42 discussion and the public consultation comments, by early November. RAC is expected to adopt its final opinion on this dossier at RAC-43 in November/December 2017.

2) Lead in PVC

The Chairman welcomed the Dossier Submitter's representatives from ECHA, the SEAC Rapporteur (following via WebEx), an industry expert accompanying a regular stakeholder observer and an occasional stakeholder observer from EuPC. He reminded the participants that this dossier (submitted by ECHA) proposes a restriction of lead compounds in PVC articles in concentrations equal to or greater than 0.1% (w/w) with a 15 year derogation for certain building and construction articles produced from recycled PVC (with a higher restriction limit of 1% w/w) and a 10-year derogation for PVC silica separators in lead acid batteries. The Rapporteurs had developed the second draft opinion on this dossier, taking into account the discussion held at RAC-41, which was made available to RAC on 4 September. The commenting round ended on 11 September with comments received from two RAC members. The Committee was invited to discuss the second draft opinion with the aim of reaching agreement on all the main components of the restriction and enabling the Rapporteurs to develop a final version of

the opinion or identify where remaining work is needed.

The Rapporteurs noted that the purpose of the restriction is to reduce the risk to human health from the use of lead compounds as stabilisers in PVC articles – by setting a restriction of lead compounds in PVC articles in concentrations equal to or greater than 0.1% (w/w) with derogations for three different reasons (to allow recycling to continue as a viable waste management measure, to allow continued use of lead compounds to stabilise PVC due to a lack of existing alternatives and to prevent double regulation). The Rapporteurs explained that the wording of the restriction may need revision based on the advice of the Forum as well as the comments received within the ongoing public consultation. A representative of one stakeholder observer informed the Committee that they have submitted comments regarding the non-threshold/threshold nature of lead in the public consultation. RAC agreed that the Rapporteurs and the Dossier Submitter will examine any further information in the public consultation comments with regard to this issue and will update the draft opinion as necessary.

The Rapporteurs explained to RAC that use of lead stabilisers within the EU has been voluntarily phased out, but users are not prevented from switching back, recycling keeps lead in the technosphere and PVC imports have steadily increased. RAC thus agreed that current risk management measures are insufficient to prevent ongoing lead releases from imported articles, and potentially also from some types of recycled PVC articles (e.g. flooring) (pending the final wording of the proposal). Furthermore, the Committee agreed that action is required on an EU wide basis, that the restriction is the most appropriate measure and that the proposed restriction is practical, enforceable and monitorable (pending the final wording of the proposal).

The Chairman informed the Committee that the public consultation on this proposal finishes on 22 September 2017. The Rapporteurs should develop the third draft opinion, taking into account the RAC-42 discussion and the public consultation comments, by early November. RAC is expected to adopt its final opinion on this dossier at RAC-43 in November/December 2017.

3) Lead in shot

The Chairman welcomed the Dossier Submitter's representatives from ECHA, an industry expert accompanying a regular stakeholder observer and a representative from the UNEP-Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA), accompanied by an expert.

He reminded the participants that this restriction proposal had been submitted by ECHA in April 2017 and had been considered in conformity by RAC in its May/June plenary. The dossier proposes a restriction on the use of lead shot in and over wetlands. The harmonisation of the conditions of use of lead in shot in wetlands is a priority at EU level, as national legislation has already been enacted by some Member States (or regions in some Member States) further to international action under the auspices of AEWA to which the EU is a Party.

The Rapporteurs presented the first draft opinion, in which they had focused on the hazard, emissions and exposure, risk characterisation and effectiveness of existing controls. The Rapporteurs explained to the Committee that hundreds of species of birds are dependent on wetlands during breeding and wintering periods. Many waterbirds are migratory species, moving between breeding and wintering sites in different countries as part of their annual cycle. Primary ingestion occurs when waterbirds ingest spent lead gunshot while feeding (mistaking it for food or the grit, which they use for food digestion). Secondary ingestion occurs via the predatory or scavenging birds that consume prey or scavenged carcasses that contain lead shot (embedded or ingested). Secondary poisoning can also occur through the consumption of tissues that have accumulated lead via the dissolution of ingested lead shot.

On hazard identification, the Rapporteurs explained that lead is highly toxic to all species and risk to birds is the primary concern addressed by this restriction proposal. They noted that the mortality associated with lead poisoning in waterbirds is quantified, while sub-lethal risks in waterbirds and risks for predatory and scavenging birds are described qualitatively. In addition, there are also concerns related to indirect exposure of humans (e.g. by eating game or contaminated drinking water), but these risks are not quantified in the Dossier. The Dossier Submitter, in line with previous assessments by RAC and EFSA, reiterated that lead is considered as a non-threshold substance causing neurodevelopmental effects in children (as well as blood pressure and renal effects in adults). Therefore, under REACH, only a qualitative assessment or risk is required for these endpoints.

After a presentation of the available hazard data, which comprises studies on mortality in both laboratory and field situations, as well information on various sub-lethal effects, the Rapporteurs concluded that there is extensive evidence supporting the Dossier Submitter's view that ingestion of spent lead shot by waterbirds (i.e. ducks, geese, swans, waders, rails and flamingos) can cause toxicological effects, ranging from sub-lethal effects to mortality. During the RAC discussion on hazard two RAC members supported the conclusions by the Rapporteurs..

The annual consumption of shotgun cartridges in the EU is estimated to be between 600 and 700 million units, which is equivalent to 18,000 to 21,000 tonnes of lead being dispersed annually into the environment from hunting. Based on the calculations done by the Dossier Submitter hunting of wildfowl in wetlands results in an annual release of 357 tonnes of lead to wetlands.

The RAC Rapporteurs advised that the use of lead shot in or where spent shot would land within a wetland results in exposure of waterbirds to lead. In addition, scavenging and predatory birds are also subject to lead poisoning. Waterbirds that have ingested lead shot are more likely to be shot, therefore there is a potential exposure of humans consuming game both by this route but primarily from the lead used to shoot the bird, whether poisoned or not. Furthermore, the Rapporteurs noted, in line with the Dossier Submitter, that waterbird species that also feed outside of wetlands will not be entirely protected by this restriction, e.g. geese and swans may feed outside of wetlands on agricultural fields contaminated with lead gunshot. RAC Members supported the conclusions by the Rapporteurs. Two RAC Members noted that direct emissions to the environment are greater than those discussed in the lead in PVC restriction and that ca. 99 % of shot pellets end up in the environment (only 1% reaches the target).

While discussing the key study used by the Dossier Submitter to estimate annual mortality rates in populations of waterbirds that ingest lead (Bellrose, 1959) the Rapporteurs expressed the view that a recalculation of the data presented in the Bellrose study submitted in the public consultation (Green, in prep) gives a more reliable estimate of mortality than the original study.

However, given that the annual mortality estimates proposed by Bellrose were clearly within the confidence intervals of the reanalysis the Rapporteurs suggested to accept and support the Dossier Submitter's estimate of an annual mortality of, in the order of, 1 million waterbirds[7].

The Rapporteurs noted that the Dossier Submitter considered this quantitative risk characterisation as describing the 'minimum impact' of the use of lead gunshot in wetlands on the basis that certain sub-lethal effects within affected species (e.g. on reproduction and lethal or sub-lethal effects on predatory or scavenging birds via secondary poisoning) are not included. In addition, as well as effects on the 33 species included in the analysis, further species of waterbirds could be affected by primary ingestion.

[7] The estimate of mortality includes waterfowl (such as ducks, geese and swans) as well as other waterbirds (such as wading birds that are not typically referred to as waterfowl).

During the discussion RAC Members generally spoke in support of the Rapporteurs' conclusions. One suggested to amend the risk characterisation part of the RAC draft opinion by including, in addition to effects of mortality, sub-lethal effects associated with lead exposure, such as on reproductive capability, increased incidence of flying accidents, immune capability.

The Rapporteurs noted that managing the risk on a Member State level has resulted in inconsistent national regulations in terms of geographic scope and wetland definition. In addition, four Member States have not implemented any controls on the use of lead gunshot in wetlands. Hence the current restriction proposal would ensure an effective implementation of AEWA in EU Member States. An EU wide restriction, including in those countries presently lacking any national restriction, is likely to protect waterbirds more efficiently, throughout their annual migration. During the discussion one RAC member noted that this is a complicated area since as well as scope, the effectiveness of national measures is, to some extent, linked to enforcement activities. Another RAC Member suggested to develop a training course for hunters on the environmental and health consequences of using lead in wetlands. Representatives of the Commission and AWEA suggested to engage with the hunting communities in Europe in order to provide them with necessary support to observe any upcoming restriction. The Dossier Submitter supported these comments recalling a positive example from the UK where following the national restriction there many coastal wildfowling clubs enforced the legal requirement to use alternative shot for hunting wildfowl on the foreshore within their membership.

In addition, the Rapporteurs presented topics for in-depth discussion at the next RAC-43 plenary meeting in November/December 2017. These topics included details on the scope of the restriction, justification if the action is required on EU-wide basis, justification whether the suggested restriction is the most appropriate EU-wide measure, effectiveness in reducing the identified risks, practicality, including enforceability, and monitorability of the proposed restriction.

Among other issues the Committee Members discussed the usefulness of buffer zones (e.g. 300m) surrounding wetlands. A representative of AEWA added that the use of buffer zones could be justified as some waterbird species feed in the areas directly adjacent to surface waters, and these may or may not be understood to be wetlands, despite the use of lead posing a risk in these areas. AEWA will supply additional information on the foraging behaviour of waterbirds that are known to feed outside of wetland areas (e.g. swans and geese) as well as a summary of the best practices of the implementation of the AWEA. However, the Secretariat reminded the Committee that the risk assessment from the Dossier Submitter sets the scope of the restriction and any buffer zones had not been included in their assessment. Therefore unless a fully justified additional restriction option was submitted in the Public Consultation, the risks to birds could not be used to justify buffer zones. However, the information supplied by AEWA could be useful in considering margins of the definition of wetlands, e.g. the shores of lakes. One stakeholder representative supported the view that peatlands should be retained within the scope of the restriction. This view was confirmed by the representative of AWEA who confirmed that some species of birds, including waterbirds, could be exposed to lead shot in peatland areas.

The RAC Chairman noted that a part of the Forum Advice stating that the establishment of wetland zones "by decree" needs to be legally clarified. He also thanked AEWA for agreeing to share information.

The Chairman informed the Committee that the second draft opinion should be developed by the Rapporteurs by early November 2017.

10. Authorisation

10.1 General authorisations issues

a) Update on incoming/future applications

The Secretariat informed the Committee that one new application for authorisation and two review reports were received during the August 2017 submission window. The received application for authorisation is an upstream application for the two uses of pentazinc chromate octahydroxide. The uses cover formulation of mixtures and the use of the substance in stoved epoxy primer for corrosion protection of aircraft engine components in aerospace and aeroderivative applications. The two received review reports are on the two identical upstream uses of phthalate DEHP: (1) formulation of recycled soft PVC containing DEHP in compounds and dry-blends and (2) industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles.

In addition, the Secretariat informed the Committee that in the November 2017 submission window it is expected to receive one new application for authorisation on the downstream use of diglyme, and possibly one review report on the use of lead chromate pigments.

b) Report ECHA workshop on 'Application for Authorisation for environmental endocrine disruptors'

Two SVHC substances with endocrine disrupting properties for the environment (Article 57(f)) were added to Annex XIV of REACH in July 2017 (OPnEO and NPnEO). These are the first two SVHCs added to Annex XIV on the basis of these properties.

The Secretariat reported to the Committee about a technical workshop hosted by ECHA in August 2017 (In Brussels) to raise awareness on key issues relevant to the hazard and risk assessment of these substances, specifically the potential role of 'thresholds' and 'dose-response' relationships in applications for authorisation for these substances.

It remains clear there that there are significant uncertainties surrounding the derivation of robust thresholds and dose-response relationships for endocrine disrupting substances. Recognising these uncertainties, RAC are not in a position to derive 'reference values' for these substances. In addition, these uncertainties are, on balance, likely to significantly complicate the evaluation of any justification for authorisation proposed by an Applicant for these substances on the bases of adequate control/safe use. A quantitative risk assessment could however be a useful way of demonstrating minimisation.

The Secretariat reported that Applicants are interested in how socio-economic analysis could be used as justification for an authorisation. Given that the hazard properties of these substances are different to those that have previously been considered in applications for authorisation, Applicants will benefit from additional support for preparing a 'fit-for-purpose' Chemical Safety Assessment and Socio-economic Analysis for these substances.

Responding to a suggestion from the Secretariat, RAC agreed to assist in the preparation of a series of Q&As on key elements of the Chemical Safety Assessment for these substances. The Q&As would be subject to a RAC consultation prior to RAC-43 and would be further discussed, prior to publication, at the RAC-43 plenary.

b) Working procedure on carcinogenicity dose-response relationships and DNEL setting for threshold substances, including reprotoxic properties

The Chairman introduced the working procedure on carcinogenicity dose-response relationships and DNEL setting for reprotoxic properties and mentioned that the Committee Working Procedure is intended to guide Rapporteurs in evaluating and amending RAC notes and the Members in the process of evaluating them.

RAC Members discussed the Working Procedure. Several Members expressed the need to insert in the initial steps of the opinion development also the involvement of Rapporteurs in setting the outline of the draft background report. Furthermore, several Members recommended to look more in detail in the timing of the steps of the opinion development.

The Chairman requested the Secretariat to revise the draft working procedure in accordance with the discussion in RAC and to launch a written commenting round on the final version of the Working Procedure. The agreed Working Procedure will be published on the ECHA website.

c) AfA DNEL/DR: Carcinogenicity dose-response relationship - development of:

1. Coal tar pitch, high temperature (CTPHT)

2. Anthracene oil

RAC noted presentations by the ECHA Consultant and the Rapporteur.

The ECHA Consultant proposed to consider the meta-analysis by Armstrong *et al.* (2003, 2004)[8] as the key source of epidemiological data for a quantitative carcinogenicity assessment of CTPHT, which is based on the findings from 39 studies. The currently derived carcinogenicity dose-response relationship for benzo[a]pyrene as a surrogate substance for CTPHT proposed by the ECHA Consultant is based on Armstrong *et al* and accounts for the uptake of other individual components of CTPHT. In addition it is unnecessary to add additional modifying factors, since it already covers combined exposure via all of the routes of exposure. In general, during the discussion RAC Members intervened in favour of choosing benzo[a]pyrene as a surrogate substance for CTPHT. Representative of the stakeholder organisation from industry supported this view.

RAC Members noted that although the study by Armstrong *et al.* (2003, 2004) contains uncertainties, it could be used as a basis for the derivation of the dose-response relationship for CTPHT.

Some RAC Members intervened in favour of having also other polyaromatic hydrocarbons (PAH) being measured at workplaces. Representative of industry explained that similar coal distillation techniques are used by industry therefore compositions of CTPHT on the European Market are similar and hence benzo[a]pyrene can serve as a proxy. He noted that the ECHA Consultant in his calculations used maximum values of individual component concentrations found in the substance registration dossiers. They contain broader individual component concentration ranges than the expected variations are likely to be. Hence the calculated values are conservative. He also noted that anthracene oil as used in EU is not carcinogenic (it contains less than 0.005 % (w/w) of benzo[a]pyrene).

One RAC Member expressed her view that the more PAH substances in the composition the higher contamination and potential exposure to the substances. Therefore the additional

[8] Armstrong, B. et al. (2003) Cancer risk following exposure to polycyclic aromatic hydrocarbons (PAHs): a meta-analysis. Prepared by the London School of Hygiene and Tropical Medicine for the Health & Safety Executive; 2003: Research Report no. 068.
Armstrong, B. et al. (2004). "Lung cancer risk after exposure to polycyclic aromatic hydrocarbons: A review and meta-analysis." Environmental Health Perspectives 112(9): 970-978.

information related with the spectrum of PAHs present in the workplaces could be considered to guarantee a more accurate exposure assessment. Another RAC Member however added that the Armstrong *et al.* studies examine PAH mixtures that were high and low in benzo[a]pyrene composition, and that it can be used as a sole indicator in the CTPHT exposure assessment. RAC requested the ECHA Consultant to investigate and to include in the report and the RAC note any comparison between workplace conditions in the Armstrong *et al.* study and the workplace conditions where CTPHT is used.

During the discussion dedicated to biomonitoring three RAC Members spoke in favour of using 1-hydroxypyrene concentration in urine. It is used since a long time as an exposure indicator to benzo[a]pyrene. It reflects the best exposure via dermal and hand-to-mouth routes of exposure. One RAC Member noted that it is important to account for the background levels in the population concerned. Concentration of this indicator substance is higher in smokers (0.7 to 0.8 µmol/mol creatinine) comparing to non-smokers (around 0.2 µmol/mol creatinine). Another RAC Member agreed that this variation in the background exposure is important to be noted in the consultant's report. However, he doubted whether Applicants will submit data containing so detailed information. Another RAC Member noted that metabolic activity influencing the concentration of 1-hydroxypyrene can differ depending on the route of uptake.

One RAC Member was of the view that biomonitoring is important in the case of CTPHT because it can be absorbed through the skin via dermal route of exposure. A representative of the Commission in response explained that for chemicals for which dermal exposure may occur the use of biomonitoring can play an important role in an overall approach to chemical risk management. However, biomonitoring is not a primary risk management measure and should not be used in isolation from a more comprehensive approach to risk management. It is important for the employer to introduce a range of risk management measures with the main objective of eliminating exposure, for example by substitution, or where this is not possible to reduce exposure to a minimum following the well understood hierarchy of control in OSH e.g. process enclosure, LEV etc. In this situation limit values (TWA, STEL and any associated notations) play an important role together with biomonitoring. Also, the use of biomonitoring is not restricted to chemicals for which dermal exposure is the main route of concern, it is also relevant for many chemicals where the primary route of exposure is by inhalation.

The Committee agreed to apply the benzo[a]pyrene surrogate approach in addressing the exposure assessment of CTPHT, i.e. that in all cases, applicants are advised to base their exposure assessment on this marker.

It was also agreed that additional information on the spectrum of PAHS (other relevant markers e.g. 4 PAH) present in the workplaces in the scope of Authorizations will be welcomed for the purpose of assessing exposure.

1-Hydroxypyrene may be used where appropriate as a biomarker for the workplace exposure and risk assessment. In addition, dose-response relationship and risk through various routes of exposure should be considered by the ECHA consultant. CTPHT is included in Annex XIV of the REACH Regulation based solely on its carcinogenic, PBT and vPvB intrinsic properties, however the substance is also mutagenic and reprotoxic according to the updated classification and labelling in Annex VI of the CLP Regulation. Therefore it is not obligatory for Applicants to consider these two properties in the future applications for authorisation. However RAC Members suggested that reprotoxicity of the substance could be included in the report by the ECHA Consultant in an Appendix. The section on PBT and vPvB properties should be included in the RAC note on CTPHT.

The Committee postponed the discussion on the draft RAC note on anthracene oil. It is included in Annex XIV of the REACH Regulation based on its carcinogenic, PBT and vPvB intrinsic properties. However anthracene oil is not to be classified as carcinogenic, if the concentration of benzo[a]pyrene is <0.005 % (w/w). None of the registration dossiers considers anthracene oil carcinogenic. This was confirmed by industry, stating that it is using benzo[a]pyrene-free anthracene oil. Therefore future applications for the use of anthracene oil will be evaluated based on its PBT and vPvB properties.

The consultant was requested to update the report and RAC note for agreement at the next meeting.

10.2 Authorisation applications

a) Discussion on key issues

The Secretariat in cooperation with the RAC Rapporteurs provided general information regarding the new applications for authorisation listed below. In the presentation of each case, the Secretariat outlined the key issues identified by the Rapporteur and asked the Committee for comments and further suggestions.

The Committee discussed the key issues. Where needed, RAC will request further clarifications from the various Applicants on the issues identified and discussed by the Committee.

1. EDC_Microbeads (1 use)

This is a narrow scope downstream user application for the single industrial use as a swelling agent during the sulfonation reaction of crosslinked polystyrene beads in the manufacture of ion exchange resins for purification of radioactive waste. 8 workers directly exposed to EDC. The annual volume used is <1tonne/year. The requested review period is 12 years.

2. CT_ZFF (1 use)

This is a narrow scope downstream user application for the single use of chromium trioxide in functional chrome plating of piston rods for automotive and rail applications.

The annual volume used is >100 kg/year for two sites and the requested review period is 21 years.

3. SC_Wesco (1 use)

This is an upstream application on the following use of strontium chromate.

Use 1: Use of strontium chromate in primers applied by aerospace and defence companies and their associated supply chains

The scope of the application is relatively broad. The number of sites relevant for the application is >100. Number of workers exposed >15,000. The Applicants requested a review period of 12 years. The substance is the main component in primers. These are one layer out of several layers of coating applied (i.e. spraying and brushing) to the surface of an aeronautic vehicle or component. The level of containment for tasks and processes is generally low.

4. DtC_Wesco (1 use)

This is an upstream application on the following use of dichromium tris(chromate).

Use 1: Use of dichromium tris(chromate) for chemical conversion coating applications by aerospace and defence companies and their associated supply chains

The scope of the application is relatively broad. The number of sites relevant for the application is >100. Number of workers exposed >10,000. The Applicant requested a review period of 12 years. The substance is the main component in chemical conversion coatings used to provide corrosion resistance to the surface of an aeronautic vehicle or component. The level of containment of the process/tasks is generally low

5. PCO_Aviall (2 uses)

This is an upstream application on the following two uses of pentazinc chromate octahydroxide.

Use 1: Formulation of mixtures,

Use 2: Use of pentazinc chromate octahydroxide in wash primer, fuel tank primer and aluminized primer for the purpose of corrosion protection in aeronautic applications.

The scope of the application is relatively broad. The number of sites relevant for the application is <5 for Use 1 and <100 for Use 2. Number of workers exposed <50 for Use 1 and <1,000 for Use 2. The Applicants requested a review period of 12 years. The substance is the main component in primers. Primers constitute one layer out of several layers of coating applied (i.e. spraying and brushing) to the surface of an aeronautic vehicle or component. For both uses, the level of containment is low

b) Agreement on Draft Opinions

1. EDC_Olon (2 uses)

The Rapporteurs presented the draft opinions on the application for authorisation submitted by Olon S.p.a. for two uses of 1,2-dichloroethane (EDC): the use of 1,2 dichloroethane (1,2-DCE) as a solvent in the manufacturing of the active pharmaceutical ingredient for epirubicin (Use 1) and the use of 1,2 dichloroethane (1,2-DCE) as a solvent in the manufacturing of the active pharmaceutical ingredient prednisolone steaglate (Use 2*).* The total number of exposed workers is 20 (Use 1) + 6 (Use 2), for the one site covered by this application. The annual tonnage used is 9,990 kg/year for Use 1 (expected in 2023; currently – 7 tonnes) and 180 kg/year for Use 2. The requested review period is 20 years.

RAC agreed by consensus on the draft opinions as proposed by the Rapporteurs. In particular, RAC was of the opinion that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC decided to recommend no additional conditions and monitoring arrangements for the authorisation and for review reports.

c) Adoption of final opinions

1. SD_Borealis (1 use)

The Chairman introduced the application for authorisation. At RAC-40, the Committee agreed on the draft opinion. The Applicant provided comments to this draft opinion on 20 July 2017, mainly to the recommended review period (SEAC issue). At this plenary, the RAC Members were asked to consider the adoption of the RAC final opinion following the comments on the draft opinion received from the Applicant.

The RAC Rapporteur presented the draft of the final opinion, in which the conclusion was unchanged but some text was added to reflect the applicant's comments on the cancer risk calculations. It was subsequently adopted by consensus, and will be sent to the Applicant, the European Commission as well as the Members States.

d) Status update

1. **CT_ Hapoc (4 uses), CT_Hapoc_2 (1 use), CT_Hapoc_3 (1 use), SD_Hapoc (1 use)**

The Rapporteurs informed RAC about the opinion development progress on the four applications for authorisation submitted by HAPOC GmbH & Co KG. Recently the Applicant submitted extensive responses to the Rapporteurs' questions. In case of SD_Hapoc, RAC had asked a set of questions to bring the application into conformity. The Applicant did not answer these questions but got back to ECHA with a request for an extended dead line until the end of 2017. Since this was already the second request for extending the deadline and in light of equal treatment of Applicants the ECHA Secretariat did not extend the deadline.
The Committee intend to discuss and, if possible, to agree on the draft opinions on these applications for authorisation at its RAC-43 plenary meeting in November/December 2017.

11. AOB

a) EU Human Biomonitoring Project: HBM4EU

Dr Marike Kolossa for the German Environment Agency UBA was invited by the Chairman to give a presentation to RAC on the HMB4EU project, the new EU-funded human biomonitoring initiative. It was hoped to highlight the need to include the collection of biomonitoring data in the workplace alongside that of the general population in such initiatives. The importance of biomonitoring to help understand the trends in human exposure over time was emphasised, in particular to be able to better assess the impact of regulation on chemical exposure. The structure of the project was described, as well as the participating countries and the proposals for the prioritisation of substances for future study, including emerging chemicals. A lively discussion followed with RAC members asking a wide range of questions.

The Chairman thanked the speaker for an inspiring presentation, noting that this was particularly relevant to the work of RAC in the light of its current discussions on the use of biomonitoring in workplace exposure assessment, as illustrated by several dossiers considered at this meeting.

b) EEB report

The European Environment Bureau, one of RAC's regular Stakeholder Observers presented the Committee with findings from their recent report on restrictions entitled '*Restricted success*'. EEB consider that the restriction process is not as fast and efficient as they had hoped for, the scope of individual restrictions is narrower and the Committees "regularly and arbitrarily modify the scope weakening proposals". EEB had made recommendations for improvement, including better communication of uncertainty, incorporation of 'new toxicology' and amongst others, a better definition of the Committee's role in relation to scope change, information requirements and assessment. The Secretariat noted the work of the Restriction Efficiency task Force in its final report in guiding RAC on some of the issues raised. With regard to scope changes, the Chairman replied that the Committee did not expand the scope of a restriction beyond the evidence provided by the Dossier Submitter and was careful to evaluate any requests for derogations on the basis of the data provided on the risks involved. The Chairman thanked EEB

for their presentation, noting that scrutiny of the Committee's by stakeholders was always welcome.

22 September 2017

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 42 18-22 September 2017

(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/42/2017**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-40 minutes.
4. Appointment of (co-)rapporteurs	
a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95(3) requests and Article 77(3)(c) requests	
5. Report from other ECHA bodies and activities	
a) Report on RAC 41 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/42/2017/02** and document **RAC/42/2017/03.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes -	
c) Annual update of RAC accredited stakeholders' list. SECR presented document RAC/42/2017/04. RAC agreed on the updated list.	SECR to publish the document on ECHA's website.
6. Requests under Article 77 (3)(c)	
6.1 General issues	
a) Interim Working procedure on the evaluation of occupational exposure limits and other values in support of CMD **SECR** presented document RAC/42/2017/05	SECR to make an editorial check of the document, based on discussion in RAC-42.

RAC agreed on the Interim Working Procedures with the additions as provided by Members.	**SECR** to publish the agreed interim Working Procedure document on the ECHA website.
6.2 Dossiers occupational exposure- opinion development	
a) Nickel and its compounds The Secretariat presented the draft ECHA proposal and the Rapporteurs presented the first draft RAC-opinion. RAC discussed the first draft opinion. The following points were supported: RAC supported that nickel ion(2+) levels in the cells are the main determinant of carcinogenicity. - More details are needed to clarify the roles of different MoAs in carcinogenicity of nickel compounds. - Additional information on the exposure levels (doses) at which key genotoxic events occur would need to be added, if available; - Practical threshold for the carcinogenic effects of nickel to be considered as an option depending on clarification of mechanism of genotoxicity and carcinogenicity.	**RAC Members** are invited to submit further comments within the written consultation round by 27 September 2017. **Rapporteurs** to prepare the revised draft RAC-opinion, taking into account the RAC-42 discussions and the results of the RAC- written commenting round. **SECR** to prepare the revised draft proposal, to align with the revised RAC-opinion and taking into account RAC-42 discussions and results RAC-written commenting round. **SECR** to launch the Public Consultation on the revised draft ECHA proposal.
b) Benzene The Secretariat presented the draft ECHA proposal and the Rapporteurs presented the first draft RAC-opinion. RAC discussed the first draft opinion in which three approaches for cancer risk assessment are presented – linear risk extrapolation, sub-linear risk extrapolation and threshold model. RAC expressed reservations on the available evidence to support a causal correlation between haematological effects and carcinogenicity. RAC suggested to explore another approach in the second draft opinion focusing on genotoxicity. RAC agreed that a further discussion on the proposed approaches would need to take place at RAC-43.	**RAC Members** are invited to submit further comments within the written consultation round until 27 September 2017. **Rapporteurs** to prepare the revised draft RAC-opinion, taking into account the RAC-42 discussions and the results of the RAC-written commenting round. **SECR** to prepare the revised draft proposal, taking into account the RAC-42 discussions and the results of the RAC-written commenting round and to align with the Rapporteurs on the revised RAC-opinion. **SECR** to launch the Public Consultation on the revised draft ECHA proposal.
c) Acrylonitrile The ECHA contractor presented the draft ECHA proposal and the Rapporteurs presented the first draft RAC-opinion.	**RAC Members** are invited to submit further comments within the written consultation round until 27 September 2017. **Rapporteurs** to prepare the revised draft RAC-opinion, taking into account the RAC-

RAC discussed the first draft opinion in which three approaches were presented (linear and non-linear for cancer effects and threshold for non-cancer effects). RAC expressed the need for additional information on the various Modes of Action, where possible, including dose response data. RAC expressed the need for a concise overview of epidemiology in the ECHA draft proposal, taking into account the new developments. RAC agreed that a further discussion on the proposed approaches for limit values, including the appropriateness of limit values for risks from non-carcinogenic effects, would need to take place at RAC-43.	42 discussions and the results of the RAC-written commenting round. **SECR** to prepare the revised draft proposal, taking into account the RAC-42 discussions and the results of the RAC-written commenting round and to align with the Rapporteurs on the revised RAC-opinion. **SECR** to launch the Public Consultation on the revised draft ECHA proposal.

7. Requests under Article 95 (3)

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8. Harmonised classification and labelling (CLH)

8.1 General CLH issues

a)Fast track agreement	

8.2 CLH dossiers

A. Substances with hazard classes for agreement by A-listing following the usual scrutiny but without plenary debate

Please mention any ATE values for acute toxicity, together with the applicable route of exposure, where these were agreed by RAC through fast-tracking.

halosulfuron-methyl (ISO): physical hazards, acute toxicity (all routes of exposure), STOT SE, skin corrosion / irritation, serious eye damage / eye irritation, respiratory or skin sensitisation, STOT RE, carcinogenicity, germ cell mutagenicity, aspiration hazard, environmental hazards

metaldehyde: acute toxicity (all routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, STOT SE, germ cell mutagenicity, toxicity to reproduction (development)

ethylene oxide, oxirane: acute toxicity (oral and inhalation), serious eye damage / eye irritation, respiratory sensitisation

B. Substances with hazard classes for agreement in plenary session

Please mention any ATE values for acute toxicity, together with the applicable route of exposure, where these were agreed by RAC, including those agreed through fast-tracking.

1. ~~titanium dioxide~~ (removed – already adopted by written procedure)
2. ethylene oxide, oxirane
3. ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl)derivatives
4. Acid Black 210 Na
5. cobalt metal
6. metaldehyde
7. halosulfuron-methyl (ISO)

8. nickel (II) sulphide [1]; nickel sulphide [2]; millerite [3] 9. nickel bis(sulfamidate) 10. dodecyl methacrylate	
2. ethylene oxide, oxirane	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below (in addition to the existing classification). [Acute Tox. 3; H301, Acute Tox. 3; H331, Eye Dam. 1; H318 (without labelling), STOT SE 3; H336, Skin Corr. 1; H314, STOT RE 1; H372 (nervous system), Repr. 1B; H360Fd]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to 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.
3. ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl)derivatives	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360D]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to 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.
4. Acid Black 210 Na	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [<u>Removal of</u> the existing HH and ENV classification]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **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. cobalt metal	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below (in addition to the existing classification). [Muta 2; H341, Carc. 1B; H350, SCL of 0,01%, Repr. 1B; H360F]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **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.

6. metaldehyde	
RAC adopted <u>by majority</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below (in addition to the existing classification). [Acute Tox. 3; H301, Repr. 2; H361f, Aquatic Chronic 3; H412] Majority agreement on no classification for carcinogenicity.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **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.
7. halosulfuron-methyl (ISO)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Acute 1; H400; Acute M-factor of 1000, Aquatic Chronic 1; H410; Chronic M-factor of 1000, Repr. 1B; H360D]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to 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.
8. nickel (II) sulphide [1]; nickel sulphide [2]; millerite [3]	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below (in addition to the existing classification).. [no additional classification]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to 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.
9. nickel bis(sulfamidate)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below (in addition to the existing classification). [Acute Tox. 4; H302, oral ATE: 853 mg/kg bw (anhydrate), oral ATE: 1098 mg/kg bw (tetrahydrate)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to 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.
10. dodecyl methacrylate	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [*<u>Retain</u>*: STOT SE 3; H335, *<u>Remove</u>*: Skin Irrit. 2; H315, Eye Irrit. 2; H319, Aquatic Acute 1; H400, Aquatic Chronic 1; H410]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **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.
9. Restrictions	
9.1 Restriction Annex XV dossiers	
a) Opinion development	
1) Diisocyanates The Rapporteurs presented and RAC discussed the second draft opinion. RAC agreed that the RMMs and OCs currently implemented are not sufficient to control the risk. RAC agreed that action is required on an EU wide basis and that that the restriction is the most appropriate measure. RAC agreed that training is effective in reducing the identified risks. RAC concluded that a number of elements in the training programme need to be further elaborated before the restriction can be implemented successfully.	**Rapporteurs** to prepare the third draft opinion, taking into account the RAC-42 discussions and the results of the public consultation, by the beginning of November 2017.
2) Lead in PVC The Rapporteurs presented and RAC discussed the second draft opinion. RAC agreed that the Rapporteurs and the Dossier Submitter should examine any further information in the PC comments with regard to the non-threshold/threshold nature of lead and update the opinion as necessary. RAC agreed that current risk management measures are insufficient to control the risk (pending the final wording of the proposal). RAC agreed that action is required on an EU wide basis and that that the restriction is the most appropriate measure (pending the final wording of the proposal). RAC agreed that the proposed restriction is practical, enforceable and monitorable (pending the final wording of the proposal).	**Rapporteurs** to prepare the third draft opinion, taking into account the RAC-42 discussions and the results of the public consultation, by the beginning of November 2017.
3) Lead in shot	**Rapporteurs** to prepare the second draft opinion, taking into account the

The Rapporteurs presented and RAC discussed the first draft opinion. RAC agreed with the conclusion that the ingestion of spent lead shot by water birds can cause toxicological effects (from sub-lethal effects to mortality). RAC agreed that the use of lead shot in or nearby wetlands results in exposure of waterbirds to lead, the secondary exposure of scavenging or predatory birds, and the potential exposure of humans consuming game. RAC agreed that the estimated annual mortality of, in the order of, one million waterbirds due to the use of lead shot in and over wetlands. RAC also noted that the existence of existing national restrictions on the use of lead shot in 24 out of 28 Member States confirm that the hazards related to the use of lead gunshot is well-recognised in most of the Member States but harmonisation is needed.	RAC-42 discussions by the beginning of November 2017.
10. Authorisation	
10.1 General authorisation issues	
a) Update on incoming/future applications	
RAC noted the information presented by the Secretariat.	
b) Report ECHA workshop on 'AfA for environmental endocrine disruptors'	
RAC noted the information presented by the Secretariat. RAC will not derive the reference values for these substances but will develop with the Secretariat a Question and Answer document on important elements that Applicants should consider when preparing their applications. RAC requested to hold a plenary discussion on the Question and Answer draft document in support for the future Applicants at the next plenary meeting in November/December 2017.	**SECR** to draft the Question and Answer document in support for the future Applicants. **SECR** to launch the RAC consultation prior to the RAC-43 plenary meeting.
c) Status update – CT_Hapoc, CT_Hapoc_2, CT_Hapoc_3 and SD_Hapoc	
RAC noted the information presented by the RAC rapporteurs.	**Rapporteurs** to develop the draft opinions for discussion and agreement at the RAC-43 plenary meeting.
c) Working procedure on carcinogenicity dose-response relationships and DNEL setting for reprotoxic properties	
SECR presented document RAC/42/2017/06 **RAC** discussed the Working Procedure	**SECR** to revise the Working Procedure in accordance with the discussion in RAC.

	SECR to launch a RAC commenting round for the final version of the Working Procedure. **SECR** to publish the agreed Working Procedure on the ECHA website.
c) AfA DNEL/DR	
1. Carcinogenicity dose-response relationship and DNEL setting for the reprotoxic properties of coal-tar pitch, high temperature (CTPHT) RAC noted the presentations by the ECHA Consultant and the RAC Rapporteur. RAC discussed the proposed approach and provided advice regarding the way forward, in particular: - Benzo[a]pyrene surrogate approach to be taken in addressing the exposure assessment to CTPHT; - To investigate and include in the report and the RAC note comparison between workplace conditions in the Armstrong *et al.* study and the workplace conditions where CTPHT is used; - To use 1-hydroxypyrene where appropriate as a biomarker for the workplace exposure and risk assessment; - To consider dose-response relationship and risk through various routes of exposure. **2. Carcinogenicity dose-response relationship of anthracene oil** Discussion on anthracene oil has been postponed until the report and the RAC note on CTPHT has been developed.	**ECHA Consultant** to consider the plenary discussion in updating of the RAC draft note on CTPHT and the RAC draft note on anthracene oil.
10.2 Authorisation applications	
a) Discussion on key issues	
1. EDC_Microbeads (1 use) **2. CT_ZFF (1 use)** **3. SC_Wesco (1 use)** **4. DtC_Wesco (1 use)** **5. PCO_Aviall (2 uses)** RAC discussed the key issues in the five applications for authorisation and provided advice as needed to the Rapporteurs, also in relation to the conformity.	**SECR** to inform SEAC about the outcome of the discussion.
b) Agreement on Draft Opinions	

1. EDC_Olon (2 uses) RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC decided to recommend no additional conditions and monitoring arrangements for the authorisation and for review reports.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicant for commenting.
c) Adoption of final opinions	
1. SD_Borealis (1 use) RAC adopted the final opinion with no changes in conclusions of the draft opinion following the received Applicant's comments.	**SECR** to send the final opinion to the EC, MSs and the Applicant.
11. AOB	
12. Action points and main conclusions of RAC-42	
SECR to upload the adopted action points to CIRCA BC.	

Table 1: CLH opinions which were adopted at RAC-42

RAC-42

1. **halosulfuron-methyl (ISO)**
2. **metaldehyde (ISO)**
3. **ethylene oxide**
4. **dodecyl methacrylate**
5. **acid Black 210 Na**
6. **nickel (II) sulphide [1]; nickel sulfide [2]; millerite [3]**
7. **nickel bis(sulfamidate); nickel sulfamate**
8. **cobalt**
9. **ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs**

1. **halosulfuron-methyl (ISO); methyl 3-chloro-5-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-1-methyl-1H-pyrazole-4-carboxylate**

	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 Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	613-RST-VW-Y	halosulfuron-methyl (ISO); methyl 3-chloro-5-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-1-methyl-1H-pyrazole-4-carboxylate	-	100784-20-1	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1000 M=1000	
RAC opinion	613-RST-VW-Y	halosulfuron-methyl (ISO); methyl 3-chloro-5-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-1-methyl-1H-pyrazole-4-carboxylate	-	100784-20-1	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360D H400 H410	GHS08 GHS09 Dgr	H360D H410		M=1000 M=1000	
Resulting Annex VI entry if agreed by COM	613-RST-VW-Y	halosulfuron-methyl (ISO); methyl 3-chloro-5-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-1-methyl-1H-pyrazole-4-carboxylate	-	100784-20-1	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360D H400 H410	GHS08 GHS09 Dgr	H360D H410		M=1000 M=1000	

2. **metaldehyde (ISO); 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane**

	Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Classification**		**Labelling**			**Specific Conc. Limits, M-factors and ATE**	**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 Annex VI entry	605-005-00-7	metaldehyde (ISO); 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane	203-600-2	108-62-3	Flam. Sol. 2 Acute Tox. 4*	H228 H302	GHS02 GHS07 Wng	H228 H302			
Dossier submitters proposal	605-005-00-7	metaldehyde (ISO); 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane	203-600-2	108-62-3	**Retain** Flam. Sol. 2 **Add** STOT RE 2 **Modify** Acute Tox. 3	**Retain** H228 **Add** H373 (oral) **Modify** H301	**Retain** GHS02 Wng **Modify** GHS06	**Retain** H228 **Modify** H301			
RAC opinion	605-005-00-7	metaldehyde (ISO); 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane	203-600-2	108-62-3	**Retain** Flam. Sol. 2 **Add** Repr. 2 Aquatic Chronic 3 **Modify** Acute Tox. 3	**Retain** H228 **Add** H361f H412 **Modify** H301	**Retain** GHS02 **Add** GHS08 **Modify** GHS06 Dgr	**Retain** H228 **Add** H361f H412 **Modify** H301			
Resulting Annex VI entry if agreed by COM	605-005-00-7	metaldehyde (ISO); 2,4,6,8-tetramethyl-1,3,5,7-tetraoxacyclooctane	203-600-2	108-62-3	Flam. Sol. 2 Repr. 2 Acute Tox. 3 Aquatic Chronic 3	H228 H361f H301 H412	GHS02 GHS06 GHS08 Dgr	H228 H361f H301 H412			

3. **ethylene oxide; oxirane**

	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 Annex VI entry	200-849-9	ethylene oxide; oxirane	200-849-9	75-21-8	Flam. Gas 1 Press. Gas Acute Tox. 3* Skin Irrit. 2 Eye Irrit. 2 Muta. 1B Carc. 1B STOT SE 3	H220 H280 H331 H315 H319 H340 H350 H335	GHS02 GHS08 GHS06 GHS04 Dgr	H220 H280 H331 H315 H319 H340 H350 H335			U
Dossier submitters proposal	200-849-9	ethylene oxide; oxirane	200-849-9	75-21-8	**Retain** Flam. Gas 1 Press. Gas Carc. 1B Muta. 1B STOT SE 3 **Add** Repr. 2 Acute Tox. 3 STOT RE 1 Skin Sens. 1 **Modify** Acute Tox. 3 Skin Corr. 1B Eye Dam. 1	**Retain** H220 H280 H350 H340 H335 **Add** H361fd H301 H372 (nervous system) H317 **Modify** H331 H314 H318	**Retain** GHS02 GHS08 GHS06 GHS04 Dgr **Add** GHS05	**Retain** H220 H280 H350 H340 H335 **Add** H301 H317 H372 (nervous system) H361fd **Modify** H331 H314 H318			**Retain** U
RAC opinion	200-849-9	ethylene oxide; oxirane	200-849-9	75-21-8	**Retain** Flam. Gas 1 Press. Gas Carc. 1B Muta. 1B STOT SE 3 **Add** Repr. 1B Acute Tox. 3 STOT SE 3 STOT RE 1 **Modify** Acute Tox. 3 Skin Corr. 1 Eye Dam. 1	**Retain** H220 H280 H350 H340 H335 **Add** H360Fd H301 H336 H372 (nervous system) **Modify** H331 H314 H318	**Retain** GHS02 GHS08 GHS06 GHS04 Dgr **Add** GHS05	**Retain** H220 H280 H350 H340 H335 **Add** H360Fd H301 H336 H372 (nervous system) **Modify** H331 H314			**Retain** U
Resulting Annex VI entry if	200-849-9	ethylene oxide; oxirane	200-849-9	75-21-8	Flam. Gas 1 Press. Gas Carc. 1B	H220 H280 H350	GHS02 GHS08 GHS06	H220 H280 H350			U

agreed by COM					Muta. 1B Repr. 1B Acute Tox. 3 Acute Tox. 3 STOT SE 3 STOT SE 3 STOT RE 1 Skin Corr. 1 Eye Dam. 1	H340 H360Fd H331 H301 H335 H336 H372 (nervous system) H314 H318	GHS04 GHS05 Dgr	H340 H360Fd H331 H301 H335 H336 H372 (nervous system) H314			

4. **dodecyl methacrylate**

	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 Annex VI entry	607-247-00-9	dodecyl methacrylate	205-570-6	142-90-5	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H319 H335 H315 H400 H410	GHS07 GHS09 Wng	H319 H335 H315 H410		STOT SE 3; H335: C ≥ 10%	
Dossier submitters proposal	607-247-00-9	dodecyl methacrylate	205-570-6	142-90-5	**Remove** Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	**Remove** H319 H335 H315 H400 H410	**Remove** GHS07 GHS09 Wng	**Remove** H319 H335 H315 H410		**Remove** STOT SE 3; H335: C ≥ 10%	
RAC opinion	607-247-00-9	dodecyl methacrylate	205-570-6	142-90-5	**Retain** STOT SE 3 **Remove** Eye Irrit. 2 Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	**Retain** H335 **Remove** H319 H315 H400 H410	**Retain** GHS07 Wng **Remove** GHS09	**Retain** H335 **Remove** H319 H315 H410		**Retain** STOT SE 3; H335: C ≥ 10%	
Resulting Annex VI entry if agreed by COM	607-247-00-9	dodecyl methacrylate	205-570-6	142-90-5	STOT SE 3	H335	GHS07 Wng	H335		STOT SE 3; H335: C ≥ 10%	

5. **disodium 4-amino-6-((4-((4-(2,4-diaminophenyl)azo)phenylsulfamoyl)phenyl)azo)-5-hydroxy-3-((4-nitrophenyl)azo)naphthalene-2,7-disulfonate (Acid Black 210 Na)**

	Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Classification**		**Labelling**			**Specific Conc. Limits, M-factors and ATE**	**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 Annex VI entry	611-159-00-6	disodium 4-amino-6-((4-((4-(2,4-diaminophenyl)azo)phenylsulfamoyl)phenyl)azo)-5-hydroxy-3-((4-nitrophenyl)azo)naphthalene-2,7-disulfonate	421-880-6	201792-73-6	Eye Dam. 1 Aquatic Chronic 3	H318 H412	GHS05 Dgr	H318 H412			
Dossier submitters proposal	611-159-00-6	disodium 4-amino-6-((4-((4-(2,4-diaminophenyl)azo)phenylsulfamoyl)phenyl)azo)-5-hydroxy-3-((4-nitrophenyl)azo)naphthalene-2,7-disulfonate	421-880-6	201792-73-6	**Remove** Eye Dam. 1 Aquatic Chronic 3	**Remove** H318 H412	**Remove** GHS05 Dgr	**Remove** H318 H412			
RAC opinion	611-159-00-6	disodium 4-amino-6-((4-((4-(2,4-diaminophenyl)azo)phenylsulfamoyl)phenyl)azo)-5-hydroxy-3-((4-nitrophenyl)azo)naphthalene-2,7-disulfonate	421-880-6	201792-73-6	**Remove** Eye Dam. 1 Aquatic Chronic 3	**Remove** H318 H412	**Remove** GHS05 Dgr	**Remove** H318 H412			
Resulting Annex VI entry if agreed by COM	611-159-00-6	disodium 4-amino-6-((4-((4-(2,4-diaminophenyl)azo)phenylsulfamoyl)phenyl)azo)-5-hydroxy-3-((4-nitrophenyl)azo)naphthalene-2,7-disulfonate	421-880-6	201792-73-6	Entry removed from Annex VI of CLP						

6. **nickel (II) sulphide [1]; nickel sulfide [2]; millerite [3]**

	Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Classification**		**Labelling**			**Specific Conc. Limits, M-factors, ATE**	**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	028-006-00-9	nickel (II) sulfide; [1] nickel sulfide; [2] millerite [3]	240-841-2 [1] 234-349-7 [2] -[3]	16812-54-7 [1] 11113-75-0 [2] 1314-04-1 [3]	Carc. 1A Muta. 2 STOT RE 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H372** H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H350i H341 H372** H317 H410			
Dossier submitters proposal	028-006-00-9	nickel (II) sulfide; [1] nickel sulfide; [2] millerite [3]	240-841-2 [1] 234-349-7 [2] -[3]	16812-54-7 [1] 11113-75-0 [2] 1314-04-1 [3]	**Add** Acute Tox. 4	**Add** H332	**Retain** GHS08 GHS07 GHS09 Dgr	**Add** H332			
RAC opinion	028-006-00-9	nickel (II) sulfide; [1] nickel sulfide; [2] millerite [3]	240-841-2 [1] 234-349-7 [2] -[3]	16812-54-7 [1] 11113-75-0 [2] 1314-04-1 [3]	-	-	-	-			**Lack of data**
Resulting Annex VI entry if agreed by COM	028-006-00-9	nickel (II) sulfide; [1] nickel sulfide; [2] millerite [3]	240-841-2 [1] 234-349-7 [2] -[3]	16812-54-7 [1] 11113-75-0 [2] 1314-04-1 [3]	Carc. 1A Muta. 2 STOT RE 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H372** H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H350i H341 H372** H317 H410			

7. nickel bis(sulfamidate); nickel sulfamate

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors, ATE	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	028-018-00-4	nickel bis(sulfamidate); nickel sulfamate	237-396-1	13770-89-3	Carc. 1A Muta. 2 Repr. 1B STOT RE 1 Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360D*** H372** H334 H317 H400 H410	GHS08 GHS09 Dgr	H350i H341 H360D*** H372** H334 H317 H410		STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,1 % ≤ C < 1 % Skin Sens. 1; H317: C ≥ 0,01 % M=1	H
Dossier submitters proposal	028-018-00-4	nickel bis(sulfamidate); nickel sulfamate	237-396-1	13770-89-3	**Add** Acute Tox. 4 Acute Tox. 4	**Add** H302 H332	**Add** GHS07	**Add** H302 H332		**Retain** STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,1 % ≤ C < 1 % Skin Sens. 1; H317: C ≥ 0,01 % M=1	**Retain** H
RAC opinion	028-018-00-4	nickel bis(sulfamidate); nickel sulfamate	237-396-1	13770-89-3	**Add** Acute Tox 4	**Add** H302	**Add** GHS07	**Add** H302		**Add** oral: ATE = 853 mg/kg bw (anhydrate) oral: ATE = 1098 mg/kg bw (tetrahydrate) **Retain** STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,1 % ≤ C < 1 % Skin Sens. 1; H317: C ≥ 0,01 % M=1	**Retain** H **Lack of data (inhalation)**
Resulting Annex VI entry if agreed by COM	028-018-00-4	nickel bis(sulfamidate); nickel sulfamate	237-396-1	13770-89-3	Carc. 1A Muta. 2 Repr. 1B Acute Tox 4 STOT RE 1 Resp. Sens. 1 Skin Sens. 1	H350i H341 H360D*** H302 H372** H334 H317	GHS07 GHS08 GHS09 Dgr	H350i H341 H360D*** H302 H372** H334 H317		oral: ATE = 853 mg/kg bw (anhydrate) oral: ATE = 1098 mg/kg bw (tetrahydrate)	H

					Aquatic Acute 1 Aquatic Chronic 1	H400 H410		H410		STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,1 % ≤ C < 1 % Skin Sens. 1; H317: C ≥ 0,01 % M=1	

8. **cobalt metal**

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	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 Annex VI entry	027-001-00-9	cobalt	231-158-0	7440-48-4	Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 4	H334 H317 H413	GHS08 Dgr	H334 H317 H413			
Dossier submitters proposal	027-001-00-9	cobalt	231-158-0	7440-48-4	**Retain** Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 4 **Add** Carc. 1B Muta. 2 Repr. 1B	**Retain** H334 H317 H413 **Add** H350 H341 H360F	**Retain** GHS08 Dgr	**Retain** H334 H317 H413 **Add** H350 H341 H360F		**Add** Carc. 1B; C ≥ 0,01 %	
RAC opinion	027-001-00-9	cobalt	231-158-0	7440-48-4	**Retain** Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 4 **Add** Carc. 1B Muta. 2 Repr. 1B	**Retain** H334 H317 H413 **Add** H350 H341 H360F	**Retain** GHS08 Dgr	**Retain** H334 H317 H413 **Add** H350 H341 H360F		**Add** Carc. 1B; C ≥ 0,01 %	
Resulting Annex VI entry if agreed by COM	027-001-00-9	cobalt	231-158-0	7440-48-4	Carc. 1B Muta. 2 Repr. 1B Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 4	H350 H341 H360F H334 H317 H413	GHS08 Dgr	H350 H341 H360F H334 H317 H413		Carc. 1B; H350: C ≥ 0,01 %	

9. **Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs**

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	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	TBD	Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs.	308-208-6	97925-95-6	Repr. 1B, H360D	H360D	GHS08 Dgr	H360D	-	-	-
RAC opinion	TBD	Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs.	308-208-6	97925-95-6	Repr. 1B, H360D	H360D	GHS08 Dgr	H360D	-	-	-
Resulting Annex VI entry if agreed by COM	TBD	Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs.	308-208-6	97925-95-6							

Part III. List of Attendees of the RAC-42 meeting

18-22 September 2017

RAC Members
AGAPIOU Agapios
ANDREOU Kostas
AQUILINA Gabriele
BARAŃSKI Bogusław
BIRO Anna
BJØRGE Christine
BRANISTEANU Radu
CARVALHO João
CHANKOVA-PETROVA Stephka
CHIURTU Elena (co-opted Member)
CZERCZAK Slawomir
DE LA FLOR TEJERO Ignacio
DUNAUSKIENĖ Lina
DUNGEY Stephen
GRUIZ Katalin
GUSTAFSON Anne-Lee
HAKKERT Betty
HÖLZL Christine
HUSA Stine
JANKOWSKA Elżbieta (co-opted Member)
KADIĶIS Normunds
KAPELARI Sonja
LEINONEN Riitta
LUND Bert-Ove
MENARD Anja
MOELLER Ruth
MULLOOLY Yvonne
MURRAY Brendan
NEUMANN Michael
PARIS Pietro
POLAKOVICOVA Helena
PRINTEMPS Nathalie
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SANTONEN Tiina
SCHLÜTER Urs
SCHULTE Agnes
SMITH Andrew
SOGORB Miguel
SØRENSEN Peter Hammer
SPETSERIS Nikolaos
STAHLMANN Ralf
TOBIASSEN Lea Stine
UŽOMECKAS Žilvinas
VAN DER HAAR Rudolf (co-opted Member)
VARNAI Veda Marija
VIEGAS Susana (co-opted Member)
Apologies, Members
ILIE Mihaela
LECLOUX Helene
MARTINEK Michal
TSITSIMPIKOU Christina

Commission observers	MIKANDER Nina, UNEP/AEWA
BINTEIN Sylvain, DG ENV	ROWE Rocky, ECPA
MORRIS Alick, DG EMPL	VEROUGSTRAETE Violaine, Eurometaux
ROZWADOWSKI Jacek, DG GROW	
VAN DER JAGT Katinka, DG ENV	**Dossier submitters**
RAC advisors	ROUW Aarnout (DE, diisocyanates)
BORG Daniel (Anne-Lee Gustafson)	TAYLOR Mike (Nickel Consortia/Terrafame, Umicore, nickel bis(sulfamidate) and nickel sulphide
JANKOWSKA Agnieszka (Slawomir Czerczak)	WALENDZIK Gudrun (DE, diisocyanates)
LOIKKANEN Jarkko (Riitta Leinonen)	
PAPPONEN Hinni (Riitta Leinonen)	**Invited experts**
PECZKOWSKA Beata (Boguslaw Baranski)	GREEN Owen (consultant, Art 77 acrylonitrile)
ROMOLI Debora (Pietro Paris)	HYNES Jarlath (consultant, EcoMole Ltd, dose-response)
STOCKMANN-JUVALA Helene (Tiina Santonen)	KOLOSSA GEHRING Marike (UBA, EU Human Biomonitoring Project)
SUUTARI Tiina (Riitta Leinonen)	
TALASNIEMI Petter (Riitta Leinonen)	RUMSBY Paul (consultant, Art 77 acrylonitrile)
UUKSULAINEN Sanni (Tiina Santonen)	STUTT Ed (consultant, Art 77 acrylonitrile)
Stakeholders observers	
ANNYS Erwin, Cefic	
BARRY Frank, ETUC	
BERNARD Alice, ClientEarth (occasional stakeholder observer)	
DE KORT Patrick, EUPC (occasional stakeholder observer)	
DOLORES Romano, EEB	
JANOSI Amaya, Cefic	

Industry experts
BINKS Steve (Eurometaux, International Lead Association, lead in PVC, lead in shot)
BOENIGK Winfried (Cefic, Rütgers Group, CTHPT´s)
BOOGAARD Peter (Cefic, Shell International B.V.)
CROMIE Ruth (Wildfowl & Wetlands Trust (WWT))
DANZEISEN Ruth (Eurometaux, The Cobalt Development Institute (CDI), cobalt metal)
JUPE Gaelle (ECPA, Nissan, halosulfuron-methyl)
KELLY Craig (Cefic, TSGE Consulting, acrylonitrile)
LAWSON Jane (Cefic, Croda Plc, ethanol)
LÜCKE-BRUNK Gudrun (Cefic, Covestro Deutschland AG, diisocyanates)
MOORE Nigel (ECPA, Lonza, metaldehyde toxicology part)
OLLER Adriana (Eurometaux, NiPERA Inc, CLH sulphine/sulphamate and CMD/CAD nickel)
PALMERSTEIN Jörg (EuPC, ISOPA, diisocyanates)
SCHOLTZ Rudolf (ECPA, Lonza, metaldehyde exotoxicology part)

REMOTE PARTICIPANTS
RAC advisers
GUICHELAAR Samantha (Betty Hakkert)
MÜLLER Andre (Betty Hakkert)
SEBA Julie (Hélène Lecloux)
SEAC Members (AfA and restriction rapporteurs)
KIISKI Johanna
KRAJNC Karmen
LUEDEKE Andreas
NORING Maria
THIELE Karen
Dossier submitters
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DROSSARD Claudia (Diisocyanates)
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HELLER-HUTORAN Svetlana (diisocyanates)
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GARCIA-JOHN Enrique		REUTER Ulrike
GUTIERREZ-MEDINA Miriam		RHEINBERGER Christoph
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BOWMER Tim, Chairman		UPHOFF Andreas
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ERICSSON Gunilla		
HELLSTEN Kati		
HOPLAND Eivind		
JONES Stella		
KANELLOPOULOU Athanasia		
KARJALAINEN Antti		
KARJALAINEN Ari		
KIVELÄ Kalle		
KOKKOLA Leila		
KOSK-BIENKO Joanna		
LIOPA Elina		
LOGTMEIJER Christiaan		
LUDBORŽS Arnis		
LUSCHUTZKY Evita		
MARQUEZ-CAMACHO Mercedes		
MAZZOLINI Anna		
MERKOURAKIS Spyridon		
MUSHTAQ Fesil		
MÜLLER Gesine		
NATHANAIL Alexis		
ORISPÄÄ Katja		
O´ROURKE Regina		
PELTOLA Jukka		

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-42 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-42 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-42 meeting

ANNEX IV Administrative issues and information items

18 September 2017
RAC/A/42/2017

Final Agenda
42nd meeting of the Committee for Risk Assessment

18-22 September 2017

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 18 September starts at 09.00
Friday 22 September ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/42/2017
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Appointment of (co-)rapporteurs

a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95(3) requests and Article 77(3)(c) requests

RAC/42/2017/01
(restricted)
Room document
For agreement

Item 5 – Report from other ECHA bodies and activities

a) Report on RAC 41 action points, written procedures and update on other ECHA bodies

RAC/42/2017/02

RAC/42/2017/03
Room document
For information

b) RAC workplan for all processes

For information

c) Annual update of RAC accredited stakeholders' list

RAC/42/2017/04
(restricted)
For agreement

Item 6 – Requests under Article 77(3)(c)

6.1 General issues

d) Interim working procedure on the evaluation of occupational exposure limits and other values in support of Carcinogens and Mutagens Directive requests from the Commission via the Executive Director

RAC/42/2017/05
For discussion/agreement

6.2 Dossiers occupational exposure- opinion development

a) Nickel and its compounds
b) Benzene
c) Acrylonitrile

For discussion

Item 7 – Requests under Article 95 (3)

a) Methodology related to the exposure of chemicals at the workplace in relation to non-threshold substances

For information and discussion

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CLH issues

8.2 CLH dossiers

A. Hazard classes for agreement without plenary debate (fast-track)

1. halosulfuron-methyl (ISO): physical hazards, acute toxicity (all routes of exposure), STOT SE, skin corrosion / irritation, serious eye damage / eye irritation, respiratory or skin sensitisation, STOT RE, carcinogenicity, germ cell mutagenicity, aspiration hazard, environmental hazards
2. metaldehyde: acute toxicity (all routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, STOT SE, germ cell mutagenicity, toxicity to reproduction

3. ethylene oxide, oxirane: acute toxicity (oral and inhalation), serious eye damage / eye irritation, respiratory sensitisation

B. Hazard classes for agreement with plenary debate

~~1. titanium dioxide (may be removed if adopted by written procedure)~~

2. ethylene oxide, oxirane
3. ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl)derivatives
4. Acid Black 210 Na
5. cobalt metal
6. metaldehyde
7. halosulfuron-methyl (ISO)
8. nickel (II) sulphide [1]; nickel sulphide [2]; millerite [3]
9. nickel bis(sulfamidate)
10. dodecyl methacrylate

For discussion and adoption

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

a) Opinion development
   1) Diisocyanates – second draft opinion
   2) Lead and lead compounds in PVC – second draft opinion
   3) Lead and lead compounds in shot – first draft opinion

For discussion

Item 10 – Authorisation

10.1 General authorisation issues

a) Update on incoming/future applications

For information

b) Report ECHA workshop on 'Application for Authorisation for environmental endocrine disruptors'

For information

c) Working procedure on carcinogenicity dose-response relationships and DNEL setting for reprotoxic properties

RAC/42/2017/06
For discussion/agreement

d) AfA DNEL/DR: Carcinogenicity dose-response relationship development of:

1. Coal tar pitch, high temperature (CTPHT)
2. Anthracene oil

RAC/42/2017/07
For discussion/agreement

e) Status update

1. CT_Hapoc (4 uses), CT_Hapoc_2 (1 use), CT_Hapoc_3 (1 use), SD_Hapoc (1 use)

For information

10.2. Authorisation applications

a) Discussion on key issues
   1. EDC_Microbeads (1 use)
   2. CT_ZFF (1 use)
   3. SC_Wesco (1 use)
   4. DtC_Wesco (1 use)
   5. PCO_Aviall (2 uses)

For discussion

b) Agreement on draft opinions
   1. EDC_Olon (2 uses)

For discussion and agreement

c) Adoption of final opinions
   1. SD_Borealis (1 use)

For discussion and adoption

Item 11 – AOB

a) EU Human Biomonitoring Project: HBM4EU

For information and discussion

Item 12 – Action points and main conclusions of RAC-42

Table with Conclusions and Action points from RAC-42

For adoption

Annex II (RAC 42)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 42 meeting.

Document number	Title
RAC/A/42/2017	Final Draft Agenda
RAC/A/42/2017 Restricted	Draft outline agenda
RAC/42/2017/01 Restricted room document	Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95 (3) requests and Article 77 (3) requests
RAC/42/2017/02	Report from other ECHA bodies
RAC/42/2017/03 Room document	Administrative issues
RAC/42/2017/04	Annual update of RAC accredited stakeholders´ list
RAC/42/2017/05	Article 95(3): Interim working procedure on the evaluation of occupational exposure limits and other values in support of Carcinogens and Mutagens Directive requests from the Commission via the Executive Director
RAC/42/2017/06	AfA dose response and DNEL: Working procedure on carcinogenicity dose-response relationships and DNEL setting for reprotoxic properties
RAC/42/2017/07	AfA DNEL/DR: Carcinogenicity dose-response relationship – development of coal tar pitch, high temperature (CTPHT) and anthracene oil

ANNEX III (RAC-42)

The following participants, including those for whom the Chairman declared the interest on their behalf, 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 PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLÜTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Harmonised classification & labelling		
-	-	-
Requests under Article 77(3) (c)		
Nickel and its compounds	-	-
Benzene	-	-
Acrylonitrile	-	-
Restrictions		
Diisocyanates **(DE)**	Agnes SCHULTE	Working for the CA submitting the dossier and involved in the preparation; asked to refrain from voting in the event of a vote on this substance - other mitigation measures may be applied by the Chairman.
	Norbert RUPPRICH	Working for the CA submitting the dossier; and involved in the preparation; asked to refrain from voting in the event of a vote on this substance - other mitigation measures may be applied by the Chairman.
	Urs SCHLÜTER	Working for the CA submitting the dossier and involved in the preparation; asked to refrain from

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		voting in the event of a vote on this substance - other mitigation measures may be applied by the Chairman.
	Michael NEUMANN	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		
Article 77.3(c)		
-	-	-
Restrictions		
Lead in gunshot	-	-
Applications for Authorisation		
-	-	-
Harmonised classification & labelling		
1) **Halosulfuron-methyl (ISO)** 2) **Acid Black 210 Na** **IT**	Pietro PARIS	Working for the CA submitting the dossier, but not involved in the submission of these dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Gabriele AQUILINA	Working for the CA submitting the dossier, but not involved in the submission of these dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
1) **Metaldehyde** 2) **Ethylene oxide, oxirane** **AT**	Christine HÖLZL	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.
	Sonja KAPELARI	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.
1) **Cobalt metal** 2) **Ethanol, 2,2'-iminobis-, N-(C13-15-branched and**	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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
linear alkyl) derivs. **NL**	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.
Dodecyl methacrylate **DE**	Agnes SCHULTE	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.
	Norbert RUPPRICH	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.
	Urs SCHLÜTER	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.
	Michael NEUMANN	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.

Annex IV

Helsinki, 14 September 2017

RAC/42/2017/03

ROOM DOCUMENT

42ND MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

18 – 22 September 2017

Helsinki, Finland

Concerns: **Administrative issues and information items**

Agenda Point: **5a**

Action requested: **For information**

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-41 Action Points

The RAC-40 action points due for RAC-42 are completed.

2 Outcome of written procedures & other consultations

2.1 Written procedures for adoption of RAC opinions / minutes of the meeting

Opinions / minutes adopted via written procedure	Deadline	Report on the outcome
Written procedure for adoption of the minutes of RAC-41	11 September 2017	closed

2.2 RAC consultations (status by 11 September 2017)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
Halosulfuron-methyl (ISO)	17 August 2017	closed
Metaldehyde (ISO)	21 August 2017	closed
Ethylene oxide, oxirane	10 July 2017	closed
Dodecyl methacrylate	18 August 2017	closed
disodium 4-amino-6-((4-((4-(2,4-diaminophenyl)azo)phenylsulfamoyl)phenyl)azo)-5-hydroxy-3-((4-nitrophenyl)azo)naphthalene-2,7-disulfonate Acid Black 210 Na	11 August 2017	closed
nickel (II) sulfide; [1] nickel sulfide; [2] millerite [3]	2 August 2017	closed
nickel bis(sulfamidate); nickel sulfamate		
Cobalt metal	22 August 2017	closed
Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs.	2 August 2017	closed
Titanium dioxide – RAC consultation on the REVISED opinion (agreed at RAC 41)	25 August 2017	closed
Application for Authorisation		
EDC_Olon Consultation on draft opinions	6 September 2017	closed
SD_Borealis Consultation on final opinion	5 September 2017	closed
EDC_Microbeads Consultation on application	4 October 2017	open

Subject / document	Deadline	Status / follow-up
CT_ZFF Consultation on application	4 October 2017	open
SC_Wesco Consultation on application	4 October 2017	open
DtC_Wesco Consultation on application	4 October 2017	open
PCO_Aviall Consultation on application	4 October 2017	open
Restrictions		
Consultation on first draft opinion on lead in shot	25 September 2017	open
Consultation on second draft opinion on lead in PVC	11 September 2017	closed
Consultation on second draft opinion on diisocyanates	12 September 2017	closed
Art. 77. 3. c request on evaluations OELs		
Nickel and its compounds	27 September 2017	open
Benzene	27 September 2017	open
Acrylonitrile	27 September 2017	open

2.3 Other written consultations of RAC (status by 11 September 2017)

Subject / document	Deadline	Status / follow-up
Consultation the draft minutes of RAC-41	3 August 2017	closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
Harmonised classification and labelling		
Call for expression of interest in rapporteurship for one CLH dossier	29 June – 6 July 2017	Three volunteers expressed their interest
Call for expression of interest in rapporteurship for CLH dossiers / new intentions	2 – 17 August 2017	Four volunteers expressed their interest – appointments to be done at RAC 42
Application for Authorisation		
Call for expression of interest in rapporteurship on applications for authorisation on SVHCs in 12 new entries in Annex XIV of the REACH Regulation. Full list of the new entries is published in		

Annex of the Commission Regulation (EU) 2017/999[9].
Restriction – no calls

2.5 Written procedures for the appointment of (co-)rapporteurs

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
Harmonised classification and labelling			
Written procedure for the appointment of (co-)rapporteurs	▪ methyl benzimidazol-2-ylcarbamate;carbendazim (ISO) ▪ sulphur dioxide	19 July 2017	closed No comments were received from RAC Members on the recommendation of the Chairman; the RAC (co-)Rapporteur was appointed with tacit agreement.
Applications for Authorisation– no written procedures			
Restrictions – no written procedures			

2.6 Follow-up on the opinions on applications for authorisation agreed by RAC and SEAC

Opinion(s)	Sent on
Opinions sent to the European Commission, the Member States and Applicants	
CT_Reachlaw (4 opinions) EDC_Biotech (1 opinion)	30 May 2017
CT_Cryospace (1 opinion) EDC_Akzo (1 opinion) EDC_ORGAPHARM (2 opinions)	8 June 2017
AD_BAE (2 opinions)	9 June 2017
CT_Clariant (1 opinion)	16 June 2017
Diglyme_LifeTechn (1 opinion) Diglyme_ROCHE (1 opinion)	21 June 2017
Diglyme_ISOCHEM (1 opinion)	29 June 2017

[9] Commission Regulation (EU) 2017/999 of 13 June 2017 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Opinion(s)	Sent on
SD_Colle (1 opinion)	11 July 2017
EDC_Bayer (1 opinion)	4 August 2017
CT_Hansgrohe (2 opinions)	29 August 2017
CT_ZFL (2 opinions) SD_ZFL (1 opinion)	11 September 2017