RAC/M/39/2016
Final
21 February 2017
Amended 16 May 2017 (point 7.2.C.a)

Minutes of the 39th Meeting of the Committee for Risk Assessment (RAC-39)

28 November starts at 14.00
2 December breaks at 13.00
7 December resumes at 9.00
9 December ends at 13.00

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 39th meeting of the Committee for Risk Assessment (RAC-39). Apologies were received from three Members. The Chairman welcomed an invited expert, whose mandate as a RAC Member will start on 17 December 2016.

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 form the 38th 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/39/2016). The Committee agreed that the following items proposed by the secretariat by the Secretariat could be added to the agenda:

a) agreement on the draft opinions for two AfA applications -Technical MDA_Polynt (2 uses) and EDC_Eurenco (1 use);

b) A first discussion on the possibility of deriving Dose Responses for repro-toxic substances such as diglyme to make health impact assessment possible

c) A short report from the authorisation rapporteurs workshop held on the morning of 28 November;

d) The addenda prepared by the Secretariat and Rapporteurs at the Commission's request to ECHA for clarification on the Dow (Blue-Cube) TCE 2a Use 2, Entek and Microporous TCE applications, are tabled for discussion and agreement by RAC.

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. No points were raised under any other business.

3. Declarations of conflicts of interests to the Agenda

The Chairman requested all participants to declare any potential conflicts of interest related to any of the agenda items. 16 Members declared potential conflicts of interest, each to specific agenda items, the majority related to concurrent employment of Members at agencies submitting dossiers 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. Report from other ECHA bodies and activities

a) Report on RAC 38 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-38 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/39/2016/01). The summary of all consultations, calls for expression of interest in rapporteurships and written procedures 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-38 had been adopted via written procedure and were uploaded to s-CIRCABC and will be published on the ECHA website, and thanked those Members who had provided comments on the draft.

b) RAC workplan for all processes

The Chairman presented the updated RAC work-plan for Q1-Q3/2017, covering the three processes of Restriction, Authorisation and Harmonised Classification and Labelling of substances. He informed Members that they could find the expected schedules for Restriction and Authorisation dossiers in the work plan. In addition, the scheduling and the endpoints to be considered for each Harmonised Classification and Labelling (CLH) dossier for the next two meetings ahead are given in the relevant section, including those for human health and the environment.

5. Requests under Article 77 (3)(c)

There are no items under this agenda point currently.

6. Requests under Article 95 (3)

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

The Chairman mentioned that the draft review paper of the RAC Members of the joint RAC-SCOEL Working Group was agreed at RAC-36 in March 2016. The draft re-analysis, taking into account the SCOEL recommendation on NMP of March 2016, was reconfirmed at its 37th meeting in June.

Following discussions with the European Commission on 17 November 2016, the joint Working Group on NMP was informed that the deadline for completion of the joint report on NMP was within 10 working days.

The Chairman explained that the RAC text of the draft final version of the joint opinion (RAC/39/2016/03 restricted document) represents the views of the RAC Members of the joint Working Group on NMP, which have not changed since the earlier agreements at RAC 36 and RAC-37 (RAC/39/2016/03 restricted document). The SCOEL part was still to be inserted, as it was received only on Monday, 28 November 2016. A final version of the joint opinion will be forwarded to the Commission by (Wednesday, 30 November 2016 and will be published on ECHA's website.

The RAC Members expressed concern that the SCOEL-text (received on Monday, 28 November 2016) contains SCOEL's interpretation of RAC's consideration did not formed part of the joint

ECHA/RAC-SCOEL review and does not reflect RAC's views, considerations or conclusions which are correctly presented in the 'joint section' at the beginning of the document. It was agreed to add a note to the reader in the final joint opinion to address this concern.

The Commission thanked the RAC Members of the Working Group for the work performed and acknowledged the efforts made to find a resolution of the different opinions. Although the joint opinion reflected the different views of both Committees, the Commission would take it forward to discuss at a policy level.

The Chairman thanked the RAC Members of the joint Working Group on the task performed.

b) OEL-DNEL methodology request

The Chairman mentioned that the mandate to create a Joint Task Force with SCOEL for the comparative critical assessment of REACH-DNEL and SCOEL-OEL methodologies a) for the inhalation route and b) for dermal route, including 'skin notation' and dermal DNEL was distributed to RAC Members in December 2015.

RAC Members were informed by the Secretariat that after the first discussions by the RAC-SCOEL Task Force, which took place at the meetings on 22 July and 23 August 2016, the RAC-Members of the Joint Task Force further elaborated their part of the joint report on comparative assessment of DNEL-OEL methodologies for the inhalation and the dermal route. These views were jointly discussed with SCOEL Members only recently at the Joint Task Force meeting on 17 November. Following discussions with COM on the same day (17 November 2016), the Joint Task Force was informed that the deadline for completion of the joint report on task 1 and task 3 of the mandate (inhalation and dermal route) is now set for the end of February 2017. To meet this deadline, two further joint TF meetings are scheduled for 14 December 2016 and 18 January 2017.

The Secretariat mentioned that the draft report (RAC/39/2016/04-restricted) of the Joint ECHA/RAC-SCOEL Task Force on DNEL-OEL methodology is an interim version to inform the RAC Members of the status of the discussions and the progress made. The text represents only the preliminary views the RAC Members of the Joint Task Force.

7. Harmonised classification and labelling (CLH)

7.1 General CLH issues

The Secretariat gave an update on the ECHA internal work on dealing with weight of evidence and uncertainty in hazard evaluations and risk assessments and provided an overview of existing frameworks and similar approaches by other organisations to ensure harmonisation of methods. In relation to reporting of weight of evidence through a standardised template, one RAC Member noted that CLP dossiers were too diverse to follow such a standardised approach. Another RAC Member emphasised that transparency was key, and that therefore any evidence should be clearly documented. Members questioned whether a dedicated weight of evidence template was needed in RAC with respect to CLP. ECHA noted that the aim is to assist various ECHA processes, on a case by case basis to perform and present Weight of Evidence data in a flexible manner; ECHA acknowledged that such an approach would not be mandatory or even needed for all types of assessments.

In a second presentation, the Secretariat introduced the Committee to an ECHA project on the regulatory applicability of alternative and non-animal approaches (ANAA) to testing under REACH, CLP and the Biocides Regulation (ANAA project/report). The Secretariat reported that the aims of the project were 1) to review the state-of-the-art of the subject; 2) to provide

comprehensive and independent scientific assessment of the current situation of the regulatory applicability of alternative and non-animal approaches, their implementation in practice, and potential obstacles to their use.

Some Members stressed the continued need for high quality animal studies as the basis for an appropriate hazard assessment of dossiers for harmonised classification and labelling by RAC. Other Members reflected on the need for proper consideration and appropriate coordination with the OECD activities on this topic. The presenter invited RAC to provide comments on the draft ANAA report. Several RAC Members asked the Secretariat to clarify the scope of the report, and prioritise the issues on which the Secretariat expected comments. The Commission representative noted the relevance of the ANAA project to the discussions which would be taking place in the upcoming biennium on alternatives to animal testing under the UN GHS.

7.2 CLH dossiers

A. Hazard classes for agreement without plenary debate[1] (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 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

a) 1-vinylimidazole

The Chairman welcomed the Dossier Submitter's representative from BASF and reported that 1-vinylimidazole is used only in industrial settings as a monomer for further polymerisation. The polymerised products are used in several applications including lubricant, coating additive, emulsifier, polymer for metal ion filtration and in both home and personal care applications.

1-vinylimidazole has no existing entry in Annex VI to the CLP Regulation and the DS proposed to classify the substance as Repr. 1B (H360D). The legal deadline for the adoption of an opinion is 10 July 2017.

RAC supported the DS proposal to classify 1-vinylimidazole in category 1B for developmental effects based on clear evidence of adverse effects – perinatal mortality and aneurysm of the great vessels in the heart - in a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rat.

In addition, the discussion focused on (the need of) setting an SCL. The Rapporteurs presented their proposal for setting an SCL in view of the relatively low ED_{10} values for relevant effects, and consideration of i) the lower power of the screening test and ii) the type of effects and their severity, which are modifying factors to be considered according to the Guidance on the application of the CLP criteria. Based on that they proposed that 1-vinylimidazole clearly fell within a higher potency group and should be assigned an SCL of 0.03% (in comparison to a GCL of 0.3%). It was then clarified that RAC can set SCLs in the absence of a proposal where relevant evidence is available; this was done in earlier cases. In conclusion, the Committee agreed that for 1-vinylimidazole an SCL following a weight of evidence analysis of the type and severity of the effects leading to the agreed classification can be proposed. RAC supported the Rapporteurs' proposal for an SCL of 0.03%.

[1] 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 Committee.

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

b) Colecalciferol; vitamin D_3

The Chairman welcomed two experts accompanying the Cefic and the ECPA stakeholder observers, as well as the Dossier Submitter's representative from Sweden who followed the debate remotely. He reported that colecalciferol ("vitamin D_3") was intended to be used in the context of Regulation (EC) No 528/2012 as a rodenticide (PT 14). Further to this, he noted that the substance was orally consumed by humans.

Colecalciferol was discussed for the first time in a RAC plenary meeting; the legal deadline for adoption of an opinion is 12 July 2017. The substance already has an existing entry in Annex VI to CLP where it is classified as Acute Tox. 3* (H301 and H311, minimum classifications), Acute Tox. 2* (H330, minimum classification) and as STOT RE 1 (H372**). The DS (Sweden) proposed the following changes to the Annex VI entry: ***Modify*** Acute Tox. 2 for all routes (H300, H310, H330), STOT RE 1 (H372) with an SCL of ≥ 0.6 % for STOT RE 1 and 0.06 % < C < 0.6 % for STOT RE 2; ***Add*** Carc. 2 (H351) and Muta. 2 (H341).

The Chairman recalled that the Committee had already agreed on Acute Tox. 2 for the dermal and the inhalation route as well as on no classification for STOT SE via the fast-track procedure and therefore, the plenary discussions should focus on acute oral toxicity, STOT RE, germ cell mutagenicity, carcinogenicity and reproductive toxicity (effects on fertility and development).

In relation to acute oral toxicity, the Rapporteur proposed classification based on a study with Wistar rats and efficacy tests: The LD_{50} to be used for classification, namely 35 mg/kg bw in males and 47 mg/kg bw in females, fall within the range for category 2 (5 < ATE ≤ 50 mg/kg). The LD_{50} values are supported by the results from rodenticide efficacy tests. The Committee agreed to this and agreed on a classification as Acute Tox. 2 (H300) for colecalciferol.

In relation to specific target organ toxicity after prolonged/repeated exposure (STOT RE), the Committee confirmed that classification as STOT RE 1 (H372) was justified on the basis of the outcome of a 90-day repeated-dose study in rats where effects were seen below the relevant guidance value (C ≤ 10 mg/kg bw/day). As to the setting of a specific concentration limit, the DS proposed 0.6%, based on a LO(A)EL of 0.06 mg/kg/d reflecting increased blood calcium concentration (4%) and microscopic changes in the kidneys. However, as adverse effects in the aorta, heart, kidney and bones were present in the majority of animals at 0.3 mg/kg bw/d, RAC decided to assign an SCL of 3% to category 1 and 0.3 for category 2.

In relation to mutagenicity, the Rapporteurs proposed not to classify colecalciferol as the condition 'other *in vivo* somatic cell genotoxicity tests which are supported by positive results from *in vitro* mutagenicity assays' as stated in the CLP Regulation was not fulfilled with the weakly positive Comet assay alone. More specifically, no clear positive *in vitro* test was available. A positive result reported in a bacterial gene mutation assay was considered irrelevant due to a lack of reproducibility in other point mutation tests. In addition, the occurrence of precipitation at the relevant test concentrations were observed. Two mammalian cell tests (mouse lymphoma assay and chromosomal aberration test) were negative. RAC concluded that the results from *in vitro* testing indicate a weak positive indication for point mutations. No indication was observed for structural aberrations. An *in vivo* mutagenicity test (micronucleus test) was clearly negative. The positive result of the *in vivo* Comet assay (indicator test) was questioned by RAC as only a weak increase in Tail Intensity (TI) was observed in the liver of rats at maximum tolerated doses (MTD) and without a dose-dependency. No such increase in TI was seen in the duodenum. RAC noted that it cannot be excluded that the weakly increased TI was induced by a liver specific

secondary mechanism. Overall, the results from *in vivo* testing confirm no indications for structural aberrations.

RAC considers that cholecalciferol, taking the weight of the evidence into account, does not meet the criteria for mutagenicity classification as defined in the regulation. The condition 'other in vivo somatic cell genotoxicity tests which are supported by positive results from in vitro mutagenicity assays' is not fulfilled with the weakly positive Comet assay alone. This view was shared by RAC and no classification was agreed for germ cell mutagenicity.

In relation to carcinogenicity, it was recognised that overall, there was an indication of carcinogenic potential of colecalciferol while there was insufficient evidence for classification. This conclusion was based on the lack of a good-quality standard two-year carcinogenicity study. The only study available was carried out for 26 weeks on a limited number of animals per group (10/group), only male rats were tested, giving an unclear dose-response relationship and a weak evidence of oncogenic potential. There were no findings of malignant tumours. Also, the role of hypercalcaemia in tumour generation appeared uncertain. Therefore, the Committee agreed on no classification of colecalciferol for carcinogenicity due to insufficient information available.

In relation to effects on fertility, RAC agreed with the Dossier Submitter not to assign a classification, taking into account that there was no robust information showing that effects on fertility parameters have been carefully investigated in a relevant dose range.

In relation to developmental effects, RAC concluded that the human data found in different reviews could not be considered sufficiently robust to support an accurate assessment of whether the intrinsic properties of the substance fulfil the criteria for classification. It was stressed that the information available was scarce while confounding factors could not be excluded. Moreover, information was restricted to effects of doses in the supplement range and to an exposure duration covering only a part of the gestation period.

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

c) Asulam sodium

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that asulam sodium is a herbicide, which is effective against annual and perennial weeds. It has no existing entry in Annex VI to the CLP Regulation and the DS (UK) proposed to classify the substance as Skin Sens 1 (H317) and for environmental hazards as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with an M-factor of 1 for both endpoints. The legal deadline for the adoption of an opinion is 12 November 2017.

RAC supported the DS proposal for no classification for all human health hazards but skin sensitisation. The proposed environmental classification was supported and agreed by the Committee via the fast track procedure.

The Committee briefly discussed the proposal to classify asulam sodium for skin sensitisation and supported classification in category 1 without sub-categorisation as the data available did not allow for sub-categorisation (sufficiently low intradermal induction concentrations were not tested).

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

d) Potassium permanganate

The Chairman welcomed the representative accompanying the Cefic stakeholder observer and reported that potassium permanganate was a highly oxidative agent, its primary uses are in control of odour and taste, remove of colour, control of biological growth and remove of iron and manganese. It is used by industrials, professionals and consumers as a laboratory and water treatment chemical in various sectors. It has an existing entry in Annex VI to the CLP Regulation as Ox. Sol. 2 (H272), minimum classification for acute toxicity via oral route of exposure (Acute Tox. 4* (H302) and for aquatic hazards (Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410)).

The DS (FR) proposed to add harmonised classification for toxicity to reproduction (Repr. 1B (H360Df)); the legal deadline for the adoption of an opinion is 15 May 2017.

The Committee discussed the proposal for classification for fertility based on the effects observed in a one-generation study in Wistar rats (decreased fertility and gestation index, and reduced number of dams with live pups and number of born pups at the highest dose) and in two 28-day studies (oral and dermal routes of exposure). In the discussion, some Members pointed out that the effects on fertility (in the one-generation study) were observed at the highest dose (320 mg/kg bw/day), in parallel with severe general toxicity namely decreased body weight (males) and food consumption (males and females), pronounced corrosive effects on gastrointestinal tract (i.e. erosion, ulceration and inflammation; males and females). In the presence of such severe general toxicity it is difficult to assess fertility effects. Due to the limited information on fertility effects of potassium permanganate, information on fertility and sexual function of other manganese compounds was provided for comparison. The industry expert concurred with the comments by Members and suggested that the highest dose effects should be disregarded. In addition, the industry representative reminded the Committee about neurotoxic effects of manganese compounds which could also affect fertility; at the same time no data / no dose-response is known for potassium permanganate itself, as it is not tested due to its high corrosivity. The Committee agreed on no classification for sexual function and fertility due to concurrent severe general toxicity observed at the highest dose.

In a one-generation reproductive toxicity study in rat, effects on the pup brain were the main finding, including increased weight and marked vacuolisation of cell nuclei in cortex and / or hippocampus in all dose groups with increasing severity with increasing dose, reaching statistical significance in the two highest dose groups. Biological significance of this effect could not be concluded on as no functional tests were performed in pups (the pups were killed on PND 21). RAC noted that neurotoxicity is also reported for other manganese compounds. In the developmental toxicity study, an increase in post-implantation losses and resorptions was observed in the highest dose. In this study the maternal toxicity included a statistically significant decrease in body weight, however, only marginal decrease in corrected body weight gain, and several clinical signs and severe microscopic changes in the stomach in the high dose group. In the discussion, Members pointed out the limitations of the developmental toxicity study (lack of statistical analysis, no historical control) and that no developmental neurotoxicity study was available; in general they supported classification in category 2 for developmental toxicity based on the evidence from the two studies and with the suspected developmental neurotoxicity seen for other manganese compounds as supporting evidence.

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

e) XTJ-568; reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-({[2-(2-aminobutoxy)ethoxy]methyl}propoxy)but-2-ylamine

The Chairman reported that XTJ-568 was a polyetherdiamine of approximately 220 molecular weight. It is designed to be a slower epoxy curing agent than conventional polyetheramines for applications such as fabrication of large composite parts where longer pot life is desirable.

XTJ-568 was discussed for the first time in a RAC plenary meeting; the legal deadline for adoption of an opinion is 3 July 2017. The substance does not have an existing entry in Annex VI to CLP. The DS (Belgium) proposed the following harmonised classification: Acute Tox. 4 (H302), Skin Corr. 1B (H314), Eye Dam. 1 (H318) and Repr. 2 (H361fd).

The Chairman recalled that the Committee had already agreed on Acute Tox. 4 (H302), Skin Corr. 1B (H314), Eye Dam. 1 (H318), the supplemental labelling statement EUH071 as well as no classification for germ cell mutagenicity via the fast-track procedure while the plenary discussions should focus on reproductive toxicity (effects on fertility and development) and the aquatic hazards.

In relation to effects on fertility, the Rapporteur reported that the 2-generation study presented in the CLH report showed a rather consistent picture of testicular toxicity. Nevertheless, there was some uncertainty caused by maternal toxicity with effects occurring at very high exposure levels, which they considered not to be that relevant for such a corrosive substance. Also, the 2-generation study had been performed on a salt of XTJ-568 and not the pure substance. They suggested that the study should still be recognised as providing some evidence of effects on fertility, thus warranting a classification as Repr. 2 (H361f). There was full support by RAC Members on this proposal.

In relation to developmental effects, the Rapporteur reported a lack of consistency between the generations, small effects and a likely correlation to lower body weight gain. Overall, the observed effects were not sufficiently adverse according to the criteria to justify classification for developmental toxicity. The other Committee Members shared this view, and XTJ-568 was finally assigned a classification for effects on fertility only (Repr. 2 (H361f)), but not for developmental effects.

In relation to the acute aquatic hazard, the lowest EC_{50} value was 88 mg/l, thus not justifying classification.

In relation to the chronic aquatic hazard, the Rapporteur noted that the two long-term studies on fish and daphnia had been performed in a country which was not adherent to the OECD GLP (Good Laboratory Practice) and MAD (Mutual acceptance of data) Convention. He asked whether RAC would agree that these studies be used for classification purposes. During the discussions it was clarified that also in other cases non-GLP studies had been accepted by RAC, and that Annex XI to REACH, which has regulatory relevance for CLP as well, allowed for the use of such data. In view of these arguments RAC agreed to accept the studies for use and therefore not to classify XTJ-568 for chronic aquatic toxicity.

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

f) Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate

The Chairman reported that ethylhexyl triazone (trade name Uvinul® T 150) has an existing entry in Annex VI to the CLP Regulation as Aquatic Chronic 4; H413. Based on new experimental

data the DS (DE) proposed to remove the existing classification as it was no longer justified. The legal deadline for the adoption of an opinion is 28 July 2017.

RAC supported the DS proposal to remove the existing environmental classification based on new experimental data showing that bioaccumulation of the substance is not expected due to a low bio-concentration factor (BCF) value.

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

g) Thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6-methyl- 1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that Thifensulfuron-methyl (ISO) (TSM) is an active substance, used as herbicide.

It has an existing entry in Annex VI to the CLP Regulation for environmental hazards (Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410)) and the DS (UK) proposed to add an M-factor of 100 to both endpoints.

Given the discrepancy between the existing harmonised classification and the recommendations in the EFSA Conclusion on carcinogenicity and reprotoxicity (during the renewal peer-review process; EFSA opinion on TSM, EFSA Journal 2015; 13(7):4207) the CLH report included also data on carcinogenicity, mutagenicity, toxicity to reproduction and repeated dose toxicity; these hazards were open for comments during the public consultation and assessed by the Committee. No classification was proposed by the DS for these hazards. Legal deadline for the adoption of an opinion is 3 July 2017.

RAC supported the DS proposal for adding an M factor of 100 to Aquatic Acute and Aquatic Chronic classification and agreed also to no classification for germ cell mutagenicity and repeated dose toxicity.

In relation to carcinogenicity, the Committee assessed two oral carcinogenicity studies (18-month carcinogenicity study in mouse and 2-year carcinogenicity study in rat), study reports and position papers submitted during the public consultation. There were no carcinogenic effects observed in mice; in the rat study adenocarcinomas in mammary glands were reported in the mid and high dose. These were considered not treatment-related; the strain of rats used in the study is known to be highly susceptible to this type of tumourigenesis. The study reports / mechanistic data and analysis related to endocrine disrupting MoA of mammary tumours submitted during the PC confirmed no endocrine disruptor potential of TSM in the test systems. RAC concurred with the DS proposal and supported no classification of TSM for carcinogenicity.

In relation to effects on fertility, no effects were observed in two studies on rats (rat dietary 2-generation study and one-generation rat study) and the Committee supported the DS proposal not to classify for effects on sexual function and fertility.

Developmental toxicity of TSM was discussed based on three studies (developmental toxicity study in rabbit, standard developmental toxicity study in SD rat and 2-generation toxicity study in SD rat – dietary administration) and on additional information submitted during the public consultation – a study report from developmental toxicity study in SD rat (Thifensulfuron Methyl (DPXM6316) Technical: Developmental Reproducibility Toxicity Study in Rats) and a position paper on comparative dosimetry of the developmental and reproduction studies in rats.

RAC noted the absent renal papilla observed in the standard developmental toxicity SD rat study in the highest dose, but took into consideration shortcomings of the study compared to current standards (no histopathology was performed and the effects were reported on the basis of

macroscopic observations only). The findings (absent or smaller renal papilla) were not reproduced in the new study submitted during the PC. RAC supported the DS conclusion and agreed on no classification for developmental effects of TSM.

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

h) Propane-1,2-diol

The Chairman welcomed the representative accompanying the Cefic stakeholder observer and reported that propane-1,2-diol (PG) is (among many other uses) commonly used to produce artificial smoke with generators in theatres, discotheques, emergency trainings or is used as a liquid for vaporisation in electronic cigarettes and a de-icing fluid in the automotive and aircraft industries.

It has no existing entry in Annex VI to the CLP Regulation and the DS (DE) proposed to classify the substance for respiratory tract irritation (STOT SE 3 (H335)). The legal deadline for the adoption of an opinion is 22 May 2017.

The proposal was based on one human study (in which humans were exposed to propane-1,2-diol alone), other human studies in which individuals were exposed to various mixtures, containing propane-1,2-diol and other glycols and/or substances; as well as animal studies (rat, rabbit and dog). RAC concluded that the studies on mixtures could not be used in the assessment as it is not possible to show that the symptoms were caused by propane-1,2-diol. In the animal studies, RAC concluded that although some respiratory and eye symptoms were seen, these were not compatible with the criteria for STOT SE. Similarly, it was noted that some effects – such as irritation of respiratory and ocular mucosa, dryness of eyes and throat - were observed after single exposure to propane-1,2-diol in the human study, but that these effects were not enough for classification of the substance as a respiratory tract irritant. Hence, RAC concluded that no classification for STOT SE 3 was justified. The representative of industry (POPG Consortium) briefly presented preliminary results of a new human volunteer study (announced during the public consultation) conducted as a follow up to the human study presented in the C&L proposal with an intention to clarify the findings and to provide better understanding of exposure to propane-1,2-diol. The results of the latter study supported the conclusion of RAC.

RAC adopted the opinion for no classification by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

i) Propiconazole (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that Propiconazole is used as fungicide. It has an existing entry in Annex VI to the CLP Regulation - a minimum classification for acute oral toxicity (Acute Tox. 4* (H302)), as skin sensitizer (Skin Sens. 1 (H317)) and for environmental hazards (Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410)).

The DS (FI) proposed to confirm the acute oral toxicity (=remove the asterisk), to add an M factor of 1 for both acute and chronic aquatic toxicity and to add classification for developmental toxicity (Repr. 2 (H361d)). The CLH report included also data on carcinogenicity and repeated dose toxicity (no classification proposed), these hazards were open for comments during the public consultation and were assessed by the Committee.

The Committee supported the DS proposal for adding an M factor of 1 for both Aquatic Acute and Aquatic Chronic classification. RAC also confirmed category 4 for acute oral toxicity (=removal of the asterisk).

The DS proposed no classification for carcinogenicity based on evidence from three studies (2-year chronic toxicity and carcinogenicity study in rat, 2-year carcinogenicity study in CD-1 mouse and 18-month carcinogenicity study in male CD-1 mouse). The statistically significant neoplastic findings in liver appeared only in one species in one sex (male mice) at the top dose; in addition, malignancy (hepatocellular carcinomas) only occurred at doses above the maximum tolerable dose. The available mechanistic studies support CAR-mediated mode of action as plausible for Propiconazole; CAR-mediated MoA is known as likely not relevant for humans. In the discussion RAC acknowledged that the overall database was sufficient to confirm no classification for carcinogenicity, but stressed that the information confirming the MoA was limited (i. e. no data on knock-out mouse).

In relation to fertility, the absence of effects in a two-generation reproduction study in rats RAC supported the DS proposal for no classification.

Four developmental toxicity studies were available (three in rat and one in rabbit) with effects such as cleft palates in the first rat study in the mid and high doses but also other developmental effects (cleft lip, skeletal effects - absent/delayed ossification, skeletal variations, renal papillae effects). Cleft palates were also observed in the second rat study, but not in the third one. In the rabbit study abortions, resorptions and skeletal variations were observed. RAC discussed the effects of Propiconazole and looked also at effects of other conazoles and their severity. Some Members considered the effects of Propiconazole (and their frequency) less severe and pointing rather to category 2, but other Members stressed that cleft palate was a rare malformation and that one case occurring already at the mid dose confirmed a dose-response relation and moreover, the incidence in the two studies were above the concurrent controls, the historical control data of the performing laboratory and the historical control data of other different laboratories. The Rapporteur noted that the absence of cleft palates in rabbits might have been masked by the high rate of resorptions and that other skeletal effects (i.e. fully formed 13th rib) were observed in rabbits too. This was supported by several Members. The ECPA expert suggested that the developmental effects in rabbits and rats might be secondary to the maternal toxicity seen (significant body weight loss at a critical period of gestation).

Taking all information into account, RAC supported classification of Propiconazole in category 1B. The Committee agreed that there was no need for setting a specific concentration limit and that the generic concentration limit should apply.

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

j) Mesosulfuron-methyl; methyl 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-4-{[(methylsulfonyl)amino]methyl}benzoate

The Chairman reported that Mesosulfuron-methyl is used as a sulfonylurea herbicide for post-emergence use in cereals (soft and durum wheat, triticale).

Mesosulfuron-methyl has no existing entry in Annex VI to the CLP Regulation and the DS (FR) proposed to classify the substance for environmental hazards only. The environmental hazards classification (Aquatic Acute 1 (H400; M=100) and Aquatic Chronic 1 (H410; M=100)) was agreed at the RAC-38 plenary meeting in September 2016. The legal deadline for the adoption of an opinion is 28 May 2017.

RAC supported the DS proposal that the substance does not meet the harmonised classification criteria for any of the human health-related hazards.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for their work on the dossier and the Committee Members who provided their comments during the RAC consultation.

k) Spirodiclofen (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer, as well as the Dossier Submitter representatives from the Netherlands who were following the debate remotely. He reported that Spirodiclofen (ISO) was approved as an active substance for authorisation in plant protection products.

Spirodiclofen (ISO) was discussed for the second time in a RAC plenary meeting; the legal deadline for adoption of an opinion is 27 February 2017. As this active substance did not have an existing entry in Annex VI to CLP, all hazard classes needed to be evaluated during the CLH process. At RAC-38, RAC had already agreed on the following hazards: Skin Sens. 1B (H317), STOT RE 2 (H373) and Aquatic Chronic 1 (H410; M=10), as had been proposed by the Dossier Submitter. The plenary discussions at RAC-39 plenary discussion focussed on the remaining hazard classes carcinogenicity and reproductive toxicity (effects on fertility and development).

The basis of the discussions was the revised draft opinion reflecting additional information from the original study reports provided by the manufacturer upon request of the Committee at RAC-38. The discussion focused on the mode of action (MoA) and the relevance for humans of Leydig cell tumours, hepatocellular adenocarcinomas and uterus adenocarcinomas observed in experimental studies. As the Committee considered that the MoA had not been conclusively demonstrated, the relevance to humans could not be excluded. Since all three types of tumours had a statistically significant incidence above the historical control data, it was agreed to classify Spirodiclofen (ISO) as Carc. 1B (H350).

As to reproductive toxicity, the discussion focused on effects related to fertility impairment of the testes as observed in dogs. It was recognised that organ weights and histopathological findings pointed to toxicity effects on reproductive organs. Also, it was noted that aspermia was observed in two species (dogs and mice). These findings were considered to be sufficient for classification, and the Committee agreed on Repr. 2 (H361f) for effects on fertility.

As to developmental toxicity, the Rapporteurs reported that in a developmental study on rabbits, some effects were observed but these were not considered relevant for classification. Additionally, two neurotoxicity studies and one rat developmental study showed no developmental effects. RAC concluded that a classification for developmental effects is not justified.

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

C. Presentation of key issues

a) Glyphosate (ISO)

The Chairman welcomed an expert from the German Dossier Submitter and another representative from the German Competent Authority who was following the discussions remotely. He also welcomed representatives and experts from the Commission, the European Food Safety Authority (EFSA), the International Agency for Research on Cancer of WHO (IARC),

the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), the Health and Environmental Alliance (HEAL), the European Crop protection Association (ECPA) and the Glyphosate Task Force (GTF). He welcomed the advisers to the Rapporteur who were also following the discussions remotely.

The Chairman explained that Glyphosate (ISO) is a herbicide that had been authorised for use in plant protection products, and that the outcome of the opinion development on harmonised classification in RAC could play a role in the pending renewal of its authorisation. The substance already has an entry in Annex VI to CLP where it is classified as Eye Dam. 1 (H318) and Aquatic Chronic 2 (H413). The Dossier Submitter (Germany), having evaluated all health and environmental hazards in accordance with CLP, proposed to retain the existing harmonised hazard classifications and to add STOT RE 2 (H373) to the entry.

The Chairman noted that there was a lot of public interest and debate worldwide surrounding Glyphosate (ISO). He informed that Glyphosate (ISO) was tabled for the first time at a RAC plenary meeting; the legal deadline for the adoption of an opinion is 1 December 2017. He clarified that the draft RAC opinion was still under development by the Rapporteurs, supported by their advisers and the Members of the RAC ad hoc working group appointed for this purpose, and that a full debate on all aspects of the draft opinion was foreseen at RAC-40 in March.

At the RAC 39 plenary meeting, the Secretariat arranged for an initial discussion, in order to fully acquaint the Committee with the dossier, including the wealth of available data and the specific scientific issues involved. To this end, presentations from EU and International bodies as well as Industry, focussing exclusively on the hazard assessment of Glyphosate had been invited, i.e. from IARC, EFSA, the DS (Germany), the GTF, HEAL representing civil society and a representative of the FAO/WHO JMPR. To conclude this key issues session, the RAC Rapporteurs for the dossier provided an overview of the comments received during the public consultation.

After each presentation, the Chairman gave the floor to RAC Members and the other participants, in order for them to provide comments or to ask questions for clarification.

The issues discussed by the Committee included the following:

- The issue of access to industry studies and to original reports was mentioned. The secretariat confirmed that RAC would evaluate the full dataset as presented by the German DS in their CLH dossier.
- It was noted that the EFSA and the German DS reports had only been available as drafts when IARC concluded its monograph on glyphosate and had therefore not been used.
- The influence of co-formulants on the toxicity of glyphosate was briefly discussed and in particular whether the results for a formulated product could help in determining the hazards of glyphosate itself.
- The difficulties with assessing studies in the published literature, including non-Guideline studies in comparison with good quality GLP-compliant regulatory studies were considered.
- In relation to analysing the carcinogenicity data, the importance of the statistical methods used was emphasised, e.g. one-tailed vs two-tailed tests and it was noted that the methods used in the GLP-compliant studies had generally been consistent with the OECD technical guidelines applicable at the time. However it was not possible in the meeting to address the question of one stakeholder observer how applicable OECD guidance was taken into consideration in the CLH dossier. It was noted by the Secretariat that the issues relating to the statistical tests used would be considered by RAC.

- One stakeholder observer questioned the involvement of a virus infection in the increased incidence of malignant lymphoma in one mouse study, because both concurrent and historical controls had an almost identical incidence.
- With regard to toxicity to reproduction, it was pointed out that deaths were seen (spontaneous or sacrificed moribund or due to abortion) in the rabbit studies, but the dose levels at which mortality occurred were not consistent between studies. In addition, a number of deaths were attributed to handling errors (e.g. mis-gavage). The Committee's attention was drawn to the question whether some of these deaths were incidental or dose-related. The nutritional state of the rabbits as opposed to the other species tested was also mentioned.
- The weight of evidence for genotoxicity was discussed, in particular the need to consider the results from the standard studies and the evidence from humans showing DNA damage.
- The design and interpretation of the human cohort study among farmers using glyphosate was discussed in relation to their previous exposure history to glyphosate and to potentially confounding issues.
- It was noted by the rapporteurs that the DS had provided an additional assessment according to the IPCS 'Conceptual Framework for Evaluating a Mode of Action for Chemical Carcinogenesis' as part of the Response to Comments (RCOM). The Secretariat clarified that the addendum was part of the RCOM and in accordance with the usual procedure, will be published together with the opinion documents after adoption.

The presentations given at the RAC-39 session were published on ECHA's website after the session on Glyphosate had ended; they are available at https://echa.europa.eu/-/the-committee-for-risk-assessment-starts-discussing-the-harmonised-classification-for-glyphosate.

The Chairman thanked the parties contributing to the session for their participation and the presentation of their views on the hazard assessment of Glyphosate.

7.3 Appointment of RAC rapporteurs for CLH dossiers

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

8. Restrictions

8.1 Restriction Annex XV dossiers

a) Conformity check

1) Diisocyanates

The Chairman welcomed the Dossier Submitter's representatives from Germany, the SEAC Rapporteurs as well as an industry expert accompanying a regular stakeholder observer. He informed the participants that the restriction dossier had been submitted by Germany in October 2016. The conformity check was launched on 7 November and the RAC commenting round finished on 18 November with comments received by one RAC Member.

The Dossier Submitter provided an introductory presentation on the dossier. The proposal limits the use of diisocyanates 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 how to get access to this package is communicated throughout the supply chain. Exemptions are defined for cases where the content of free monomeric diisocyanates in the substance or mixture placed on the market or used is less than 0.1% by weight, as well as for mixtures containing diisocyanates 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 presented the outcome of the conformity check and explained that although they acknowledge the Dossier Submitter's efforts in preparing this restriction proposal (high quality data and justifications provided for the most of issues), the information on the proposed RMOs – Trainings and Measures – is considered by the Rapporteurs in its current form, not to allow a sufficiently independent evaluation by RAC in terms of effectiveness regarding risk reduction capacity, as well as practicality and monitorability.

A few RAC Members, as well as the Commission observer, were of the view that this dossier could be considered in conformity, as there is no need to have a detailed description of the training at this stage. An industry expert present at the meeting expressed support for this restriction proposal and confirmed that industry is willing to contribute to the development of the training programme. Some other Members, however, supported the Rapporteurs and agreed that it be more efficient, to fill the identified information gaps before commencing the evaluation. The Committee agreed that the dossier does not conform to the Annex XV requirements and also agreed with the recommendations to the Dossier Submitter as presented by the Rapporteurs.

The Chairman mentioned that the Dossier Submitter will be informed about the reasons for non-conformity and about the further steps and actions to be taken.

b) Opinion development

1) TDFAs – second draft opinion

The Chairman welcomed the RAC Rapporteurs and the dossier submitter’s representatives from Denmark, as well the industry expert accompanying the regular stakeholder representative. A restriction is proposed on the use of TDFA ((3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)-silanetriol) and any of its mono-, di- or tri-O-(alkyl) derivatives in mixtures containing organic solvents placed on the market or used in spray products for consumers (aerosol dispensers, hand pump and trigger sprays and mixtures marketed for spray application). It is targeted at mixtures with organic solvents in spray products for supply to the general public. TDFAs have been shown to cause serious acute lung injury in mice exposed to aerosolised mixtures containing TDFAs and organic solvents at certain concentration levels.

The Rapporteurs presented and RAC discussed their second draft opinion. In general, RAC Members supported the Rapporteurs conclusions, emphasised that although the animal data indicated that there is potentially a risk, this may not currently exist since relevant consumer sprays may not be on the EU market anymore.

Furthermore, an industry expert questioned the large difference between ConsExpo and SprayExpo estimates. The dossier submitter responded that the ConsExpo is more conservative method. The RAC Rapporteurs agreed to reconfirm the parameters with the dossier submitter.

In conclusion, RAC supported the plausibility of the link between the identified hazards, the clinical cases and presence of TDFAs/organic solvents in consumer spray products. The Rapporteurs supported (and RAC concurred) that fluorosilanes (and potentially TDFAs) are assumed to be the active ingredients in the Magic Nano products linked to incidents. Also RAC agreed on the DNELs derived with two approaches.

RAC agreed, in principle, on the RCRs for aerosol sprays that have to be finalised in line with the exposure estimates. Subject to final outcome of the public consultation, RAC also agreed in principle that there may be a risk for pump and trigger sprays that needs to be addressed. RAC accepted that there is a need for EU-wide action is justified, and that the scope will cover all consumer sprays. The Chairman invited the rapporteurs to take the discussion and the outcome of public consultation into account in the third draft opinion due by end of January 2017.

2) Diisobutyl phthalate (DIBP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), bis(2-ethylhexyl) phthalate (DEHP) – second draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA and Denmark, an industry expert accompanying a regular stakeholder observer, an occasional stakeholder observer (with an accompanying expert) and the SEAC Rapporteurs. He reminded the participants that the dossier had been submitted in April 2016 and had been considered in conformity by RAC and SEAC in June 2016. The dossier proposes a restriction on articles containing the four phthalates (diisobutyl phthalate (DIBP); dibutyl phthalate (DBP); benzyl butyl phthalate (BBP) and bis(2-ethylhexyl) phthalate (DEHP)) for: i) indoor use and ii) outdoor use, if in contact with human skin or mucous membranes. The Chairman reminded that the Rapporteurs had developed the second draft opinion on this dossier, which had been made available for the RAC commenting prior to RAC-39 and that comments were received from one RAC Member. The Chairman also mentioned that at this RAC-39 plenary, the Committee is invited to discuss the second draft opinion, with the aim of reaching agreement on all main components of the restriction to enable the Rapporteurs to develop a final version of the opinion or identify where remaining work in needed.

The Rapporteurs presented their second draft opinion focussing on the following issues: the conditions and derogations of the restriction proposal, immunotoxicity; effectiveness in reducing the identified risks, risk reduction capacity of alternatives as well as practicality and monitorability.

With regard to immunotoxicity, the Rapporteurs explained that the Dossier Submitter has added new information in the updated Background Document (BD), including information that was received during the ongoing public consultation. The data shows clear associations/indications for effects on the immune system, especially adjuvant effects, and the Rapporteurs were interested to hear the views of other Members how to address these effects. After a short discussion, the Committee confirmed its conclusion of the previous RAC-38 meeting that other effects (immunological, metabolic, neurodevelopmental) will be addressed in the uncertainty analysis and SEA. The industry expert reminded the Committee that the public consultation is ongoing until 15 December 2016 and RAC should therefore be cautious in making final conclusions yet. The Secretariat confirmed that the comments received within the consultation are looked at on a regular basis and considered within the ongoing work on the opinions and the BD.

The Rapporteurs then reminded the Committee that they had agreed in principle at the previous meeting that there is an EU-wide risk for both children and mothers, based on 95th percentile biomonitoring levels for combined exposure to the four phthalates and that this risk needs to be addressed. The Rapporteurs supported the conclusion of the Dossier Submitter that the proposed restriction is capable of significantly reducing the risks to human health of combined exposure within a reasonable period of time, starting from 2020, although some delay is caused by the service-life of articles in use. They noted also that the proposed restriction will reduce any associated risks for the environment from articles in scope and also occupational risks due

to substitution of DEHP in the production of articles in the EU. The Committee supported the views of the Rapporteurs on this and concluded that the proposed restriction is the most effective and appropriate EU-wide measure to reduce the risk.

With regard to the risk reduction capacity of alternatives, the Rapporteurs noted that the alternatives (e.g. DINP, ASE, ATBC, DEGD, DGD, DEHT) are less toxic for human health, are not classified, are not PBT or vPvB nor have they been identified as SVHC Annex XIV substances. Except for DINP, the alternatives also have no anti-androgenic properties and DINP is less potent than the four phthalates. The Rapporteurs concluded that alternatives are less toxic than the four phthalates and the restriction will lead to overall reduction of risk, for workers and the general population. The Committee was in support with this view of the Dossier Submitter and the Rapporteurs.

The Rapporteurs continued their presentation with explaining changes made in the wording of the proposed restriction by the Dossier Submitter. Two options for the wording have been proposed by the Dossier Submitter and version B (positive list of what is to be restricted) is preferred by the Forum and by the Rapporteurs over the approach in the proposal as it was submitted (total ban with derogations). RAC agreed to support the revised wording of the restriction, as recommended by the Rapporteurs.

Finally, the Rapporteurs highlighted that they consider the proposed restriction to be a practical and monitorable measure for industry and enforcement authorities. It builds on the existing industry compliance and Member States enforcement practices on phthalates in articles. The Committee concluded that the proposal is implementable, enforceable and manageable.

The Chairman informed that the public consultation will finish on 15 December and the Rapporteurs are expected to take the RAC-39 discussion as well as the outcome from the public consultation into account in the preparation of the next version of the opinion. RAC is expected to adopt its opinion on this dossier at RAC-40 in March 2017.

8.2 Appointment of RAC rapporteurs for restriction dossiers (closed session)

RAC agreed in the closed session on the updated pool of Rapporteurs for the restriction dossiers on Lead and its compounds (as stated in the restricted room document RAC/39/2016/07).

9. Authorisation

9.1 General authorisations issues

a) Update on incoming/future applications

b) Report on AfA Task Force and related activities

The Secretariat informed the Committee that the two new applications for authorisation covering three uses of chromium(VI) compounds were received during the November 2016 submission window. The Secretariat also reported on the progress of the AfA Task Force in relation to the development of the practical guide and the impact assessment for the non-adequate control cases.

9.2 Authorisation applications

a) Outcome of the conformity check and presentation of the key issues

The Secretariat in cooperation with the RAC rapporteurs provided general information regarding the 20 new applications for authorisation listed below. In the presentation of the cases, the

Secretariat outlined the key issues identified by the Rapporteurs, which would need further clarification by the Applicants and asked the Committee for comments and further suggestions. The Committee discussed these key issues, as well as the draft conformity reports for the 18 applications presented below. The draft conformity reports for the CT_Hapoc_2 and CT_Hapoc_3 applications will be discussed at a future RAC meeting. RAC agreed on the conformity of the 18 applications for authorisation which were discussed at this plenary meeting. Where needed, RAC will request further clarifications from the Applicants on the issues identified and discussed by the Committee.

1. CT_Hapoc_2 (1 use)

This application for authorisation is submitted in the German language.

It is a single use upstream application on use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of plastic, with or without current flow.

The application currently appears to cover several downstream users (oral communication by the applicant, not apparent from the application), number of sites potentially covered: not apparent from the AfA.

Number of involved workers: <20 exposed workers per site.

Tonnage and requested review period: 100 tonnes of Cr(VI) per annum over a requested review period of 25 years.

The Committee discussed the key issues in the application for authorisation. The draft conformity report for the CT_Hapoc_2 will be discussed at a future RAC meeting.

2. CT_Hapoc_3 (1 use)

This application for authorisation is submitted in the German language.

It is a single use upstream application on use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of brass, bronze, copper and other copper alloys for medical engineering, aviation and automation products.

The application currently appears to cover 1 downstream user, yet the number of sites potentially covered is not apparent from the AfA. About 5 exposed workers per site based on the one known site.

Tonnage and requested review period: 250 kg of Cr(VI) per annum over a requested review period of 30 years.

The Committee discussed the key issues in the application for authorisation. The draft conformity report for the CT_Hapoc_3 will be discussed at a future RAC meeting.

3. CT_Haas (1 use)

Use 1: Use of chromium trioxide for chemical conversion and slurry coating applications by aerospace companies and their suppliers. Slurry coating as a use was not covered by the CCST consortium; while it was covered by use 4 of the CTAC consortium. This Application does not cover formulation – import and supply of aqueous solutions from non-EU countries is envisaged.

The total number of exposed workers is several thousand, for the >100 sites covered by this application. The annual tonnage used is 2 tonnes (~1 t/y of Cr(VI)) and the Applicant requested a 12-year review period.

The Committee discussed the key issues in the applications for authorisation and agreed on its conformity.

4. SD_Haas (1 use)

Use 1: Use of sodium dichromate for sealing after anodizing applications by aerospace companies and their suppliers. On-site formulation is covered as a WCS.

The total number of exposed workers is several thousand, for the >100 sites covered by this application. The annual tonnage used is 5 tonnes and the Applicant requested a 12-year review period.

The Committee discussed the key issues in the applications for authorisation and agreed on its conformity.

5. PD_Haas (1 use)

Use 1: Use of potassium dichromate for sealing after anodizing applications by aerospace companies and their suppliers. On-site formulation is covered as a WCS.

The number of workers involved is estimated in the thousands, and a low tonnage, small scale use at individual sites but potentially at very many sites is described in all three uses.

The total number of exposed workers is several thousand, for the >100 sites covered by this application. The annual tonnage used is <5 tonnes (<2 tonnes/year of Cr(VI) and the Applicant requested a 12-year review period.

GCCA Consortium (Haas)

These above three upstream (importers) applications together with SC Aviall are submitted with one use each (with exception of SC Aviall): while many aspects of the applications are closely related to those of CCST and the CTAC, less processes are covered. The prime consideration from the GCCA consortium is that each of these chromate chemicals are used as surface treatments primarily for the prevention of corrosion of metal components within the constructions of aircraft (civil and military), helicopters, satellites, launchers, etc.

The Committee discussed the key issues in the applications for authorisation and agreed on its conformity.

6. CT_Reachlaw (4 uses)

Application by the only representative of the company located in a third country (Russia). The assessment reports (CSR, AoA and SEA) are identical to those submitted in the CT_Lanxess (CTAC) application for uses 1, 2, 3 and 5 (April 2015). The only differences identified in the application are the smaller tonnages used and the number of sites covered.

Use 1: Formulation of mixtures of chromium trioxide for functional chrome plating, functional chrome plating with decorative character and surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering. Annual tonnage: 1,400 tonnes. Requested review period – 12 years.

Use 2: Functional Chrome Plating. Functional chrome plating may include use of chromium trioxide in pre-treatment and surface deposits unlimited in thickness but typically between 2 µm and 5,000 µm. Functional chrome coatings are widely used in many industry sectors. Annual tonnage: 150 tonnes. Requested review period – 12 years.

Use 3: Functional chrome plating with decorative character. Annual tonnage: 6 tonnes. Requested review period – 7 years.

Use 4: Surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering. Annual tonnage: 20 tonnes. Requested review period – 7 years.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

7. CT_Clariant (1 use)

Downstream user application on the use of chromium trioxide in a catalyst for the dehydrogenation of propane to propene

Scope of the application is narrow and well-defined. The operations with chromium trioxide take place in one site. Ca. 100 workers are potentially exposed. Annual tonnage: less than 10 tonnes. Requested review period – 12 years.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

8. CT_ZFL (2 uses)

This is a downstream user application for two uses of chromium trioxide – for a functional chrome plating of metal parts of helicopter transmissions (=use 1) and surface treatment for applications in the aeronautics and aerospace industries (unrelated to Functional chrome plating or Functional chrome plating with decorative character) (=use 2).

The functional chrome plating process is characterised as a wet process within which treatment solutions are recirculated in a closed loop. The main form of application is dipping or immersion of parts in a tank or through a series of tanks containing solutions in partially closed or open systems. It covers one site only and the total annual tonnage is <50kg and the requested review period is twelve years for both uses.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

9. SD_ZFL (1 use)

This a downstream user application for one use of sodium dichromate for surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites, sealing of anodic films. The substance is used for passivation of metal parts of helicopter transmissions. The process includes the following steps: pre-treatment, rinsing, chromating, drying in an oven and conservation. The main form of application is dipping or immersion of parts in a tank or through a series of tanks containing solutions in partially closed or open systems. The total annual tonnage is <50kg and the requested review period is twelve years.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

10. CT_Cryospace (1 use)

This is a downstream user application covering one use of chromium trioxide for the surface preparation of aluminium alloy cryogenic tanks used in the Ariane 5 launcher. Chromium trioxide is used in the surface preparation (pickling) of aluminium alloys used on cryogenic tanks for the Ariane 5 launcher. Chromium trioxide allows the formation of highly adhesive metallic oxide

layers on the aluminium alloys used to construct the cryogenic tanks. This treatment prepares the surface of the alloy for the adhesive bonding in the processing steps that follow. The annual tonnage used is < 1 tonne/year. Review period requested is seven years. Less than 10 workers are potentially exposed.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

11. SC_Aviall (2 uses)

As part of GCCA Consortium, this is an upstream user application (importer) covering two uses:

Use 1: Formulation of mixtures of sodium chromate for sealing after anodizing, chemical conversion coating, pickling and etching applications by aerospace companies and their suppliers. The total number of exposed workers ca. 100, for the 1-10 sites covered by this application. The annual tonnage used is 1 tonne and the Applicant requested a 12-year review period.

Use 2: Use of sodium chromate for sealing after anodizing, chemical conversion coating, pickling and etching applications by aerospace companies and their suppliers.

The total number of exposed workers is several thousand, for the >100 sites covered by this application. The annual tonnage used is 1 tonne and the Applicant requested a 12-year review period.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

12. SD_Borealis (1 use)

Downstream user application on the use of sodium dichromate as in-situ corrosion inhibitor in a closed water/ammonia absorption cooling system.

Scope of the application is narrow and well-defined. The operations with chromium trioxide take place in one site. < 10 workers are potentially exposed. Annual tonnage: <100 kg. Requested review period – 18 years.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

13. SD_Ormezzano (2 uses)

Downstream user application covering two uses:

Use 1: Repackaging of sodium dichromate to be supplied as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings

Use 2: Use of sodium dichromate as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings

Use 1 covers the repackaging of the sodium dichromate solution into separate containers for shipment onwards to the downstream users. These containers range in size from 25 kg drums to 2 tonnes IBCs. The sodium dichromate solution is received from a non-EU supplier, and stored in a bulk storage container, located outside, at a single site (<100 employees). Annual tonnage: 130 tonnes/year of 61% sodium dichromate solution, which equals approximately 80 t/y of sodium dichromate.

Use 2 is done in 8 dyeing companies, in the same region, employing 50 workers/company, and 3 textile manufacturers, employing 377 workers/company. Requested review period – 7 years.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

14. AD_BAE (2 uses)

Downstream user application with a well-defined scope for two uses:

Use 1: Industrial use of Ammonium Dichromate in the process of manufacturing holographic combiners for diffractive head-up displays intended to be used in military aircrafts.

Number of sites covered is 2, number of workers is < 20, volume used per year is < 10 kg and review period requested is 12 years.

Use 2: Industrial use of Ammonium Dichromate in the process of manufacturing Cathode Ray Tubes for head up displays intended to be used in military and civilian aircrafts.

Number of sites covered is 1, number of workers is < 10, volume used per year is < 1kg and review period requested is 4 years.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

15. EDC_Biotech (1 use)

A Downstream User Application for the use of EDC as a solvent in manufacture of polymeric particles for pharmaceutical and research purification processes. The number of exposed workers is <10 at one site covered by this application. The annual tonnage used is 1.25 tonnes and the Applicant requested a 12-year review period.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

16. EDC_ORGAPHARM (2 uses)

A Downstream User Application with a well-defined scope for two uses of EDC:

Use 1: as process solvent in the manufacture of an Active Pharmaceutical Ingredient: Flecainide acetate

Use 2: as process solvent in the manufacture of an Active Pharmaceutical Ingredient: Nefopam

The number of exposed workers is <50 at one site covered by this application. The annual tonnage used is between 10-100 tonnes/year (Use 1) and 10-100 tonnes/year (Use 2). The Applicant requested a 7-year review period.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

17. EDC_Akzo (1 use)

A Downstream Use Application with a well-defined scope for the use of EDC as a recyclable solvent in the production of a polyacrylate surfactant. The total number of exposed workers is < 50 at one site covered by this application. The annual tonnage used is 2 tonnes and the Applicant requested a 9-year review period.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

18. EDC_Bayer (1 use)

A Downstream User Application for the use of EDC as an industrial solvent in the manufacture of the high-grade pure final intermediate of Iopromide, the Active Pharmaceutical Ingredient for the X-ray contrast medium Ultravist®. The application covers one site. The number of workers exposed is ca. 200 internal and external (maintenance) workers. The annual tonnage used is 100-1,000 tonnes/year and the Applicant requested a 13-year review period.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity**.**

19. EDC_Olon (2 uses)

A Downstream User Application with two uses of EDC:

Use 1: The use of 1,2 dichloroethane (EDC) as a solvent in the production of the active pharmaceutical ingredient for epirubicin;

Use 2: The use of 1,2 dichloroethane (EDC) as a solvent in the manufacturing of the active pharmaceutical ingredient for prednisolone steaglate.

The application covers one site. The number of workers exposed: < 50 (Use 1) aqnd < 10 (Use 2). The annual tonnage used is < 10 tonnes/year for Use 1 and < 1 tonne/year for Use 2. The Applicant requested a 20-year review period.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

20. MOCA_Reachlaw (1 use)

Application by the only representative of the company located in the third country (China). A single use application on industrial use of MOCA as a curing agent/chain extender in cast polyurethane elastomer production. Annual tonnage: 516 tonnes.

MOCA is used at circa 90 sites, in approximately 89% automatic and remaining 11% manual processes. The total number of exposed workers is estimated to be ca.200. Requested review period – 12 years.

The Committee discussed the key issues in the application for authorisation and agreed on its conformity.

b) Agreement on Draft Opinions

1. Diglyme_Merck (1 use)

The Chairman invited the Rapporteurs to present the RAC draft opinion. The Rapporteurs presented the draft opinion on the application for authorisation submitted by a downstream user for the industrial use of diglyme as a solvent in the manufacturing process of cryptand intermediates for further conversion into cryptand 221 and cryptand 222. The annual volume of the substance used is 1-10 tonnes and the applicant requested a 12 years review period.

The draft opinion was agreed by consensus as proposed by the Rapporteurs. In particular, RAC concluded that adequate control has been demonstrated both for workers and the general population exposed via the environment and that the RMMs and OCs described in the application are appropriate and effective in limiting the risk.

RAC did not propose any additional conditions for the authorisation. However, RAC recommended conditions for the review report in order to strengthen the level of certainty of the exposure assessment. RAC agreed to offer no advice to SEAC concerning the length of the review period.

2. Diglyme_Isochem (1 use)

The Rapporteur presented the draft opinion on the application for authorisation submitted by a downstream user for the industrial use of diglyme as a process solvent in the manufacturing of an intermediate for an active pharmaceutical ingredient (API). The annual volume of the substance used is 5-6 tonnes per batch (freshly added 2-3 tonnes per year) and the applicant requested a 12 years review period.

The draft opinion was agreed by consensus as proposed by the Rapporteur. In particular, RAC concluded that adequate control has **not** been demonstrated for worker exposure. RAC also concluded that the RMMs and OCs described in the application are **not** appropriate and effective in limiting the risk, in particular for workers.

RAC decided to recommend additional conditions and monitoring arrangements for the authorisation, including requests for occupational exposure measurements (for dermal and inhalation exposure), as well as technical RMMs for loading-unloading, sampling and storage.

Taking into account the uncertainties, RAC agreed to recommend to SEAC a shorter review period.

3. Diglyme_Roche (1 use)

[*please note that the following detailed minutes for this case will be publicly available only after the Applicant has been informed following the RAC consultation and the agreement by Written Procedure*]

The Rapporteurs presented their initial conclusions on the application for authorisation submitted by the downstream user Roche Diagnostics GmbH for the industrial use of Diglyme as a process chemical in the manufacture of one specific type of bead, used in the immunodiagnostic assays market. The annual volume of the substance used is 8 tonnes, expected to rise to 11 tonnes/year, and 2 workers are potentially exposed (possibly growing to 7 workers). The Applicant requested a 12 year review period.

RAC Members were informed of the similarities of this downstream application to the Diglyme Life Technologies AS application for authorisation, from which the Applicant has purchased the technology to produce this specific type of bead.

The draft opinion will be subject of RAC consultation and agreed by written procedure or tabled for agreement at the next plenary.

4. Diglyme_LifeTech (1 use)

[*please note that the following detailed minutes for this case will be publicly available only after the Applicant has been informed following the RAC consultation and the agreement by Written Procedure*]

The Rapporteurs presented their initial conclusions on the application for authorisation submitted by the downstream user Life Technologies AS for the industrial use of Diglyme as a process chemical in the manufacture of beads, which are mono-sized particles used in biomolecular

research and in the in-vitro immunodiagnostic assays market. The annual volume of the substance used is ca. 10 tonnes, which is expected to rise to ca. 35 tonnes, 2 sites are covered by the application and less than 10 workers are potentially exposed at each site. The Applicant requested a 12 year review period.

During the discussion RAC noted the Rapporteurs concerns on the declared effectiveness of the PPE. The Committee advised the Rapporteurs to use the applicant's calculations based on the 95% effectiveness of RPE and 98% for chemical resistant gloves but RAC asked the Rapporteurs to reflect all uncertainties in the draft opinion. The RAC Members pointed that the technical RMMs should be improved. Additionally an improved PPE-management should be implemented by the applicant, including that all workers should be properly trained how to use PPE.

The draft opinion will be subject of RAC consultation and agreed by written procedure or tabled for agreement at the next plenary.

5. Diglyme_Acton (2 uses)

[*please note that the following detailed minutes for this case will be publicly available only after the Applicant has been informed following the RAC consultation and the agreement by Written Procedure*]

The Rapporteurs presented their assessment of the application for authorisation submitted by the Acton Technologies Limited. This is a downstream user application for the two uses.

Use 1:

bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (in-house processes). The annual volume of the substance used is 20 tonnes and the applicant requested a 12 year review period.

The Rapporteurs informed RAC that according to their assessment the highest risk characterisation ratio for combined exposure for a production worker is 7.85. The applicant already suggested further improvements to be implemented at the site within 6-12 months by installing robotised placing of the mandrils into the etchant boxes. This would change/ reduce the exposure linked to WCS6 as it would remove/reduce worker contact with the mandrils. The applicant is also committed to continue their monitoring program in order to ensure control of exposures to diglyme. However, RAC was unable to further investigate such intentions.

During the discussion RAC Members expressed concerns if the installation of the robotic system of handling of the mandrils would reduce the workers exposure to the level where the adequate control of risk can be achieved. One Member pointed to the significant exposure to diglyme in the offices where no work is done with the substance and suggested that some measures (i.e. positive air pressure) should be implemented to avoid contamination of the office.

The draft opinion will be subject of RAC consultation and tabled for agreement at the next plenary.

Use 2:

bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (downstream user processes). The annual volume of the substance used is 10 tonnes. The Applicant requested 12 years review period.

The use 2 contains use of the substance by 5 downstream users of the applicant. While tasks represented by WCSs according to the Rapporteurs are described in sufficient detail for

downstream user (DU) 1, only very basic information has been provided about tasks performed under different WCSs for DU2 through DU5, and thus adequate control has not yet been demonstrated by the applicant.

The draft opinion will be subject of RAC consultation and tabled for agreement at the next plenary.

6. Diglyme_Bracco (1 use)

The Chairman invited the Rapporteurs to present the RAC draft opinion. The Rapporteurs presented the draft opinion on the application for authorisation submitted by a downstream user for the industrial use of diglyme as a processing aid in the purification of 5-amino-2,4,6-triiodoisophthalic acid dichloride by precipitation. There are 10 exposed workers. The annual volume of the substance used is 200 - 300 tonnes and the applicant requested a 12 years review period.

The draft opinion was agreed by consensus as proposed by the Rapporteurs. In particular, RAC concluded that adequate control has been demonstrated both for workers and the general population exposed via the environment and that the RMMs and OCs described in the application are appropriate and effective in limiting the risk. The highest RCR for workers was 0.2.

Furthermore, RAC did not propose any additional conditions for the authorisation nor the review report as the risk appears to be adequately controlled. RAC agreed to offer no advice to SEAC concerning the length of the review period.

7. Diglyme_Maflon (1 use)

This is a downstream user application for the use of bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity submitted by the MAFLON S.P.A. The annual volume of the substance used is 10-100 tonnes and 7 workers are exposed to Diglyme. The Applicant requested a 12 year review period.

The Rapporteurs informed RAC that according to their assessment the highest risk characterisation ratio for combined exposure for a production worker of 0.9 which is likely to be an overestimate as not all of the tasks are performed the same day.

The draft opinion was agreed by consensus as proposed by the Rapporteurs. In particular, RAC agreed that the risk management measures and operational conditions described in the application were appropriate and effective in limiting the risk to workers and the general population. RAC did propose additional conditions and monitoring arrangements for the review report with the special emphasis on the need to find more sensitive method to monitor background exposure. Finally, RAC agreed to offer no advice to SEAC on the length of the review period.

8. Chromium trioxide_HAPOC (4 uses) (CT_HAPOC)

CT Hapoc is an upstream application for four uses of chromium trioxide. The first use covers the formulation of mixtures; the other three relate to the use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of metal or plastic, with or without electric current flow. The difference between the Uses 2 to 4 is in the excess risk levels associated with the use of chromium trioxide: Uses 2, 3 and 4 correspond to a lifetime excess risk level of 2:100, 4:1,000 and 4:10,000, respectively.

The RAC rapporteurs presented a progress report on the opinion development. They explained that despite the fact that the application for authorisation CT Hapoc was received during the February 2016 submission window, the opinion development had been slowed down by the need for translation, since the application was submitted in German. The RAC rapporteurs requested advice from the Committee on how to address the applicant's use specification based on the different risk levels. During the discussion RAC noted that the application is missing substantiated justification of the risk-driven differences in Uses 2 to 4, e.g. the epidemiological analysis presented does not justify the approach taken, real operational conditions and efficiency of risk management measures in concrete workplaces remains unknown, etc. Some RAC Members pointed out the broadness of the uses and similar level of uncertainties in this application as in the previously evaluated upstream applications for authorisation of chromates, e.g. uses do not specify workers' tasks and the state of the substance (i.e. solid or liquid) involved in each of the tasks, manual vs. automated industrial processes, open/closed processes, etc. The RAC Members also emphasised the deficient evaluation of the man via the environment in the application for authorisation.

The Committee concluded on the way forward with the application for authorisation. The RAC rapporteurs will draft a first version of the draft opinions prior to the next RAC plenary meeting in March 2017.

9. Potassium dichromate GENTROCHEMA BV (2 uses) (PD_Gentrochema)

10. Sodium dichromate GENTROCHEMA BV (3 uses) (SD_Gentrochema)

These are upstream applications covering use of potassium dichromate and sodium dichromate in formulation of mixtures and subsequent use of these substances for the surface treatment of metals in the aviation sector. The application for authorisation SD Gentrochema in addition covers the use of sodium dichromate for the electrolytic passivation of tin-plated steel for the packaging industry.

RAC noted that Gentrochema BV submitted the assessment reports (chemical safety report, analysis of alternatives and socio-economic analysis) identical in content as those in two applications that were previously submitted by the CCST consortium (lead applicant Brenntag UK Ltd) and that Gentrochema BV had acquired written permission to use these assessment reports. The Committee then considered the specific information on tonnage intended and similarity of the supply chains reported by Gentrochema BV. The Committee was of the view that its opinion and the justifications on the applications for authorisation by Brenntag UK Ltd are also valid for the applications for authorisation submitted by Gentrochema BV.

RAC agreed on the draft opinions on the applications for authorisation PD Gentrochema and SD Gentrochema by consensus.

11. Technical MDA_Polynt

This is the application for authorisation submitted by the downstream user Polynt Composites France for two uses of technical MDA (Formaldehyde, oligomeric reaction products with aniline). The first use concerns formulation of an epoxy resin hardener containing technical MDA (tMDA). The hardener, containing approximately 36% (w/w) of tMDA, is produced in >20 batches per year. The second use concerns the industrial use of an epoxy resin hardener containing tMDA at different sites in a process designed to immobilise spent ion exchange resins in a high containment matrix. The Applicant requested a 12 year review period.

The draft opinion was agreed by consensus as proposed by the Rapporteur. In particular, RAC agreed that the risk management measures and operational conditions described in the

application were appropriate and effective in limiting the risk to workers and the general population. RAC did however propose additional conditions and monitoring arrangements for the review report for use 1. Finally, RAC agreed to offer no advice to SEAC on the length of the review period.

12. EDC_EURENCO

This is the application for authorisation submitted by the downstream user EURENCO for the industrial use of 1,2-Dichloroethane as a solvent for the synthesis of Polyepichlorohydrin used as a precursor in the production of Glycidyl Azide Polymer, used to increase the energetic performance of propellants and explosives. It is described as a relatively open process with many manual operations. The annual volume of the substance used is 2.6 tonnes, and 6 workers are being potentially exposed. The Applicant requested a four year review period.

. The Rapporteurs pointed that the Applicant did **not** implemented any RMMs for EDC-containing wastewater. RAC therefore considered that the exposure is **not** reduced to as low a level as is technically and practically possible in order to comply with REACH Article 60 (10).

The draft opinion was agreed by consensus as proposed by the Rapporteur. In particular, RAC agreed that the risk management measures and operational conditions described in the application were **not** appropriate and effective in limiting the risk to workers and the general population. RAC proposed additional conditions and monitoring arrangements for the authorisation. Finally, due to the exposure control concerns, RAC proposed to recommend a shorter review period to SEAC.

c) Adoption of Final Opinion

1. Chromium trioxide_Cromomed (1 use) (CT_Cromomed)

The RAC rapporteurs on the application for authorisation CT Cromomed informed the Committee about the applicant's comments related to the RAC parts of the draft opinion. In response, Rapporteurs proposed some editorial changes in the opinion. RAC agreed to this proposal without discussion an adopted the opinion on CT Cromomed by consensus.
RAC adopted the final opinion with changes in the text addressing the comments by the Applicants, as proposed by the Rapporteurs.

2. Chromium trioxide_Burscheid (1 use) (CT_Burscheid)

3. Chromium trioxide_Friedberg (1 use) (CT_Friedberg)

4. Chromium trioxide_Valvetrain (1 use) (CT_Valvetrain)

5. Sodium dichromate_Akzo (2 uses) (SD_Akzo)

6. Sodium dichromate_Arkema (1 use) (SD_Arkema)

7. Chromic acid_Bosch (1 use) (CA_Bosch)

The RAC rapporteurs for the CA Bosch, CT Burscheid, CT Friedberg, CT Valvetrain, SD Akzo and SD Arkema applications for authorisation informed the Committee that the comments received from the applicants were not relevant to the RAC-related parts of the respective draft opinions. They proposed not to change the opinions (except for an editorial change in the opinion on the Use 1 in SD Akzo, and the opinion on the Use in SD Arkema). RAC agreed to this proposal and adopted the opinions on the aforementioned applications for authorisation by consensus.

8. **Potassium dichromate_Brenntag (2 uses) (PD_Brenntag)**
9. **Sodium dichromate_Brenntag (3 uses) (SD_Brenntag)**
10. **Dichromium tris(chromate)_Henkel (2 uses) (DtC_Henkel)**
11. **Strontium chromate_Akzo (2 uses) (ST_Akzo)**
12. **Potassium hydroxyoctaoxodizincatedichromate_PPG (2 uses) (PH_PPG)**

The above five applications for authorisation were submitted by the same consortium (CCST) and bore strong similarities, therefore they were considered together for discussion at this plenary meeting. Four uses have been applied for: formulation (by all five applicants), surface treatment (by three applicants), painting and coating (by two applicants) and electrolytic passivation of tin plated steel (by one applicant). A consultation was held on these draft final opinions with Members from 11 to 16 November.

The Chairman informed Members on the state of play of the applications, reminding them that the draft opinions had been agreed at RAC-38 and were subsequently sent to the Applicants for their comments. The Chairman then asked the Rapporteurs to present the draft final opinions on the total 11 uses applied for.

The Rapporteurs explained that for the uses on ETP plating and formulation the Applicants' comments referred mostly to the SEAC part of the opinions, and thus the RAC rapporteurs were of the opinion that no changes were needed in the RAC opinions and only editorial changes were made in the justification to the opinion for Use 1 (formulation).

Regarding the opinions on surface treatment and on paints and coatings, some modifications were made in the RAC opinions in order to clarify aspects in the justifications regarding the limited exposure and emission data from downstream users in the application, as well as the periodicity of measurements for machining operations and biomonitoring in the proposed additional conditions and monitoring arrangements.

Following the update by the Rapporteurs, the discussion continued with some further clarifications on the frequency of biomonitoring, as well as on some further editorial modifications which were needed in the opinions.

RAC adopted the final opinions by consensus. The opinions will be sent to the Applicants, European Commission and Member States following their adoption at SEAC.

The Chairman thanked the Rapporteurs and Secretariat for their work on these five applications.

9.3 Appointment of Rapporteurs for authorisation applications (closed session)

The Committee Members expressed their interest in rapporteurships, applying to the pool of Rapporteurs and indicating absence of conflict of interest. The expanded pool of Rapporteurs, as outlined in the amended restricted room document RAC/39/2016/06 rev.1, was then agreed by RAC.

10. AOB

None.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 39 28 November–2 December 2016
7-9 December 2016
(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/39/2016**) was adopted.	**SECR** to upload the adopted Agenda to the RAC s-CIRCABC and to the ECHA website as part of the RAC-39 minutes.
4. Report from other ECHA bodies and activities	
a) Report on RAC 38 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/39/2016/01** and document **RAC/39/2016/02.**	**SECR** to upload the document to the s-CIRCABC non-confidential website.
b) RAC work plan for all processes SECR presented the update on Q1-Q3/2017 work plan for RAC covering the Classification and Labelling, Restriction and Authorisation processes.	**SECR** to upload the presentation to non-confidential folder of the RAC-39 meeting on s-CIRCABC.
7.2 CLH dossiers	
A. Substances with hazard classes for agreement by A-listing following the usual scrutiny but without plenary debate • Asulam sodium: Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with M=1 for both hazards; no classification for physical hazards, acute toxicity (all routes), serious eye damage / eye irritation, STOT SE, STOT RE, respiratory sensitisation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, aspiration toxicity • XTJ 568: Acute Tox. 4 (H302), Skin Corr. 1B (H314), Eye Dam. 1 (H318), EUH071; no classification for acute dermal and inhalation toxicity and for germ cell mutagenicity • Thifensulfuron-methyl (ISO): Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with M=100 for both hazards; no classification for STOT RE, germ cell mutagenicity, reproductive toxicity (effects on fertility) • Propiconazole (ISO): Acute Tox. 4 (H302), Skin Sens. 1 (H317): no classification for acute dermal and inhalation toxicity and STOT RE • Mesosulfuron-methyl:	

no classification for physical hazards, acute toxicity (all routes), serious eye damage / eye irritation, STOT SE, STOT RE, respiratory and skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, aspiration toxicity	
B. Substances with hazard classes for agreement in plenary session a) 1-vinylmidazole b) Colecalciferol, vitamin D_3 c) Asulam sodium d) Potassium permanganate e) XTJ 568; reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-({[2-(2-aminobutoxy)ethoxy]methyl}propoxy)but-2-ylamine f) Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate g) Thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6-methyl- 1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate h) Propane-1,2-diol i) Propiconazole (ISO) j) Mesosulfuron-methyl; methyl 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-4-{[(methylsulfonyl)amino]methyl}benzoate k) Spirodiclofen (ISO)	
a) 1-vinylmidazole	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B (H360D), SCL: Repr. 1B (H360D): C ≥ 0.03%]	**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.
b) Colecalciferol, vitamin D_3	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 2 (H300, H310 and H330), STOT RE 1 (H372) with SCL ≥ 0.3%]	**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.
c) Asulam-sodium	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

[Skin. Sens. 1 (H317), Aquatic Acute 1 (H400; M=1), Aquatic Chronic 1 (H410; M=1)]	**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.
d) Potassium permanganate	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 2 (H361d)]	**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.
e) XTJ 568; reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-({[2-(2-aminobutoxy)ethoxy]methyl}propoxy)but-2-ylamine	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4 (H302), Skin Corr. 1B (H314), Eye Dam. 1 (H318)], Repr. 2 (H361f); EUH071]	**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.
f) Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate	
RAC adopted <u>by consensus</u> the opinion with a proposal to remove the harmonised classification and labelling as indicated in Table 1 below. [**remove** Aquatic Chronic 4 (H413)]	**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.
g) Thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6-methyl- 1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate	
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; M=100), Aquatic Chronic 1 (H410; M=100)]	**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.

h) Propane-1,2-diol	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [no classification agreed]	**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.
i) Propiconazole (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4 (H302), Skin Sens. 1 (H317), Repr. 1B (H360D), Aquatic Acute 1 (H400; M=1), Aquatic Chronic 1 (H410; M=1)]	**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.
j) Mesosulfuron-methyl; methyl 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl] sulfamoyl}-4-{[(methylsulfonyl)amino]methyl}benzoate	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [No classification for HH hazards.] [at RAC 38: Aquatic Acute 1 (H400; M=100) and Aquatic Chronic 1 (H410; M=100)]	**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.
K) Spirodiclofen (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 1B (H350), Repr. 2 (H361f)] [at RAC 38: Skin Sens. 1B (H317), STOT RE 2 (H373), Aquatic Chronic 1 (H410; M=10)]	**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.
C. Presentation of key issues	
a) Glyphosate (ISO) Through presentations of EFSA, IARC, JMPR, Germany (CLH Dossier Submitter), Glyphosate Task Force and	**SECR** to make the presentations available on ECHA's website.

Health and Environmental Alliance, RAC received an overview of the data used and methods applied in the relevant hazard evaluations performed on glyphosate.	
7.3 Appointment of RAC (co-)rapporteurs for CLH dossiers	
RAC appointed the new (co-)rapporteurs for CLH dossiers.	**SECR** to upload the list of appointed (co-) rapporteurs to s-CIRCA BC confidential.
8. Restrictions	
8.1 Restriction Annex XV dossiers	
a) Conformity check	
1) Diisocyanates – outcome of conformity check and presentation of key issues RAC agreed that the dossier does not conform to the Annex XV requirements. RAC took note of the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to s-CIRCABC IG. **SECR** to inform the dossier submitter on the outcome of the conformity check.
b) Opinion development	
1) TDFAs Rapporteurs presented and RAC discussed the RAC second draft opinion. RAC supported the plausibility of the link between the identified hazards, the clinical cases and TDFAs/solvents in spray products. RAC supported that fluorosilanes (and potentially TDFAs) are assumed as active ingredients in the Magic Nano products linked to incidents. RAC agreed on the DNELs derived with two approaches. RAC agreed, in principle, on the RCRs for aerosol sprays that have to be finalised in line with the exposure estimates. Subject to final outcome of public consultation, RAC also agreed in principle that there may be a risk for pump and trigger sprays that needs to be addressed. RAC agreed that the need for EU-wide action is justified, and that the scope will cover all consumer sprays.	**Rapporteurs** to take the discussion and the outcome of public consultation into account in the third draft opinion due by end of January 2017.
2) Diisobutyl phthalate (DIBP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), bis(2-ethylhexyl) phthalate (DEHP)	**Rapporteurs** to take the discussion and the outcome of public consultation into account in the third draft opinion due by end of January 2017.

The Rapporteurs presented and RAC discussed the second draft opinion. RAC confirmed its conclusion of RAC-38 that other effects (immunological, metabolic, neurodevelopmental) will be addressed in the uncertainty analysis and SEA. RAC concluded that the proposed restriction is the most effective and appropriate EU-wide measure to reduce the risk. RAC concluded that alternatives are less toxic than the 4 phthalates and the restriction will therefore lead to an overall reduction of risk. RAC agreed to support the revised wording of the restriction, as recommended by the Rapporteurs. RAC concluded that the proposed restriction is a practical and monitorable measure for industry and enforcement authorities.	
8.2 Appointment of RAC (co-)rapporteurs for restriction dossiers	
RAC agreed on the updated pool of Rapporteurs for the restriction dossiers as stated in the restricted room document **RAC/39/2016/07**.	
9. Authorisation	
9.2 Authorisation applications	
a) Outcome of the conformity check and presentation of the key issues	
1. CT_Hapoc_2 (1 use) **2. CT_Hapoc_3 (1 use)** The CT_Hapoc_2 and CT_Hapoc_3 applications were not discussed for conformity, but only for key issues. **3. CT_Haas (1 use)** **4. SD_Haas (1 use)** **5. PD_Haas (1 use)** **6. CT_Reachlaw (4 uses)** **7. CT_Clariant (1 use)** **8. CT_ZFL (2 uses)** **9. SD_ZFL (1 use)** **10. CT_Cryospace (1 use)** **11. SC_Aviall (2 uses)** **12. SD_Borealis (1 use)** **13. SD_Ormezzano (2 uses)** **14. AD_BAE (2 uses)** **15. EDC_Biotech (1 use)**	**SECR** to upload to s-CIRCABC the agreed Conformity Reports. **SECR** to inform SEAC about the outcome of the Conformity check.

16. EDC_ORGAPHARM (2 uses) **17. EDC_Akzo (1 use)** **18. EDC_Bayer (1 use)** **19. EDC_Olon (2 uses)** **20. MOCA_Reachlaw (1 use)** RAC agreed on conformity of the applications for authorisation CT_Haas, SD_Haas, PD_Haas, CT_Reachlaw, CT_Clariant, CT_ZFL, SD_ZFL, CT_Cryospace, SC_Aviall, SD_Borealis, SD_Ormezzano, AD_BAE, EDC_Biotech, EDC_ORGAPHARM, EDC_Akzo, EDC_Bayer, EDC_Olon, MOCA_Reachlaw. RAC discussed the key issues in the applications for authorisation and provided advice to the Rapporteurs.	
b) Agreement on Draft Opinions	
1. Diglyme_Merck (1 use) RAC agreed on the draft opinion by consensus. RAC is of the opinion that RMMs and OCs are appropriate and effective in limiting the risk. RAC decided to recommend additional conditions and monitoring arrangements for the review report. RAC agreed to give no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
2. Diglyme_Isochem (1 use) RAC agreed on the draft opinion by consensus. RAC is of the opinion that adequate control has **not** been demonstrated and that the RMMs and OCs are **not** appropriate or effective in limiting the risk, in particular for workers. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation, including requests for: - Occupational exposure measurements (for dermal and inhalation exposure) - Technical RMMs including their maintenance for loading-unloading, sampling and storage. Given the risk control concerns, RAC agreed to recommend a shorter review period in addition to the conditions mentioned above to SEAC.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
3. Diglyme_Roche (1 use) RAC agreed in principle that the adequate control of risk has been demonstrated on paper (the facility is under construction) and expected RCR<1.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to **SECR**. **SECR** to launch a RAC consultation on the revised draft opinion.

The applicant shall validate the exposure scenario by appropriate measurements. RAC agreed to recommend conditions and monitoring arrangements for the authorisation.	**Rapporteurs** to revise the opinion in accordance with comments received during the RAC consultations as necessary and to provide it to the SECR. **SECR** to table the dossier for discussion and agreement at RAC 40 or by **written procedure**.
4. Diglyme_ LifeTech (1 use) RAC agreed in principle that RMMs and OCs are appropriate in limiting the risk and the adequate control has been demonstrated for workers. RAC supports the applicant's assessment of the 95% effectiveness of PPE but the associated uncertainties should be reflected in the draft opinion. RAC agreed to recommend conditions and monitoring arrangements for the authorisation and for the review reports emphasizing the following: On the basis of dermal exposure modelling or – preferably- dermal exposure measurements, the applicant shall review the tasks with the highest exposure potential and develop specific measures to reduce dermal exposure. RAC agreed to give no advice to SEAC on the length of the review period.	**Use 1:** **Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to **SECR**. **SECR** to launch a RAC consultation on the revised draft opinion. **Rapporteurs** to revise the opinion in accordance with comments received during the RAC consultations as necessary and to provide it to the SECR. **SECR** to table the dossier for discussion and agreement at RAC 40 or by **written procedure**.
5. Diglyme_Acton (2 uses) **Use 1:** RAC agreed in principle that RMMs and OCs are not appropriate in limiting the risk and the adequate control has not been demonstrated for workers. RAC agreed to recommend conditions and monitoring arrangements for the authorisation and for the review reports. RAC recommended a shorter review period to SEAC based on exposure control concerns. **Use 2:** After further assessment RAC agreed in principle that it was not possible to evaluate the application for use 2 <u>in its current form</u>. Therefore, it cannot be confirm that the operational conditions and risk management measures are appropriate and effective in limiting the risk, unless the applicant provides in full, the already requested missing information on OC and RMMs within a deadline set by the ECHA Secretariat. This should allow RAC to conclude on its opinion in March 2017.	**Use 1:** **Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to **SECR**. **SECR** to launch a RAC consultation on the revised draft opinion. **Rapporteurs** to revise the opinion in accordance with comments received during the RAC consultations as necessary and to provide it to the SECR. **SECR** to table the dossier for discussion and agreement at RAC-40 or by **written procedure**. **Use 2:** **SECR** and **Rapporteurs** to ask the applicant to provide missing information on use 2. **Rapporteurs** to revise the opinion in accordance with additional information provided by the applicant (if applicable) and the discussion in RAC and to provide it to **SECR**.

	SECR to launch a RAC consultation on the revised draft opinion. **Rapporteurs** to revise the opinion in accordance with comments received during the RAC consultations as necessary and to provide it to the SECR. **SECR** to table the dossier for discussion and agreement at RAC-40 or by **written procedure**.
6. Diglyme_Bracco (1 use) RAC agreed on the draft opinion by consensus. RAC is of the opinion that RMMs and OCs are appropriate and effective in limiting the risk. RAC did not recommend additional conditions or monitoring arrangements. RAC agreed to give no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
7. Diglyme_Maflon (1 use) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk and the adequate control has been demonstrated. RAC recommended conditions and monitoring arrangements for the review report. RAC agreed to give no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
8. Chromium trioxide_HAPOC (4 uses) (CT_HAPOC) RAC took note of the information presented by the Rapporteurs on the progress of the opinion development, noting the difficulties in assessing this application in its current form. RAC discussed the approach taken by the Rapporteurs in the opinion development process requesting the rapporteurs to clearly identify missing information, particularly but not exclusively on OC and RMM's.	**Rapporteurs** to draft the first version of the draft opinions for RAC consultation before the March 2017 plenary meeting.
9. Potassium dichromate-Gentrochema (2 uses) (PD_Gentrochema) **10. Sodium dichromate-Gentrochema (3 uses) (SD_Gentrochema)** **General** RAC noted that the assessment reports are identical to those submitted by Brenntag UK Ltd. for the same uses of the same substances.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicant for commenting.

RAC agreed on an approach that refers to the opinion justification of Brenntag UK Ltd. and discusses specific information reported by Gentrochema BV (e.g. on the tonnage expected and the similarities in the supply chains) in addition to the information included in the assessment reports. RAC agreed on the draft opinions by consensus. **Common to all uses:** RAC considered that the applicant's assessment of the exposure, risk and impacts for humans via the environment is based on a series of default assumptions that are likely to result in a significant overestimate of impacts. This introduces considerable uncertainty to the applicant's assessment, which should be addressed in any review report. The re-use of the estimated additional statistical fatal cancer cases outside of the socio-economic analysis is advised against. **Common to Formulation and Surface treatment** RAC considered that the operational conditions and risk management measures described in the application **do not** limit the risk, however the suggested conditions and monitoring arrangements are expected to improve the situation. RAC proposes conditions and monitoring arrangements (e.g., more appropriate exposure scenarios without delay and their validation; air monitoring for workers; monitoring of emissions to the environment) and conditions related to the review report as listed in the opinions. **Formulation**: RAC proposed to include a specific condition on waste management to this use. RAC gave no advice to SEAC on the length of the review period. **Surface treatment**: In addition to the conditions and monitoring arrangements above, RAC proposed to include specific conditions (i.e., regarding waste management and control of exposure during decanting and weighing of solids). RAC recommended to SEAC a review period of no longer than 7 years. **Passivation of tin-plated steel**: RAC confirmed that the operational conditions and risk management measures described in the application limit the risk, provided that the risk management measures and operational conditions as described in	

the application and the suggested conditions and monitoring arrangements are adhered to. RAC proposed conditions and monitoring arrangements (e.g., more appropriate OCs & RMMs; air monitoring for workers) and conditions related to the review report (e.g. monitoring of emissions to the environment) as listed in the opinions. RAC gave no advice to SEAC on the length of the review period.	
11. Technical MDA_Polynt Uses 1 and 2 RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs are appropriate in limiting the risk for workers and the environment. RAC agreed to recommend conditions and monitoring arrangements for the review report for use 1. RAC agreed to give no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicant for commenting.
12. EDC_EURENCO RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that RMMs and OCs are not appropriate in limiting the risk. RAC agreed to recommend conditions and monitoring arrangements for the authorisation and the review report. RAC recommended a shorter review period to SEAC.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
c) Adoption of final opinions	
1. Chromium trioxide_Cromomed (1 use) (CT_Cromomed) RAC adopted the final opinion with changes in the text addressing the comments by the Applicants, as proposed by the Rapporteurs.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the opinion to the EC, MSs and the Applicant.
2. Chromium trioxide_Burscheid (1 use) (CT_Burscheid) RAC adopted the final opinions with no changes following the Applicants' comments on the draft opinion.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the opinion to the EC, MSs and the Applicant.

3. Chromium trioxide_Friedberg (1 use) (CT_Friedberg) RAC adopted the final opinions with no changes following the Applicants' comments on the draft opinion.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the opinion to the EC, MSs and the Applicant.
4. Chromium trioxide_Valvetrain (1 use) (CT_Valvetrain) RAC adopted the final opinions with no changes following the Applicants' comments on the draft opinion.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the opinion to the EC, MSs and the Applicant.
5. Sodium dichromate_Akzo (2 uses) (SD_Akzo) RAC adopted the final opinions with no changes following the Applicants' comments on the draft opinion.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the opinion to the EC, MSs and the Applicant.
6. Sodium dichromate_Arkema (1 use) (SD_Arkema) RAC adopted the final opinions with no changes following the Applicants' comments on the draft opinion.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the opinion to the EC, MSs and the Applicant.
7. Chromic acid_Bosch (1 use) (CA_Bosch) RAC adopted the final opinions with no changes following the Applicants' comments on the draft opinion.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the opinion to the EC, MSs and the Applicant.
8. Potassium dichromate_Brenntag (2 uses) (PD_Brenntag) RAC adopted the final opinion with changes in the text addressing the comments by the Applicants, as proposed by the Rapporteurs.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the opinion to the EC, MSs and the Applicant.
9. Sodium dichromate_Brenntag (3 uses) (SD_Brenntag) RAC adopted the final opinion with changes in the text addressing the comments by the Applicants, as proposed by the Rapporteurs.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the opinion to the EC, MSs and the Applicant.
10. Dichromium tris(chromate)_Henkel (2 uses) (DtC_Henkel)	**Rapporteurs** together with **SECR** to do the final editing of the opinion.

RAC adopted the final opinion with changes in the text addressing the comments by the Applicants, as proposed by the Rapporteurs.	**SECR** to send the opinion to the EC, MSs and the Applicant.
11. Strontium chromate_Akzo (2 uses) (ST_Akzo) RAC adopted the final opinion with changes in the text addressing the comments by the Applicants, as proposed by the Rapporteurs.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the opinion to the EC, MSs and the Applicant.
12. Potassium hydroxyoctaoxodizincatedichromate_PPG (2 uses) (PH_PPG) RAC adopted the final opinion with changes in the text addressing the comments by the Applicants, as proposed by the Rapporteurs.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the opinion to the EC, MSs and the Applicant.
9.3 Appointment of RAC (co-)rapporteurs for authorisation applications	
RAC/39/2016/06 RAC agreed on the updated pool of Rapporteurs for the applications for authorisation.	**SECR** to upload the pool of Rapporteurs to s-CIRCABC restricted.
10. AOB	
11. Action points and main conclusions of RAC-39	
SECR to upload the adopted action points to s-CIRCA BC.	

Table 1: CLH dossiers for which RAC adopted an opinion

Note: where hazard classes of an existing entry were not proposed to be changed by the Dossier Submitter, these are highlighted in grey colour

RAC-39

1. **Mesosulfuron-methyl**
2. **Spirodiclofen (ISO)**
3. **1-vinylimidazole**
4. **Colecalciferol; vitamin D_3**
5. **Asulam sodium**
6. **Potassium permanganate**
7. **XTJ568**
8. **Tri-tri-tribenzoate**
9. **Thifensulfuron-methyl (ISO)**
10. **Propane-1,2-diol**
11. **Propiconazole (ISO)**

Table 1: Classification & labelling tables for substances for which RAC adopted an opinion

Mesosulfuron-methyl (ISO); methyl 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl] sulfamoyl}-4-{[(methylsulfonyl)amino]methyl}benzoate

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	TBD	mesosulfuron-methyl; methyl 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl] sulfamoyl}-4-{[(methylsulfonyl)amino]methyl}benzoate	-	208465-21-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410	-	M=100 M=100	-
RAC opinion	TBD	mesosulfuron-methyl; methyl 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl] sulfamoyl}-4-{[(methylsulfonyl)amino]methyl}benzoate	-	208465-21-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410	-	M=100 M=100	-
Resulting Annex VI entry if agreed by COM	TBD	mesosulfuron-methyl; methyl 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl] sulfamoyl}-4-{[(methylsulfonyl)amino]methyl}benzoate	-	208465-21-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410	-	M=100 M=100	-

Spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statementCode(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	TBD	spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate	-	148477-71-8	Carc. 1B Repr. 2 Skin Sens. 1B STOT RE 2 Aquatic Chronic 1	H350 H361f H317 H373 H410	GHS07 GHS08 GHS09 Dgr	H350 H361f H317 H373 H410	-	M=10	-
RAC opinion	TBD	spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate	-	148477-71-8	Carc. 1B Repr. 2 Skin Sens. 1B STOT RE 2 Aquatic Chronic 1	H350 H361f H317 H373 H410	GHS07 GHS08 GHS09 Dgr	H350 H361f H317 H373 H410	-	M=10	-
Resulting Annex VI entry if agreed by COM	TBD	spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate	-	148477-71-8	Carc. 1B Repr. 2 Skin Sens. 1B STOT RE 2 Aquatic Chronic 1	H350 H361f H317 H373 H410	GHS07 GHS08 GHS09 Dgr	H350 H361f H317 H373 H410	-	M=10	-

1-vinylimidazole

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling				
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	Specific Conc. Limits, M-factors	Notes
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	613-RST-00-Y	1-vinylimidazole	214-012-0	1072-63-5	Repr. 1B	H360D	GHS08 Dgr	Repr. 1B	H360D	-	-
RAC opinion	613-RST-00-Y	1-vinylimidazole	214-012-0	1072-63-5	Repr. 1B	H360D	GHS08 Dgr	Repr. 1B	H360D	Repr. 1B; H360D: C ≥ 0.03%	-
Resulting Annex VI entry if agreed by COM	613-RST-00-Y	1-vinylimidazole	214-012-0	1072-63-5	Repr. 1B	H360D	GHS08 Dgr	Repr. 1B	H360D	Repr. 1B; H360D: C ≥ 0.03%	-

Colecalciferol; cholecalciferol; vitamin D_3

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	603-180-00-4	colecalciferol; cholecalciferol; vitamin D_3	200-673-2	67-97-0	Acute Tox. 3* Acute Tox. 3* Acute Tox. 2* STOT RE 1	H301 H311 H330 H372**	GHS06 GHS08 Dgr	H301 H311 H330 H372**			
Dossier submitters proposal	603-180-00-4	colecalciferol; cholecalciferol; vitamin D_3	200-673-2	67-97-0	**Modify** Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 STOT RE 1 **Add** Carc. 2 Muta. 2	**Modify** H300 H310 H330 H372 **Add** H351 H341	GHS06 GHS08 Dgr	**Modify** H330 H310 H300 H372 **Add** H351 H341		STOT RE 1; H372: C ≥ 0.6 % STOT RE 2; H373: 0.06 % < C < 0.6 %	
RAC proposal	603-180-00-4	colecalciferol; cholecalciferol; vitamin D_3	200-673-2	67-97-0	**Modify** Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 STOT RE 1	**Modify** H300 H310 H330 H372	GHS06 GHS08 Dgr	**Modify** H330 H310 H300 H372		STOT RE 1; H372: C ≥ 3 % STOT RE 2; H373: 0.3 % ≤ C < 3 %	
Resulting Annex VI entry if agreed by COM	603-180-00-4	colecalciferol; cholecalciferol; vitamin D_3	200-673-2	67-97-0	Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 STOT RE 1	H300 H310 H330 H372	GHS06 GHS08 Dgr	H330 H310 H300 H372		inhalation: ATE[2] = 0.05 mg/L (dusts or mists) dermal ATE[3] = 50 mg/kg oral: ATE = 35 mg/kg	

[2] Converted acute toxicity point estimate according to Table 3.1.2 of Annex I.

[3] Converted acute toxicity point estimate according to Table 3.1.2 of Annex I.

										STOT RE 1; H372: C ≥ 3 % STOT RE 2; H373: 0.3 % ≤ C < 3 %	

Sodium methyl [(4-aminophenyl)sulphonyl]carbamate; sodium methyl (*EZ*)-sulfanilylcarbon-imidate; asulam-sodium

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	607-RST-VW-Y	sodium methyl [(4-aminophenyl)sulphonyl]carbamate; sodium methyl (*EZ*)-sulfanilylcarbonimidate; asulam-sodium	218-953-8	2302-17-2	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410	-	M=1 M=1	-
RAC opinion	607-RST-VW-Y	sodium methyl [(4-aminophenyl)sulphonyl]carbamate; sodium methyl (*EZ*)-sulfanilylcarbonimidate; asulam-sodium	218-953-8	2302-17-2	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410	-	M=1 M=1	-
Resulting Annex VI entry if agreed by COM	607-RST-VW-Y	sodium methyl [(4-aminophenyl)sulphonyl]carbamate; sodium methyl (*EZ*)-sulfanilylcarbonimidate; asulam-sodium	218-953-8	2302-17-2	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410	-	M=1 M=1	-

Potassium permanganate

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	025-002-00-9	potassium permanganate	231-760-3	7722-64-7	Ox. Sol. 2 Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H272 H302 H400 H410	GHS03 GHS07 GHS09 Dgr	H272 H302 H410	**-**	-	-
Dossier submitters proposal	025-002-00-9	potassium permanganate	231-760-3	7722-64-7	**Add** Repr. 1B	**Add** H360Df	**Add** GHS08 Dgr	**Add** H360Df	**-**	**-**	**-**
RAC opinion	025-002-00-9	potassium permanganate	231-760-3	7722-64-7	**Add:** Repr. 2	**Add:** H361d	**Add:** GHS08	**Add:** H361d	**-**	**-**	**-**
Resulting Annex VI entry if agreed by COM	025-002-00-9	potassium permanganate	231-760-3	7722-64-7	Ox. Sol. 2 Repr. 2 Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H272 H361d H302 H400 H410	GHS03 GHS07 GHS08 GHS09 Dgr	H272 H361d H302 H410	**-**	**-**	**-**

Reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-({[2-(2-aminobutoxy) ethoxy]methyl}propoxy)but-2-ylamine ("XTJ-568")

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	612-RST-00-Y	reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-({[2-(2-aminobutoxy)ethoxy]methyl}propoxy)but-2-ylamine	447-920-2	-	Repr. 2 Acute Tox. 4 Skin Corr. 1B Eye Dam. 1	H361fd H302 H314 H318	GHS05 GHS07 GHS08 Dgr	H361fd H302 H314	-	-	-
RAC opinion	612-RST-00-Y	reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-({[2-(2-aminobutoxy)ethoxy]methyl}propoxy)but-2-ylamine	447-920-2	-	Repr. 2 Acute Tox. 4 Skin Corr. 1B Eye Dam. 1	H361f H302 H314 H318	GHS05 GHS07 GHS08 Dgr	H361f H302 H314	EUH071	-	-
Resulting Annex VI entry if agreed by COM	612-RST-00-Y	reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-({[2-(2-aminobutoxy)ethoxy]methyl}propoxy)but-2-ylamine	447-920-2	-	Repr. 2 Acute Tox. 4 Skin Corr. 1B Eye Dam. 1	H361f H302 H314 H318	GHS05 GHS07 GHS08 Dgr	H361f H302 H314	EUH071	-	-

Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate (Uvinul® T 150)

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-414-00-6	tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate	402-070-1	88122-99-0	Aquatic Chronic 4	H413	-	H413	-	-	-
Dossier submitters proposal	607-414-00-6	tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate	402-070-1	88122-99-0	**Remove** Aquatic Chronic 4	**Remove** H413	-	**Remove** H413	-	-	-
RAC opinion	607-414-00-6	tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate	402-070-1	88122-99-0	**Remove** Aquatic Chronic 4	**Remove** H413	-	**Remove** H413	-	-	-
Resulting Annex VI entry if agreed by COM	607-414-00-6	tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate	402-070-1	88122-99-0	-	-	-	-	-	-	-

Thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6-methyl- 1,3,5-triazin-2-ylcarbamoyl-sulfamoyl)thiophene-2-carboxylate

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	016-096-00-2	thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl) thiophene-2-carboxylate	not available	79277-27-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410	-	-	-
Dossier submitters proposal	016-096-00-2	thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl) thiophene-2-carboxylate	not available	79277-27-3	**Retain** Aquatic Acute 1 Aquatic Chronic 1	**Retain** H400 H410	**Retain** GHS09 Wng	**Retain** H410	-	**Add** M-factor 100 M-factor 100	-
RAC opinion	016-096-00-2	thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl) thiophene-2-carboxylate	not available	79277-27-3	**Retain** Aquatic Acute 1 Aquatic Chronic 1	**Retain** H400 H410	**Retain** GHS09 Wng	**Retain** H410	-	**Add** M-factor 100 M-factor 100	-
Resulting Annex VI entry if agreed by COM	016-096-00-2	thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6-methyl-1,3,5-triazin-2-ylcarbamoylsulfamoyl) thiophene-2-carboxylate	not available	79277-27-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410	-	M-factor 100 M-factor 100	-

Propane-1,2-diol

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	propane-1,2-diol	200-338-0	57-55-6	STOT SE 3	H335	GHS07 Wng	H335	-	-	-
RAC opinion	TBD	propane-1,2-diol	200-338-0	57-55-6	No classification	-	-	-	-	-	-
Resulting Annex VI entry if agreed by COM	TBD	propane-1,2-diol	200-338-0	57-55-6	-	-	-	-	-	-	-

Propiconazole (ISO); (2*RS*,4*RS*;2*RS*,4*SR*)-1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1*H*-1,2,4-triazole

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-205-00-0	propiconazole (ISO); (2*RS*,4*RS*;2*RS*,4*SR*)-1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1*H*-1,2,4-triazole	262-104-4	60207-90-1	Acute Tox. 4 * Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H317 H400 H410	GHS07 GHS09 Wng	H302 H317 H410	-	-	-
Dossier submitters proposal	613-205-00-0	propiconazole (ISO); (2*RS*,4*RS*;2*RS*,4*SR*)-1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1*H*-1,2,4-triazole	262-104-4	60207-90-1	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 2 **Modify** Acute Tox. 4	**Retain** H302 H400 H410 **Add** H361d	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** H302 H410 **Add** H361d	**-**	**Add** M=1 M=1	**-**
RAC opinion	613-205-00-0	propiconazole (ISO); (2*RS*,4*RS*;2*RS*,4*SR*)-1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1*H*-1,2,4-triazole	262-104-4	60207-90-1	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 1B **Modify** Acute Tox. 4	**Retain** H302 H400 H410 **Add** H360D	**Retain** GHS07 GHS09 **Add** GHS08 **Modify:** Dgr	**Retain** H302 H410 **Add** H360D	**-**	**Add** M=1 M=1	**-**
Resulting Annex VI entry if agreed by COM	613-205-00-0	propiconazole (ISO); (2*RS*,4*RS*;2*RS*,4*SR*)-1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1*H*-1,2,4-triazole	262-104-4	60207-90-1	Repr. 1B Acute Tox. 4 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H302 H317 H400 H410	GHS07 GHS08 GHS09 Dgr	H360D H302 H317 H410	-	M=1 M=1	-

Part III. List of Attendees of the RAC-39 meeting

28 November-2 December 2016 and 7-9 December 2016

RAC Members
ANDREOU Kostas
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
DI PROSPERO FANGHELLA Paola
DUNAUSKIENĖ Lina
DUNGEY Stephen
GRUIZ Katalin
GUSTAFSON Anne-Lee
HAKKERT Betty
HUSA Stine
ILIE Mihaela
JANKOWSKA Elżbieta (co-opted Member)
KADIĶIS Normunds
KAPELARI Sonja
LECLOUX Helene
LEINONEN Riitta
LUND Bert-Ove
MARTINEK Michal
MENARD Anja
MOELLER Ruth
MULLOOLY Yvonne
MURRAY Brendan
NEUMANN Michael
PARIS Pietro
PASQUIER Elodie
POLAKOVICOVA Helena
RUCKI Marian
RUPPRICH Norbert
SANTONEN Tiina
SCHLÜTER Urs
SCHULTE Agnes
SMITH Andrew
SOGORB Miguel
SØRENSEN Peter Hammer
SPETSERIS Nikolaos
STAHLMANN Ralf
STAŠKO Jolanta
TOBIASSEN Lea Stine
TSITSIMPIKOU Christina
UŽOMECKAS Žilvinas
VAN DER HAAR Rudolf (co-opted Member)
VARNAI Veda Marija
VIEGAS Susana (co-opted Member)
Apologies
COPIN Stephanie (maternity leave)
HÖLZL Christine
PRONK Marja

Invited experts
PRINTEMS Nathalie (her RAC mandate will start 17/11/2016)
SUUTARI Tiina (9.12. replacing RAC Member Riitta Leinonen)
Commission observers
BINTEIN Sylvain, DG ENV
GARCIA-JOHN Enrique, DG GROW
WACHTLER Volker, SANTE (glyphosate)
RAC advisors
CATONE Tiziana (Paola di Prospero)_thifensulfuron methyl
ESPOSITO Dania (Pietro Paris)_tris(2-ethylhexyl..)
LOIKKANEN Jarkko (Riitta Leinonen)
PAPPONEN Hinni (Riitta Leinonen)
ROMOLI Debora (Pietro Paris)
STOCKMANN-JUVALA Helene (Tiina Santonen)
SULGA Marius (Zilvinas Uzomeckas)_asulam sodium, thifensulfuron-methyl
SUUTARI Tiina (Riitta Leinonen)
TALASNIEMI Petteri (Riitta Leinonen)
UUKSULAINEN Sanni (Tiina Santonen)
VEGA Milagros (Joao Carvalho)_propiconazole

Stakeholders observers
ANNYS Erwin, Cefic
BARRY Frank, ETUC
BERNARD Alice (occasional stakeholder observer, AfA, restriction)
CLAUSING Peter (occasional stakeholder observer, AfA, restriction, CLH glyphosate)
DE KORT Patrick (occasional stakeholder observer, restriction phthalates)
GUYTON Kate Z, IARC (glyphosate)
MUNARI Tomaso (EuCheMs)
PORTER Christopher, NGO (glyphosate)
ROMANO Dolores
ROWE Rocky, ECPA
VERGER Philippe, JMPR (glyphosate)
VEROUGSTRAETE Violaine, Eurometaux
Dossier submitters
NEUMANN Lars (DE, glyphosate)
ROUW Aarnout (DE, diisocyanates)
SCHULTE Stefan (DE, 1-vinylmidazole)
WALENDZIK Gudrun (DE, diisocyanates)

Industry experts	
DALTON Pamela (Cefic, Monell Chemical Senses Center, propane-1,2-diol)	
FRAME Steven (Ecpa, DuPont, thifensulfuron-methyl)	
KROESCHE Christoph (Cefic, EVONIK Industries, TDFAs)	
LLOYD Sara (Ecpa, Syngenta, CLH propiconazole)	
MARTENS Mark (Ecpa, GTF, glyphosate)	
McGOUGH Doreen (Cefic, International Manganese Institute)	
SARGINSON Nigel (EuPC, ExxonMobil, phthalates)	
SEMINO-BENINEL Giovanna (Ecpa, Bayer, cholecalciferol D3)	
TEMORASKI Michael (Ecpa, BCS, spirodiclofen)	
THIEL Anette (Cefic, DSM Nutritional Products Ltd, cholecalciferol D3)	
VAN ESBROECK Christine (Ecpa, UPL, asulam)	
EFSA	
COURT MARQUES Danièle	
TARAZONA José V.	

REMOTE PARTICIPANTS		**Netherlands**
RAC Members:		GERAETS Liesbeth (CLH spirodiclofen)
HÖLZL Christine		MÜLLER Andre (CLH sprirodiclofen)
MÖLLER Ruth		
PRONK Marja		**Sweden**
		BIRGANDER Pernilla (CLH cholecalciferol)
Advisors		
LINDEMAN Birgitte (Christine Bjoerge)		**Commission**
LOSERT Annemarie (Christine Hölzl)		BERTATO Valentina
VAN DER HAGEN Marianne (Christine Bjoerge)		JAMERS An
		LUVARA Giuseppina
Dossier submitters:		ROZWADOWSKI Jacek
Denmark		
HOLMBERG Rikke (phthalates)		**EFSA**
WINTHER Toke (phthalates)		ISTACE Frederique
		KARDASSI Dimitra
Germany		PARRA Juan Manuel
AVERBECK Frauke (diisocyanates)		
DROSSARD Claudia (diisocyanates)		
GUHE Christine (diisocyanates)		
HEESCHE-WAGNER Kerstin (diisocyanates)		
HERMANN Georgia (CLH glyphosate)		
ROTHER Dag (diisocyanates)		
Finland		
MOILANEN Marianne (CLH propiconazole)		
RISSANEN Eeva (CLH propiconazole)		
France		
CHARLES Sandrine (CLH potassium permanganate)		

ECHA staff	SOSNOWSKI Piotr
BERGES Markus	SOTIRIOS Kiokias
BLAINEY Mark	SPJUTH Linda
BOWMER Tim, Chairman	STOYANOVA Evgenia
BROECKAERT Fabrice	
BROERE William	
CLENAGHAN Conor	
DVORAKOVA Dana	
ERICSSON Gunilla	
HENRICSSON Sanna	
HOPLAND Eivind	
JONES Stella	
KANELLOPOULOU Athanasia	
KARJALAINEN Ari	
KIVELÄ Kalle	
KOKKOLA Leila	
KOSK-BIENKO Joanna	
KOULOUMPOS Vasileios	
LAPENNA Silvia	
LINNA Risto	
LIOPA Elina	
LOGTMEIJER Christiaan	
LUDBORŽS Arnis	
MARQUEZ-CAMACHO Mercedes	
MAZZOLINI Anna	
MERKOURAKIS Spyridon	
MULLER Gesine	
NICOT Thierry	
NYGREN Jonas	
ORISPÄÄ Katja	
O´ROURKE Regina	
PELTOLA Jukka	
PENNESE Daniele	
PERAZZOLA Chiara	
PILLET Monique	
PREVEDOUROS Konstantinos	
RANTALA Terhi	
REGIL Pablo	
RHEINBERGER Christoph	
RODRIGUEZ-IGLESIAS Pilar	
ROGGEMAN Maarten	
SADAM Diana	
SIMOES Ricardo	
SIMPSON Pete	
SMILOVICI Simona	

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC 39 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC 39 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC 39 meeting

ANNEX IV Administrative issues and information items

ANNEX V Short summary: Rapporteur's preparatory workshop on the Authorisation Applications from the February Authorisation window

28 November 2016
RAC/A/39/2016

Final Agenda

39th meeting of the Committee for Risk Assessment

28 November – 9 December 2016

ECHA Conference Centre (Annankatu 18, Helsinki)

28 November starts at 14.00
2 December breaks at 13.00
7 December resumes at 9.00
9 December ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/39/2016
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

For information

Item 4 – Report from other ECHA bodies and activities

a) Report on RAC 38 action points, written procedures and update on other ECHA bodies

RAC/39/2016/01

RAC/39/2016/02
Room document
For information

b) RAC workplan for all processes

For information

Item 5 – Requests under Article 77 (3)(c)

No requests.

Item 6 – Requests under Article 95 (3)

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

RAC/39/2016/03
Restricted room document
For discussion

b) OEL-DNEL methodology request

RAC/39/2016/04
Restricted document
For discussion

Item 7 – Harmonised classification and labelling (CLH)

7.1 General CLH issues

7.2 CLH dossiers

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

- Asulam sodium: physical hazards, acute toxicity, serious eye damage / eye irritation, STOT SE, STOT RE, respiratory sensitisation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, environmental hazards
- XTJ568: acute toxicity, skin corrosion (incl. additional labelling with EUH071), serious eye damage, germ cell mutagenicity
- Thifensulfuron-methyl (ISO): environmental hazards
- Propiconazole (ISO): acute toxicity (oral route of exposure), skin sensitisation, environmental hazards
- Mesosulfuron-methyl: physical hazards, acute toxicity, serious eye damage / eye irritation, STOT SE, STOT RE, respiratory or skin sensitisation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, aspiration hazard

B. Hazard classes for agreement with plenary debate

a) 1-vinylmidazole

b) Colecalciferol, vitamin D_3

c) Asulam sodium

d) Potassium permanganate

e) XTJ568; reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-({[2-(2-aminobutoxy)ethoxy]methyl}propoxy)but-2-ylamine

f) Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate
g) Thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6-methyl- 1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate
h) Propane-1,2-diol
i) Propiconazole (ISO)
j) Mesosulfuron-methyl; methyl 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-4-{[(methylsulfonyl)amino]methyl}benzoate
k) Spirodiclofen (ISO)

For discussion and adoption

C. Presentation of key issues

b) Glyphosate (ISO)

For discussion

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

RAC/39/2016/05
Restricted room document
For agreement

Item 8 – Restrictions

8.1 Restriction Annex XV dossiers

a) Conformity check
   1. Diisocyanates – outcome of conformity check and presentation of key issues

For agreement

b) Opinion development

   2. TDFAs – second draft opinion
   3. 4 phthalates- second draft opinion

For discussion/agreement

8.2 Appointment of (co-)rapporteurs for restriction dossiers

For information

Item 9 – Authorisation

9.2 General authorisation issues

a) Update on incoming/future applications

b) Report on AfA Task Force and related activities

For information

9.3 Authorisation applications

a) Outcome of the conformity check and presentation of the key issues

1. CT_Hapoc_2 (1 use)
2. CT_Hapoc_3 (1 use)
3. CT_Haas (1 use)
4. SD_Haas (1 use)
5. PD_Haas (1 use)
6. CT_Reachlaw (4 uses)
7. CT_Clariant (1 use)
8. CT_ZFL (2 uses)
9. SD_ZFL (1 use)
10. CT_Cryospace (1 use)
11. SC_Aviall (2 uses)
12. SD_Borealis (1 use)
13. SD_Ormezzano (2 uses)
14. AD_BAE (2 uses)
15. EDC_Biotech (1 use)
16. EDC_ORGAPHARM (2 uses)
17. EDC_Akzo (1 use)
18. EDC_Bayer (1 use)
19. EDC_Olon (2 uses)
20. MOCA_Reachlaw (1 use)

For agreement

b) Agreement on Draft Opinions

1. Diglyme_Merck (1 use)
2. Diglyme_Isochem (1 use)
3. Diglyme_Roche (1 use)
4. Diglyme_LifeTech (1 use)
5. Diglyme_Acton (2 uses)
6. Diglyme_Bracco (1 use)
7. Diglyme_Maflon (1 use)
8. Chromium trioxide_HAPOC (4 uses) (CT_HAPOC)
9. Potassium dichromate GENTROCHEMA BV (2 uses) (PD_Gentrochema)

10. Sodium dichromate GENTROCHEMA BV (3 uses) (SD_Gentrochema)
11. Technical MDA_Polynt (2 uses)
12. EDC_Eurenco (1use)

For discussion and/or agreement

c) Adoption of final opinions

1. Chromium trioxide_Cromomed (1 use) (CT_Cromomed)
2. Chromium trioxide_Burscheid (1 use) (CT_Burscheid)
3. Chromium trioxide_Friedberg (1 use) (CT_Friedberg)
4. Chromium trioxide_Valvetrain (1 use) (CT_Valvetrain)
5. Sodium dichromate_Akzo (2 uses) (SD_Akzo)
6. Sodium dichromate_Arkema (1 use) (SD_Arkema)
7. Chromic acid_Bosch (1 use) (CA_Bosch)
8. Potassium dichromate_Brenntag (2 uses) (PD_Brenntag)
9. Sodium dichromate_Brenntag (3 uses) (SD_Brenntag)
10. Dichromium tris(chromate)_Henkel (2 uses) (DtC_Henkel)
11. Strontium chromate_Akzo (2 uses) (ST_Akzo)
12. Potassium hydroxyoctaoxodizincatedichromate_PPG (2 uses) (PH_PPG)

For discussion and adoption

9.4 Appointment of (co-)rapporteurs for authorisation applications

RAC/39/2016/06
Restricted room document
For agreement

Item 10 – AOB

Item 11 – Action points and main conclusions of RAC 39

Table with Conclusions and Action points from RAC 39

For adoption

Annex II (RAC 39)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 39 meeting.

Document number	Title
RAC/A/39/2016	Final Draft Agenda
RAC/A/39/2016 Restricted	Draft outline agenda
RAC/39/2016/01	Report from other ECHA bodies
RAC/39/2016/02 Room document	Administrative issues
RAC/39/2016/03 Restricted document	1-methyl-2-pyrrolidone (NMP)
RAC/39/2016/04 Restricted document	OEL-DNEL methodology request
RAC/39/2016/05 Room document Restricted	Appointment of Rapporteurs for CLH dossiers
RAC/39/2016/06 Restricted	Appointment of Rapporteurs authorisation

ANNEX III (RAC 39)

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		
Spirodiclofen (ISO) (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.
	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.
Restrictions		
TDFAs (DK)	Lea Stine TOBIASSEN	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.
	Peter Hammer SØRENSEN	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.
4-phthalates (DK)	Lea Stine TOBIASSEN	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.
	Peter Hammer SØRENSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		substance - no other mitigation measures applied.

New dossiers

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW		
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 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.
Applications for Authorisation		

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
Harmonised classification & labelling		
Colecalciferol, vitamin D_3 **(SE)**	Anne-Lee GUSTAFSON	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.
	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Asulam sodium **Thifensulfuron-methyl (ISO)** **(UK)**	Andrew SMITH	Working for the CA submitting the dossier and involved in the preparation; asked to refrain from voting in the event of a vote on these substances - other mitigation measures may be applied by the Chairman.
	Steve DUNGEY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on these substances - no other mitigation measures applied.
Potassium permanganate **Mesosulfuron-methyl (ISO)** **(FR)**	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on these substances - no other mitigation measures applied.
XTJ568; reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-({[2-(2-aminobutoxy)ethoxy]methyl}propoxy)but-2-ylamine **(BE)**	Helene LECROUX	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.
Propiconazole (ISO)	Riitta LEINONEN	Working for the CA submitting the dossier;

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
(FI)		asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Tiina SANTONEN	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. Glyphosate (ISO) **2. Tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate** **3. Propane-1,2-diol** **(DE)**	Agnes SCHULTE	1. 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. 2. 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. 3. 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	1. 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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		be applied by the Chairman. 2. and 3. Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on these substances - 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 these substances - 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 these substances - no other mitigation measures applied.
Article 95(3) requests		
1-methyl-2-pyrrolidone (NMP)	Marja PRONK Betty HAKKERT	Working for the CA previously submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

Helsinki, 25 November 2016

RAC/39/2016/02

ROOM DOCUMENT

39TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

28 November – 2 December 2016
7 – 9 December 2016

Helsinki, Finland

Concerns: **Administrative issues and information items**

Agenda Point: **4a**

Action requested: **For information**

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC 38 Action Points

The RAC 38 action points due for RAC 39 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 38	27 November 2016	ongoing

2.2 RAC consultations (status by 24 August 2016)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
Spirodiclofen (ISO)	7 November 2016	closed
Potassium permanganate	21 October 2016	closed
propiconazole (ISO); (2RS,4RS;2RS,4SR)-1-{[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl}-1H-1,2,4-triazole	26 October 2016	closed
tris(2-ethylhexyl) 4,4',4''-(1,3,5-triazine-2,4,6-triyltriimino)tribenzoate	14 October 2016	closed
propane-1,2-diol	27 October 2016	closed
1-vinylimidazole	6 November 2016	closed
thifensulfuron-methyl (ISO); methyl 3-(4-methoxy-6-methyl- 1,3,5-triazin-2-ylcarbamoylsulfamoyl)thiophene-2-carboxylate	4 November 2016	closed
Colecalciferol (vitamin D_3)	6 November 2016	closed
sodium methyl [(4-aminophenyl)sulphonyl]carbamate; sodium methyl (EZ)-sulfanilylcarbonimidate; asulam-sodium	4 November 2016	closed
Mesosulfuron-methyl (HH)	2 November 2016	closed
XTJ 568; Reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-({[2-(2-aminobutoxy)ethoxy]methyl}propoxy)but-2-ylamine	2 November 2016	closed
Application for Authorisation		
CT_Hapoc_2	15 November 2016	closed

Subject / document	Deadline	Status / follow-up
Consultation on conformity		
CT_Hapoc_2 Consultation on application	4 January 2017	ongoing
CT_Hapoc_3 Consultation on conformity	15 November 2016	closed
CT_Hapoc_3 Consultation on application	4 January 2017	ongoing
CT_Haas Consultation on conformity	15 November 2016	closed
CT_Haas Consultation on application	4 January 2017	ongoing
SD_Haas Consultation on conformity	15 November 2016	closed
SD_Haas Consultation on application	4 January 2017	ongoing
PD_Haas Consultation on conformity	15 November 2016	closed
PD_Haas Consultation on application	4 January 2017	ongoing
CT_Reachlaw Consultation on conformity	15 November 2016	closed
CT_Reachlaw Consultation on application	4 January 2017	ongoing
CT_Clariant Consultation on conformity	15 November 2016	closed
CT_Clariant Consultation on application	4 January 2017	ongoing
CT_ZFL Consultation on conformity	15 November 2016	closed
CT_ZFL Consultation on application	4 January 2017	ongoing
SD_ZFL Consultation conformity	15 November 2016	closed
SD_ZFL Consultation on application	4 January 2017	ongoing
CT_Cryospace Consultation on conformity	15 November 2016	closed
CT_Cryospace Consultation on application	4 January 2017	ongoing
SC_Aviall Consultation on conformity	15 November 2016	closed
SC_Aviall Consultation on application	4 January 2017	ongoing

Subject / document	Deadline	Status / follow-up
SD_Borealis Consultation on conformity	15 November 2016	closed
SD_Borealis Consultation on application	4 January 2017	ongoing
SD_Ormezzano Consultation on conformity	15 November 2016	closed
SD_Ormezzano Consultation on application	4 January 2017	ongoing
AD_BAE Consultation on conformity	15 November 2016	closed
AD_BAE Consultation on application	4 January 2017	ongoing
EDC_Biotech Consultation on conformity	15 November 2016	closed
EDC_Biotech Consultation on application	4 January 2017	ongoing
EDC_ORGAPHARM Consultation on conformity	15 November 2016	closed
EDC_ORGAPHARM Consultation on application	4 January 2017	ongoing
EDC_Akzo Consultation on conformity	15 November 2016	closed
EDC_Akzo Consultation on application	4 January 2017	ongoing
EDC_Bayer Consultation on conformity	15 November 2016	closed
EDC_Bayer Consultation on conformity	4 January 2017	ongoing
EDC_Olon Consultation on conformity	15 November 2016	closed
EDC_Olon Consultation on application	4 January 2017	ongoing
MOCA_Reachlaw Consultation on conformity	15 November 2016	closed
MOCA_Reachlaw Consultation on application	4 January 2017	ongoing
PD_Gentrochema Consultation on draft opinions	15 November 2016	closed
SD_Gentrochema Consultation on draft opinions	15 November 2016	closed
Diglyme Bracco Consultation on draft opinion	14 November 2016	closed
Diglyme_Maflon	17 November 2016	closed

Subject / document	Deadline	Status / follow-up
Consultation on draft opinion		
Diglyme_Isochem Consultation on draft opinion	16 November 2016	closed
Diglyme_Merck Consultation on draft opinion	16 November 2016	closed
CT_Cromomed Consultation on draft final opinion	16 November 2016	closed
CCST Consortium (SD_Brenntag, PD_Brenntag, DtC_Henkel, ST_Akzo, PH_PPG) Consultation on draft final opinions	16 November 2016	closed
Restrictions		
Consultations on the second draft versions of TDFAs And 4phthalates	23 November 2016 23 November 2016	closed closed
Consultations on the conformity check outcome of diisocyanates	18 November 2016	closed

2.3 Other written consultations of RAC (status by 24 November 2016)

Subject / document	Deadline	Status / follow-up
Consultation the draft minutes of RAC 38	10 November 2016	closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
Harmonised classification and labelling		
Call for expression of interest for rapporteurship	15 – 21 November 2016	1 CLH dossier (appointment to be done at RAC 39 plenary)
Applications for Authorisation – no calls		
Restrictions – no calls		

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

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
Harmonised classification and labelling – no written procedures			
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	
SD_Kemira (1 opinion), SD_Caffaro (1 opinion), SD_Ercros (1 opinion), SD_ELECTROQUIMICA (1 opinion), SD_Solvay (1 opinion), AD_Micrometal (1 opinion)	19 September 2016
CT_Praxair (2 opinions), PD_Sofradir (2 opinions), SD_Lanxess (1 opinion), CT_DtC_Nexter (4 opinions), CT_Rimex (1 opinion), EDC_BASF (1 opinion), Diglyme_Novartis (1 opinion)	20 September 2016
AD_Veco (1 opinion), EDC_Bio-Sciences (1 opinion)	15 November 2016
CT_Abloy (1 opinion)	17 November 2016

ANNEX V (RAC 39)

Short summary

Rapporteur's preparatory workshop on the Authorisation Applications from the February Authorisation window

28 November 2016
ECHA (Annankatu 18, Helsinki) the auditorium on the top (7th) floor
09:00-13:00

A preparatory workshop on Authorisation may be held on an ad hoc basis in advance of RAC plenary meetings. The need is partly determined by the volume of dossiers tabled for discussion and any specific scientific issues arising in preparing the work of the Committees. The intention is to encourage an exchange of views on common issues in workplace exposure assessment methodology and the effectiveness of RMMs.

The Rapporteur's preparatory workshop held in advance of RAC 39 was held in the light of the Applications from the February Authorisation window, and focused mainly on dermal exposure. The discussion was based on a presentation by an ECHA expert in dermal exposure and two Authorisation cases presented by the Rapporteurs (see the Agenda below).

The ECHA expert recommended that first of all the hierarchy of control needed to be properly implemented in each workplace, i.e. in the form of relevant RMM's to prevent dermal exposure and workplace contamination before PPE would be considered, i.e. the use of closed systems where possible. This is important especially when substances such as aprotic solvents are used; these are generally not visible, not volatile and can penetrate skin.

The stated breakthrough time of gloves, while important was not the main factor determining exposure but the way in which the equipment was used and maintained. With proper use, exposure should be consistently low, while with improper use, exposure could be high, not due to breakthrough but due to contamination of the hands or forearms under the gloves. It seems that the declared effectiveness, e.g. of 98 or 99% by some applicants may be too high, unless there is evidence of proper training to demonstrate that correct usage is the norm in that workplace. It was considered that in such cases, concerns of rapporteurs should be addressed as uncertainties in the justification of the opinion. The participants agreed that it would be useful to develop (or adapt existing) criteria for interpreting the effectiveness of PPE in the reduction of the dermal exposure, taking training different levels of training into account.

The participants also considered that in the case of substances which are difficult to control, or are known to penetrate the skin readily, monitoring of surface contamination in the workplace could be considered e.g. through the wipe testing and analysis.

The usefulness of biomonitoring as a 'catch-all' (where methods are available) was also emphasised in signalling worker exposure, including dermal.

Agenda

1.	9:00–9:10	Welcome	Tim Bowmer
2.	9:10-9:40	Presentation of AfA case 1	Lina Dunauskienė
3.	9:40-10:10	Introduction to dermal exposure modelling	Andrew Phillips ECHA
4.	10:10-10:30	General discussion on AfAs scheduled at RAC 39 and approach to the cases where the modelling of dermal exposure is critical to adequate control	Tim Bowmer
	10:30-11:00	Coffee break	
5	11:00-12:00	Presentation of AfA Case 2	Urs Schlüter
6.	12:00-13:00	Discussion and conclusions - report back to RAC	