RAC/M/33/2015
Final
1 September 2015

Minutes of the 33rd Meeting of the Committee for Risk Assessment (RAC-33) 1-5 June 2015

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 33rd meeting of the Committee for Risk Assessment (RAC-33). Apologies were received from three Members. The Chairman welcomed one new RAC Member and informed the Committee that one RAC Member had resigned. The participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed once no longer needed. The Chairman noted that the minutes would be published on the ECHA website and would include a full list of participants as given in Part III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting and proposed three additional items:

- The authorisation application TCE 2a use 5, at the request of the Secretariat;
- An Article 95 request from the European Commission regarding NMP, at the request of the Secretariat and;
- A guidance related issue under Any Other Business at the request of a Member.

The Agenda (RAC/A/33/2015) was adopted by the Committee with the above additions. The agenda and the list of all meeting documents, including conclusions and action points are attached to these minutes as Annexes I and II, respectively.

3. Declarations of conflicts of interests to the Agenda

The Chairman requested all participants to declare any potential conflicts of interest to any of the agenda items. Nine Members declared potential conflicts of interest, each to specific agenda items. 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. 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 32 action points, written procedures and an update on other ECHA bodies

The Chairman informed the Committee that all action points of RAC-32 had been completed, or were on-going. The summary of all consultations, calls for expression of interest in Rapporteurships and written procedures is available in the usual meeting document on CIRCABC (see Annex IV). He also informed the Committee that the final minutes of RAC-32 had been adopted via written procedure and were uploaded to CIRCABC and on the ECHA website on 21 May 2015, 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 the third and fourth quarters of 2015, 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.

c) General RAC procedures

Admission of stakeholders

RAC discussed and agreed on the revised general approach for the admission to the Committee of accredited stakeholder organisations as proposed by the Secretariat.

Under the new approach, stakeholder organisations that represent a larger industry group or other general/cross-sectorial/broader interests shall be considered as 'regular observers'. On the other hand, organisations representing industry sectors with more specific interests and who wish to participate in a meeting for a specific case, substance, agenda item or Committee discussion, and whose regular involvement in the work of the Committee may not be justified shall be regarded as 'occasional observers'.

The revised procedure will be published on ECHA's website and applied in the update of the RAC stakeholders' list. The list of proposed stakeholders will then be presented at RAC-34 for agreement under the new procedure.

Co-opted Members to RAC

The Chairman informed the meeting on the state of play of the appointment of co-opted Members to RAC and SEAC, reminding the Committee that the draft paper and the draft call for expression of interest had been distributed for comments, closing on 3 May. Following supportive reactions from five RAC and one SEAC Members, the call for expression of interest was launched on 6 May, ahead of RAC-33 in order to speed up the process and to make sure suitable candidates would be available for review and agreement at RAC-34/SEAC-28 in September. The Chairman invited the Members to agree on the draft proposal for co-opting additional Members, which confirms the selection procedure, the required competences and the proposed non-voting rights. The Secretariat also provided a general overview of the results of the call for expression of interest (nearly 100 candidates) for co-opted Members, which was open during 6 May - 4 June 2015.

RAC agreed on the selection procedure and the required competences as proposed by the Secretariat.

Amendment to the Rules of Procedure

The Chairman invited the meeting to agree on the proposed revisions to the Rules of Procedure for RAC and SEAC. The Chairman reminded the Members that these were first agreed in March 2008, with some adjustments in the following year. Since then, only minor revisions have been proposed by the Secretariat with the Committees' agreement and approved by the Management Board of ECHA. It was felt that a number of adjustments needed to be made to bring the Rules of Procedure up to date and in particular to facilitate the increased workload of the Committees.

The Secretariat then presented the proposed revisions concerning: a) the removal of voting rights from co-opted Members (see above), b) the addition of an article on concurrent employment in relation to Conflict of Interest declarations, c) improved flexibility in decision-making during long plenary meetings by aligning the voting majority with the voting procedures of other Committees, e.g. BPC and d) alignment with ECHA's policy on confidentiality.

Concerning 'c)' above, i.e. the proposal to base the voting majority on all '*Members present and having the right to vote*' instead of all '*Members having the right to vote*', one Member

expressed the view that this would not preclude a remote participant from indicating a minority position during the vote. The Member argued that as minority opinions are recorded in the minutes and any interventions of a remote participant made during the discussion preceding the vote are recorded as well, minority positions of remote participants preceding the vote could also be recorded as part of the minutes. The Chairman took note of the view but mentioned that the issue was not part of the current proposal. At present, Members who participate remotely do not have the right to vote or the right to a minority position, and that there are no plans at present to change this - any such proposal would require a much more detailed analysis.

RAC agreed with the proposed revisions to the Rules of Procedure. After agreement on the same changes to their Rules of Procedure by SEAC, both are scheduled for adoption by the Management Board at their forthcoming meeting.

d) Request from the European Commission under REACH Article 95 regarding NMP

The Chairman reported that the Commission under Art. 95 of REACH had requested the Agency, in cooperation with the Scientific Committee on Occupational Exposure Limits (SCOEL), to resolve the differences, between the Derived No Effect Level (DNEL) and the Occupational Exposure Limit (OEL) for the aprotic solvent n-methylpyrrolidone (NMP). An equivalent request was sent by the Commission to SCOEL. He also pointed out that the Commission intended to submit a second, more general request, regarding the resolution of methodological differences in deriving such reference values.

The Chairman then proposed that the resolution of the conflicting values for NMP should be addressed through a Joint Working Group, comprising RAC and SCOEL Members, and through a joint opinion adopted by both Committees. As both Committees hold plenaries every quarter, both RAC and SCOEL plenary sessions could be informed about the progress of the work.

In the subsequent discussion, broad agreement to the general idea of aligning benchmark values between the two Committees was expressed by RAC Members. As to NMP, it was considered that a main reason for divergence was the use of different methodologies, which might not easily be resolved by a Joint Working Group set up under this mandate. This concern was shared by many RAC Members. The Cefic stakeholder observer expressed interest in being involved in subsequent discussions about aligning methodologies.

The Commission urged for quick resolution of the NMP-related divergence in order to be able to proceed with the regulatory process in relation to the proposed restriction on NMP[1]. The Chairman asked the RAC Members whether they would agree to the establishment of a Joint Working Group which would be composed of RAC and SCOEL experts and which would work specifically on NMP. RAC Members agreed by consensus. The Chairman indicated that the call for joining the Joint Working Group would be sent to RAC Members after RAC-33.

[1] Committee for Risk Assessment (RAC), Opinion on an Annex XV dossier proposing restrictions on 1-Methyl-2-pyrrolidone. ECHA/RAC/RES-O-0000005316-76-01/F, Adopted 5 June 2014

5. Harmonised classification and labelling (CLH)

5.1 CLH dossiers

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

Note: for the sake of completeness, substances for which all endpoints were subject to fast-track agreement without plenary debate are described briefly below.

a) Tefluthrin (ISO): Acute toxicity, Skin corrosion/irritation, Eye damage/irritation, Skin sensitisation, Germ cell mutagenicity, Carcinogenicity, Reproductive toxicity

b) Cyanamide: Acute toxicity (oral and dermal), Skin corrosion/irritation, Skin sensitisation, STOT SE, Germ cell mutagenicity

c) Dichlofluanid: Acute toxicity, Skin sensitisation

Dichlofluanid (ISO) is a biocidal active substance and is used in wood preservatives, film preservatives and antifouling products. It has an existing entry in Annex VI of the CLP Regulation as Skin Sens 1; H317, Eye Irrit 2; H319, Acute Tox 4*; H332 and as Aquatic Acute 1; H400 with M-factor of 10.

The Dossier Submitter (United Kingdom) proposed to confirm the classification for acute inhalation toxicity and to update the classification for skin sensitisation with a subcategory (Skin Sens. 1B). RAC concurred with the proposal to remove the minimum classification for acute toxicity and to classify dichlofluanid in category 4 based on the data from an acute inhalation toxicity study in the rat (Shiotsuka, 1986) and supporting data from another acute inhalation toxicity study by Pauluhn (1988). Concerning the proposal for skin sensitisation, RAC found that the data used did not provide sufficient information on the sensitising properties at the intradermal induction concentration needed for sub-categorisation. The RAC therefore concluded that the current classification as Skin Sens. 1; H317 without a subcategory should be retained. RAC adopted the opinion by consensus.

d) Triadimenol (ISO): Acute toxicity, Skin corrosion/irritation, Eye damage/irritation, STOT RE, Germ cell mutagenicity

e) Terbuthylazine (ISO): Acute toxicity, STOT SE, Skin corrosion/irritation, Eye damage/irritation, Skin sensitisation, Germ cell mutagenicity

f) Salicylic acid: Acute toxicity, Eye damage

g) Quinolin-8-ol; 8-hydroxyquinoline: Acute dermal toxicity, Skin corrosion/irritation, Eye damage/irritation

h) Fipronil (ISO): Aquatic acute and long-term hazard

Fipronil is an active biocidal substance with an existing harmonised classification in Annex VI to the CLP Regulation. It has a minimum classification for acute toxicity (Acute Tox. 3* for all routes of exposure) and repeated dose toxicity, and a classification for aquatic acute (M=10) and aquatic chronic toxicity.

The DS (France) proposed to review the M-factors for ENV classification with M-factors of 10000 for both aquatic acute and aquatic chronic toxicity based on the results published in Weston & Lydy (2014) for *Chironomus dilutus*.

RAC did not consider the Weston & Lydy study reliable for classification purposes and agreed that it could be only used as supporting information. The classification of fipronil was thus based on the lowest reliable toxicity data available in the CLH report. RAC agreed to an M-factor of 1000 for aquatic acute toxicity and supported the DS proposal for an M-factor of 10000 for aquatic chronic toxicity. RAC adopted the opinion by consensus.

B. Substances with hazard classes for agreement in plenary session

a) Tefluthrin (ISO)

The Chairman welcomed the representative accompanying the ECPA stakeholder observer as well as the Dossier Submitter's representative from Germany who followed the discussion remotely.

He reported that tefluthrin (ISO) belonged to the pyrethrin group of insecticides. As it does not have an entry in Annex VI, all hazard classes need to be evaluated. Germany proposed that classification as Aquatic Acute 1 and Aquatic Chronic 1 with M-factors as well as Acute Tox. 1 (H330), Acute Tox. 2 (H300, H310) and STOT RE 1 (H372 (nervous system)) be harmonised. For other human health hazards, no classification was proposed. The legal deadline for adoption of the CLH opinion is 3 February 2016.

The Chairman noted that the Committee had already agreed at RAC-32 to classify tefluthrin (ISO) as Aquatic Acute 1 and Chronic 1, with M=10000 for both hazards, and at this meeting on classifications as Acute Tox. 1 (H330), Acute Tox. 2 (H300, H310) including agreement not to classify for the hazard classes skin corrosion/irritation, eye damage/irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity and reproductive toxicity. The Chairman noted that the Committee still needed to discuss whether a classification for STOT RE, STOT SE or the supplemental hazard statement EUH070 (toxic by eye contact) was justified.

The Rapporteur proposed not to classify for STOT RE because the neurotoxicological effects observed in the studies included in the CLH report appeared to be due to acute toxicity rather than to repeated dose toxicity. This view was shared by the RAC Members and 'no classification' for STOT RE was agreed.

As to STOT SE, the Rapporteur reported that according to the criteria, this classification should be considered where there was clear evidence for specific target organ toxicity after single exposure in the absence of lethality. As lethality was pronounced at the relevant doses, RAC decided not to classify for STOT SE.

In relation to EUH070 (toxic by eye contact), one RAC Member noted that labelling with EUH070 would not be consistent with other cases on Annex VI. The other RAC Members agreed to this view, and EUH070 was not considered justified for tefluthrin (ISO).

The Committee adopted the opinion by consensus.

The Chairman thanked the Rapporteurs for the helpful analysis of the case and the Committee for the thorough discussion.

b) Cyanamide

The Chairman welcomed the representative accompanying the ECPA stakeholder observer in person as well as the Dossier Submitter representative from Germany who followed the discussion remotely.

The Chairman reported that cyanamide was a biocidal active substance. It has an existing entry in Annex VI to CLP as Acute Tox. 3* (oral), Acute Tox. 4* (dermal), Eye Irrit. 2, Skin Irrit. 2 and Skin. Sens. 1. Germany proposed to modify the entry with the following classifications: remove the minimum classification for acute toxicity, leading to Acute Tox. 3 (oral and dermal), upgrade the classification for skin irritation to Skin Corr. category 1B (revised to category 1 without subcategory after public consultation) and to assign sub-category 1B to the skin sensitisation classification. Germany also proposed to add STOT RE 1 (thyroid)(oral), Repr. 2 (H361fd) and Aquatic Chronic 1 (M=1) (revised to Aquatic Chronic 3; H412 after public consultation). Since Skin Corr. 1B was proposed, Germany further proposed to remove Eye Irrit. 2.

The Chairman noted that RAC had already agreed on classifications as Acute Tox. 3 (H301 and H311), Skin Corr. 1 (H314, no sub-category) and Skin Sens. 1 (H317, no sub-category) and

that the Committee still needed to discuss whether harmonised classifications for acute inhalation toxicity, repeated dose toxicity, reproductive toxicity, carcinogenicity and aquatic chronic toxicity, as well as the removal of the current eye irritation classification, were justified.

The Rapporteur presented the evaluation of the hazards in detail. The Committee agreed not to classify for acute inhalation toxicity and eye irritation. As to repeated dose toxicity, RAC agreed on category 2 (STOT RE 2) with effects on the thyroid, but without specifying the route of exposure. The rationale for category 2 was that the effects seen were considered relevant to humans while humans were deemed less sensitive when compared to rats and dogs, warranting category 2 instead of category 1.

In relation to fertility, effects in the rat and on the testis in dogs were discussed. While it was concluded that clear effects were seen in several studies, it was considered that since the effects were seen together with general toxicity, category 2 was more appropriate, and RAC finally agreed on category 2 for fertility effects.

In relation to developmental effects, RAC Members noted that the malformations, while being severe, were seen together with maternal toxicity, thus justifying a classification into category 2. The Chairman noted that overall the reproductive toxicity classification was concluded to be Repr. 2 (H361fd).

As to carcinogenicity, it was recognised that several types of tumours were formed in different studies, while a clear association between them was lacking. It was noted that cyanamide was not genotoxic in vivo. Specific historical control data (HCD) were not available in the CLH report, the Rapporteur had however found relevant HCD data and included this in the opinion. It was concluded that some of the tumours were formed at incidences above these HCD, thus justifying Carc. 2. The expert accompanying the ECPA stakeholder observer noted that the HCD used were not considered relevant as they were of a much later date than the studies and that the only study considered relevant by ECPA was considered as negative. RAC, however, in view of the findings and taking all relevant, available information into account, agreed to classify cyanamide as Carc. 2.

In relation to aquatic chronic toxicity, the Rapporteur proposed to use the lowest chronic NOEC value of 0.104 mg/l, and consequently to classify for Aquatic Chronic 3 (H412) and the Committee agreed to this proposal.

The Committee then adopted the opinion by consensus.

The Chairman thanked the Rapporteurs for their analysis of the case and the Committee for the thorough discussion.

c) Triadimenol (ISO)

The Chairman reported that triadimenol is used as a fungicide in seed and foliar spray treatment within the EU. It has no entry in Annex VI to the CLP Regulation. The Dossier Submitter proposed a harmonised classification of the substance as Acute Tox. 4 (H302), Repr. 2 (H361f) and Aquatic Chronic 2 (H411). The Rapporteurs supported the harmonised classification proposal for Acute Tox. 4 (H302) and no classification for skin and eye corrosion/irritation, STOT RE and germ cell mutagenicity. The Rapporteurs proposed to discuss the justification for no classification for specific target organ toxicity after single exposure (STOT SE) and carcinogenicity, the potential classification for skin sensitisation due to the metabolite/impurity that has a harmonised classification entry in Annex VI to the CLP Regulation as Skin Sens. 1, the classification for reproductive toxicity and for effects via lactation, and the classification for aquatic hazard. The legal deadline for adoption of the CLH opinion is 24 March 2016.

In the discussion on STOT SE, some Members and an industry expert reflected on the observed hyperactivity in the dosed animals. However, as the observed transient hyperactivity did not seem to fulfil the classification criteria for STOT SE, RAC therefore agreed on no classification. Two RAC Members expressed concerns regarding this effect, since hyperactivity in children can be quite prevalent, noting that this effect might need to be added to the classification criteria and/or elaborated in the associated guidance.

RAC Members discussed triadimenol as a potentially skin sensitising substance due to the presence of a skin sensitising metabolite/impurity (Cat. 1), present in the range of 0 to 1 % (1 % is the generic concentration limit triggering classification of a mixture as Skin Sens. Cat.1) according to the CLH dossier. The available Buhler and GPMT tests on triadimenol were negative, but there was no information on the concentration of the skin sensitising impurity in the tested batches and, in addition, the CLP Guidance recommends taking conclusion on skin sensitisation with great caution when having a negative outcome in a test on a mixture. In the discussion of skin sensitisation it was noted that the EU-specific hazard statement (EUH208:"Contains <name of sensitising substance> May produce an allergic reaction") only applies to mixtures and not substances. One RAC Member noted the inconsistency in the application of EUH208 for mixtures and substances containing a sensitising substance in a concentration equal to or greater than that specified in Table 3.4.6 of Annex I and requested ECHA to communicate this to the Commission.

The industry representative informed the Committee that in their new specification the maximum content of the impurity was set at <= 0.9 % or <= 9 g/kg, i.e. below the generic concentration limit for classification. RAC therefore agreed not to classify triadimenol for skin sensitisation. It was also noted that if any batch of triadimenol would contain ≥ 1 % of the skin sensitising impurity, it would be the responsibility of the classifier to take that into consideration in the classification of the substance.

Based on the carcinogenicity data presented, RAC agreed on no classification of the substance for carcinogenicity.

RAC discussed the observed adverse effects on reproduction and whether decreased pregnancy rates were an adverse effect on sexual function and fertility and/or on development. In addition, the potential impact of maternal toxicity and study deficiencies on the developmental toxicity effects observed was briefly discussed. However, as the allotted time for this agenda item had passed, The Chairman proposed to continue the discussion on reproduction at RAC-34 in September, and to discuss then also the classification for aquatic hazard.

d) Terbuthylazine (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that terbuthylazine was a broad spectrum herbicide belonging to the triazine group. It is effective against a wide range of annual and perennial broad leaved weeds. This active substance has currently no existing entry in Annex VI to the CLP Regulation and as a result all hazard classes would need to be assessed.

The DS proposed to classify the substance for acute toxicity via oral exposure (Acute Tox. 4; H302), for carcinogenicity (Carc. 2; H351), for specific target organ toxicity after repeated exposure (STOT RE 2; H373) and for environmental hazards (as Aquatic Acute 1; H400 with an M-factor of 10 and Aquatic Chronic 1; H410 with an M-factor of 10).

The Rapporteurs concurred with the original DS proposal for all hazard classes except for carcinogenicity.

The Committee agreed on classification as Acute Tox. 4; H302 and on no classification for acute toxicity via the dermal and inhalation routes, STOT SE, skin/eye corrosion/irritation, skin sensitisation and germ cell mutagenicity.

The Committee agreed with the proposal to classify terbuthylazine as STOT RE 2 based on decreased body weight, body weight gain and food consumption which occurred consistently in all tested species.

RAC discussed the proposal for carcinogenicity which was based on two studies in the rat, one in SD rats, and one in Han Wistar rats, both showing evidence of mammary gland tumours. In the mouse no evidence of carcinogenicity was seen in three studies. RAC also discussed the two new mechanistic studies (Handa, 2014 and Stump, 2014) which were made available during the public consultation. The DS proposed not to take the effects in SD rats into account, due to read across to the structurally similar substance atrazine, whose Mode of Action in SD rats (suppression of pre-ovulatory LH surge) is well-known as not relevant to humans. The original DS proposal for Carc. 2; H351 was therefore based on the effects in Han Wistar rats, for which the MoA was not clear. The two new mechanistic studies provided during public consultation however showed that the mechanism is the same in Han Wistar rats. Hence, RAC concluded that the tumours seen in Han Wistar rat were not relevant to humans either. The studies also showed that the level of suppression is comparable between the two chlorotriazines.

Leydig cell tumours observed in the highest dose in rats (SD male rats) were considered as not treatment-related as they only occurred in ageing rats. The Committee concurred with the conclusion of the Rapporteur and agreed on no classification for carcinogenicity.

The Committee supported the proposal for no classification for toxicity to reproduction as no effects providing sufficient evidence for classification were seen without concurring severe maternal toxicity.

The Committee briefly discussed the relevance of the metabolite terbutryn for long-term aquatic hazard classification of terbuthylazine and agreed with the DS that based on a very low rate of formation of the metabolite, an M-factor of 10 would be sufficient for both acute and chronic toxicity of terbuthylazine.

RAC adopted the opinion by consensus.

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

e) Salicylic acid

The Chairman welcomed the representatives of the Dossier Submitter (NOVACYL S.A.S.) and reported that salicylic acid is used as a preservative in a very wide variety of industrial, professional and consumer uses. It has no entry in Annex VI to the CLP Regulation. The Dossier Submitter proposed a harmonised classification of the substance as Acute Tox. 4 (H302) and Eye Dam. 1 (H318). The Rapporteurs supported the harmonised classification proposal by the Dossier Submitter, and in addition proposed to discuss at the RAC plenary meeting the following two options for a reproductive toxicity: Repr. 2 (H361d) or no classification. The legal deadline for adoption of the CLH opinion is 16 April 2016.

RAC agreed on the harmonised classification for oral acute toxicity and eye damage.

Reproductive toxicity on fertility of salicylic acid was assessed by RAC on the basis of read-across data from studies on methyl-salicylate and acetylsalicylic acid. RAC supported the proposal for no classification of the substance for effects on fertility.

In the discussion on developmental effects, RAC considered the relevance of the doses of salicylic acids used in the animal and epidemiological studies. The Committee discussed the

plasma concentrations of salicylic acid in humans and rats as a function of administered dose. One Member, supported by the Dossier Submitter, noted that a factor of four (4) seemed to be appropriate for recalculations of the plasma levels of salicylic acid in rats to the plasma levels in humans. This observation was based on the report "*Relevance of plasma levels in humans and rats to establish equivalence of exposure levels*" [NOVACYL S.A.S. unpublished report, April 2013]. If some foetal toxicity effects have been seen in foetuses of rats at the dose level of 100 mg/kg bw/day, it would correspond to 25 mg/kg bw/day in humans. Members of the Committee supported the necessity to further examine the epidemiological studies.

Members also requested the Dossier Submitter to make a developmental toxicity study on monkeys available to RAC as part of the weight of evidence analysis, regardless of its Klimisch score of 3. The RAC Members requested the Rapporteurs to evaluate available information on the possible effects of the substance on *ductus arteriosus* with relevance to humans. Due to the fact that conclusions on the developmental toxicity of the substance were mainly made by using read-across data, one RAC Member requested the Rapporteurs to include a summary table of the harmonised classification for all the substances used for the read-across(if the harmonised classification is not available, self-classification by industry should be given). The Rapporteurs agreed to provide this.

RAC agreed that the Secretariat will request further relevant human epidemiological data as well as the monkey study from the Dossier Submitter to enable assessment of the relevance of findings in animals (rats and monkeys). RAC postponed the discussion on developmental toxicity of salicylic acid to RAC-34 in September.

f) Methylhydrazine

The Chairman informed the Committee that the Secretariat had received further information from the Dossier Submitter on the day before the plenary discussion was scheduled. He made it clear that according to the rules of procedure any information relevant to a case should be submitted a minimum of 10 days before the meeting. He therefore proposed to postpone consideration of the dossier to the September meeting. The Committee agreed to this proposal.

g) Dibutyltin dilaurate

The Chairman reported that dibutyltin dilaurate is an organotin compound which is used as a catalyst. The substance has currently no Annex VI entry to CLP. The legal deadline for adoption of the opinion is 14 March 2016. The Dossier Submitter (Norway) proposed a harmonised classification for mutagenicity (Muta. 2; H341), reproductive toxicity (Repr. 1B; H360FD) and specific target organ toxicity after repeated exposure (STOT RE 1; H372 (immune system)). It was noted that the classification proposal was based mainly on read-across data to dibutyltin dichloride (DBTC).

For developmental toxicity and fertility, as well as for the specific target organ toxicity after repeated exposure, the Rapporteurs' assessment coincided with the DS proposal. Following discussion with Members, RAC agreed with the Repr. 1B; H360FD and STOT RE 1; H372 (immune system) classifications as proposed by the DS.

For germ cell mutagenicity, the Rapporteurs examined the possibility of classifying dibutyltin dilaurate as Muta. 1B instead of Muta.2, based on a positive Comet assay with focus on the brain. During the discussion it was however noted that no direct evidence was available indicating that the substance is systemically distributed to testis and sperm and that interaction with the genetic material of germ cells was actually not demonstrated. Based on the lack of clear evidence on the effect on germ cells, RAC agreed with the DS proposal for classification for mutagenicity (Muta. 2; H341).

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

h) Quinolin-8-ol; 8-hydroxyquinoline

The Chairman reported that quinolin-8-ol is a preventive and curative fungicide as a bactericide, as an active substance in plant protection products and as a laboratory reagent. It has no existing entry in Annex VI to the CLP Regulation.

The DS (Spain) proposed to harmonise classification and labelling as follows: Acute Tox. 3; H301, Eye Dam. 1; H318, Skin Sens. 1; H317, Repr. Cat 2; H361d (revised to Repr. 1B; H360D after public consultation), Aquatic Acute 1; H400 with an M-factor of 1 and Aquatic Chronic 1; H410 with an M-factor of 10. As quinolin-8-ol is an active substance with no existing harmonised classification, all hazard classes were assessed.

RAC agreed on the classification as Eye Dam. 1; H318 and on no classification for acute dermal toxicity and skin irritation/corrosion.

RAC concurred with the DS on classification for acute oral toxicity based on the effects observed in the most sensitive species, the mouse. RAC also concluded that the effects observed in several studies could not be considered narcotic effects and agreed with the DS on no classification for STOT SE.

Based on the sensitisation rates in Patch tests in four studies and on the effects reported in one case study, RAC agreed to classify quinolin-8-ol as a skin sensitiser in category 1. In addition, the Committee agreed that the evidence to assess potency of the substance was weak and thus sub-categorisation was not justified.

RAC agreed with the conclusion of the DS that no effects were observed in the studies summarised in the CLH report that would justify classification for either specific target organ toxicity after repeated exposure or for mutagenicity.

Two studies (one in rats and the other in mice) were performed to assess the carcinogenicity of quinolin-8-ol. RAC agreed with the conclusion of the DS that the findings in neither study were sufficient for classification.

RAC concurred with the DS that all findings relevant to the assessment of fertility in the 2-generation study in rats were likely to have been related to maternal toxicity and did not provide evidence for classification for fertility. Developmental toxicity was assessed based on two developmental toxicity studies (one in rats and the other in rabbits). The Committee agreed with the conclusion of the DS (as revised after public consultation) to classify the substance as Repr. 1B based mainly on the malformation (omphalocele) observed in the offspring of rabbits which was not secondary to maternal toxicity.

The Committee concurred with the DS on classification for aquatic acute hazard but briefly discussed the aquatic long-term hazard classification of quinolin-8-ol. After a short discussion RAC agreed to apply an M-factor of 1 (instead of the originally proposed M-factor of 10) based on the NOEC of 0.039 mg/L for *Daphnia magna*. This NOEC was preferred to the lowest (sub-) chronic NOEC for *O. mykiss* as no effects were seen at the highest concentration tested. RAC noted that a test that involved more sensitive fish life stages and/or the un-dissociated substance might possibly result in effects at a lower concentration, but as the target group was fungi/bacteria, the uncertainty was acceptable.

RAC adopted the opinion by consensus.

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

i) 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one

The Chairman welcomed the representatives of the Dossier Submitter (BASF) and reported that 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one is used as a photosensitive agent in industrial formulations. The main applications are in products like coatings, adhesives and inks for industrial and professional use. Consumer use is not supported. The substance has an Annex VI entry in the CLP Regulation for human health acute toxicity effect (minimum classification) via the oral route of exposure Acute Tox. 4* (H302). For aquatic hazards, the harmonised classification is toxic to aquatic life with long lasting effects Aquatic Chronic 2 (H411). In addition to the existing classification the Dossier Submitter proposed a harmonised classification of the substance for reproductive toxicity Repr. 1B (H360Df). The Rapporteurs supported the harmonised proposal for category 1B for developmental toxicity, but in addition proposed to classify the substance as Repro 1B for effects on sexual function and fertility (instead of Repr. 2).

RAC discussed the observed effect of an increased number of irregular cycles in female rats, though with no clear dose-response relationship. RAC Members acknowledged a significantly decreased fertility in female rats in the high-dosed group (12/25 not pregnant) and that the observed decreased fertility has a dose-response relationship. Hence, RAC supported the proposal of the Rapporteurs for Repr. 1B for fertility. Regarding developmental toxicity RAC Members agreed with the proposal by the Dossier Submitter to classify the substance in category 1B. The observed effects were not considered to be secondary non-specific consequences of parental toxicity.

In conclusion, RAC agreed to classify 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one as toxic for reproduction in category 1B for both effects on sexual function and fertility and development, adopting the opinion by consensus.

The Chairman thanked the Rapporteur for the presentation of the arguments, the Dossier Submitter and the Committee Members for their comments.

5.2 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.

6. Restrictions

6.1 General restriction issues

The Secretariat informed the participants of the meeting on the outcome of the Restriction Workshop held at ECHA on 7 and 8 May 2015. Recommendations and the key outcomes from the Restriction Task Force (RETF), which involved Member States, ECHA's Committees and the Secretariat, were also presented, as well as a progress update on the implementation of the RETF-recommendations for continuous improvement of the process.

6.2 Restriction Annex XV dossiers

a) Opinion Development

1) Isopropylidenediphenol (bisphenol A, BPA) – revised draft opinion

The Chairman welcomed an expert accompanying the Cefic stakeholder observer in person, the Dossier Submitter representatives (France) and the SEAC Rapporteurs who followed the discussion remotely via WebEx. Based on the discussion and conclusions at RAC-32, the Rapporteurs revised the draft opinion. A written commenting round was organised on the 4th draft opinion from 15 April until 4 May during which ten comments were received from eleven RAC Members. Taking into account the comments received, the Rapporteurs have revised the draft opinion and the 5th draft opinion was made available to RAC Members on 22 May. No final Forum advice has been submitted (i.e. the draft Forum advice will be considered as final).

The RAC Rapporteurs then presented the 5th draft opinion to the Committee.

RAC considered that the available hazard data on the effects did not allow a quantification of the dose-response relationship for effects on the mammary gland, as well as for reproductive, metabolic, neurobehavioural and immunotoxic effects.

RAC agreed to follow the EFSA approach (EFSA (2015) using the point of departure based on kidney effects and applying an uncertainty factor of 6 to account for the uncertainties regarding mammary gland, reproductive, metabolic, neurobehavioural and immune effects.

For derivation of the oral DNELs, RAC started with the EFSA HED of 609 µg/kg/day for kidney effects in mice and applied in line with EFSA's approach an additional assessment factor of 6 to account for the uncertainties related to other effects. The oral DNEL is then 4 µg/kg/day for the general population and 8 µg/kg/day for workers.

Using either the Fischer/Yang or Mielke model for dermal DNEL derivation, RAC calculated DNELs for the total BPA dose dermally absorbed of 0.05 µg/kg/day for the general population and 0.1 µg/kg/day for workers. RAC acknowledged that the available data are indicative of dermal metabolism and considered that 50% was the most reasonable assumption. Thus the dermal DNELs for the total BPA dose dermally absorbed are 0.1 µg/kg/day for the general population and 0.2 µg/kg/day for workers.

RAC concluded that modelling results for exposure to BPA from thermal paper are consistent with biomonitoring data for the general population showing that the risk from exposure to BPA from thermal paper is adequately controlled (RCR<1).

With respect to workers, the reasonable worst case exposure estimates from probabilistic and deterministic modelling was considered consistent with exposure estimates from biomonitoring studies. RAC agreed that 400 ng/kg bw/day represents an appropriate reasonable worst case exposure estimate for workers and used this value in risk characterisation. RAC concluded that for workers the risk from BPA exposure from dermal contact with thermal paper is not adequately controlled (RCR=2). RAC acknowledged that the main source of uncertainty to the risk estimates comes from the uncertainties to the derived DNELs.

RAC agreed that action needs to be taken on EU wide basis and supported the French proposal to restrict the placing on the market of BPA–containing thermal paper.

RAC adopted its opinion on the dossier on BPA by consensus. It was agreed that the Rapporteurs, together with the Secretariat, will make the final editorial changes to the adopted opinion and will ensure that the supporting documentation (Background Document and Response-to-Comments) is in line with the adopted RAC opinion. The Secretariat will forward the adopted opinion and its supporting documents to SEAC as well as publish it on the ECHA website and CIRCABC.

The Chairman thanked the Rapporteurs for their hard work on developing the opinion on behalf of the Committee and the participants for their contributions.

Following adoption of the opinion, RAC discussed a question posed by the SEAC Rapporteurs as part of the latter Committee's opinion development process. The SEAC Rapporteurs had calculated disease incidence rates reflecting the monetised disease burden derived from and

equal to the costs of the proposed restriction on BPA. They requested RAC's view on the likelihood of all of these incidence rates occurring concurrently in the population at risk. RAC stressed that in the absence of a dose-response relationship, the incidences of the relevant effects in the population at risk cannot be estimated. Without the underlying assumptions to the calculations being presented to RAC, the Committee was only able to provide a reply to SEAC on the basis of general considerations and responded that such disease incidence rates were extremely unlikely. Several Members were strongly of the view that RAC could not give an informed response to SEAC on the basis of such narrow information, two Members taking a minority position against the above response.

2) DecaBDE – revised draft opinion

The Chairman welcomed the Dossier Submitter's representatives (ECHA and Norway), and an industry expert accompanying stakeholder observer (Cefic) to the meeting. The proposal focuses on the hazard and risk of the use of decaBDE as a flame retardant in plastics and textiles. He reminded the participants that decaBDE was identified as an SVHC and included in the Candidate List as PBT/vPvB. DecaBDE has a widespread occurrence in the environment, including remote areas and in wildlife. It debrominates in the environment to lower homologues which are PBTs/vPvBs or act as precursors to substances with PBT/vPvB properties. Other potential impacts of exposure to decaBDE may result in neurotoxicity in mammals, including humans.

The Chairman noted that agreement on the main elements of the RAC opinion had been reached at RAC-32, where RAC concluded that there is a risk to be addressed based on the PBT/vPvB hazard without an identified threshold and that the emissions of decaBDE are a suitable proxy for the emissions (and risks) of hazardous transformation products. RAC also agreed that action needs to be taken on EU wide basis and that the proposed restriction is the most appropriate measure to reduce the emissions and thereby the risks of decaBDE. Furthermore, RAC agreed that despite concerns that some of the alternatives could pose similar hazards, at least some are likely to be less hazardous overall.

Based on the discussions held at RAC-32 and on the public consultation comments received by 17 March 2015 (there were 13 public consultation comments submitted), the Rapporteurs prepared the revised draft opinion which was submitted for RAC comments in May (two comments received from RAC Members during the written commenting round). No final Forum advice has been submitted (i.e. the draft Forum advice will be considered as final).

The RAC Rapporteurs then explained that within the public consultation, a proposal for derogation had been received from industry to exempt the use of decaBDE in automotive vehicles and spare parts (decaBDE is used in suede-effect leather, in electrical and powertrain applications and in the fuel system). Regarding the use in the automotive sector, RAC noted that the tonnages involved are high and that no information on emissions of decaBDE from the use was provided. For these reasons RAC concluded that the derogation could not be supported based on the available information. RAC also noted that the derogation relates mainly to technical and economic issues.

Regarding some possible minor uses of decaBDE (e.g. in adhesives), RAC noted that since no specific information was provided during the public consultation, there was no possibility of considering this in a meaningful way. Regarding recycling, RAC noted that the information received during the public consultation did not indicate any issues related to recycling and the proposed concentration limit.

With regard to the human health conclusions, RAC pointed out that there is additional concern for developmental neurotoxicity, as proposed by the Dossier Submitter. RAC noted that DecaBDE has the capacity to cause (or contribute to) developmental neurotoxicity in mammals

(and potentially other taxonomic groups). However, RAC was not able to perform any quantification of potential human health risks as relevant exposure data were not available in the restriction dossier.

RAC adopted its opinion on the dossier on decaBDE by consensus.

The Chairman thanked the Rapporteurs for their efficient handling of the case and the participants for their contributions.

3) Perfluorooctanic acid (PFOA) – first draft opinion

The Chairman welcomed the Dossier Submitters' representatives (Germany and Norway) as well as an industry expert accompanying a stakeholder observer. The Dossier Submitters propose a restriction on manufacture, marketing and use of PFOA, its salts and PFOA-related substances, as well as of articles and mixtures containing these substances. The Chairman informed the participants that the draft opinion prepared by the Rapporteurs was made available to RAC on 7 May and comments were received from four RAC Members in the following written consultation. The discussion of the first draft opinion focused on the scope of PFOA-related substances and on the human health risk assessment.

The Rapporteurs explained that based on the available information on transformation, 'PFOA-related substances' seem to degrade to PFOA in amounts >0.1% per year, and are therefore relevant to include in the proposed restriction. There is no information showing that there are substances with linear or branched perfluoroheptyl- or perfluorooctyl-derivatives that cannot degrade or be transformed into PFOA. The Rapporteurs suggested that a potential restriction should encompass an open-ended list of PFOA-related substances/precursors, i.e. similar to the current EU PFOS restriction (Commission Regulation (EU) No 757/2010 of 24 August 2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III[2]). The Committee agreed to support the scope of the proposal as proposed by the Rapporteurs (with derogations and the concentration limit to be discussed later, after the public consultation has ended).

The Commission observer pointed out that RAC should make sure that all substances included in the scope are fully justified by the risk assessment. An industry expert added that it should be clarified that all C8 products are included in the scope, as they are a potential source of PFOA and expressed disagreement with the Rapporteurs' statement that the biggest emissions of PFOA come from textiles and fire-fighting foams, as especially fire-fighting foams are nowadays mainly based on C6. The Chairman recommended industry to submit this latter comment via the ongoing public consultation.

With regard to human health, amongst others effects on the mammary gland, the Rapporteurs expressed their concern for such effects, but considered that it is not currently possible to set a robust NOAEL as the basis for a DNEL for use in risk characterisation. RAC agreed with the Rapporteurs' conclusion. With regard to the decreased birth weight, the Rapporteurs questioned whether the epidemiological data is sufficiently convincing to consider this end-point for the risk characterisation. RAC noted the epidemiological studies suggesting an association between PFOA-exposure and decreased birth weights, but considered that due to unclear adversity and uncertainties in dose-response it cannot be used in the risk characterisation. The Committee reached the same conclusion with regard to cholesterolemia. It was also proposed to look further at the animal studies which might provide an alternative point of departure to the epidemiological studies.

[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:223:0029:0036:EN:PDF

Finally, the Rapporteurs listed the requests for derogations received within the ongoing public consultation and explained that the need for them will depend on the chosen threshold. The Chairman urged the Rapporteurs to propose the concentration limit and derogations as soon as possible after the end of the public consultation, noting that the opinion was scheduled for adoption at RAC 34 in September.

4) Methanol – key issues document

The Chairman welcomed the Dossier Submitter's representative from Poland and the SEAC Rapporteur, both of whom followed the meeting remotely via WebEx. The proposed restriction is aimed to prevent misuse of some mixtures containing high concentrations of methanol as an ethyl alcohol surrogate. The scope of the restriction proposal is targeted at windscreen washing fluids and denatured alcohol used as a fuel for touristic appliances or as a cleaning agent and their availability to consumers. The Committee was informed that the Key Issues Document was made available on 11 May and that the RAC commenting round finished on 22 May, with comments received from three RAC Members.

RAC supported the Rapporteurs' proposal to use the lowest oral dose leading to blindness, i.e. 0.05 g/kg bw as the LOAEL for the risk assessment (instead of lethality). Additionally, RAC agreed to use an assessment factor of 3 to allow for the extrapolation of the LOAEL to the NOAEL taking into account the limitations of the available data.

In relation to whether to restrict ethanol (in addition to methanol) in windscreen washing fluid/denaturated alcohol, the Secretariat clarified that as this was not contained in the restriction proposal (and had not been subject to public consultation) it was considered to be outside the scope of this restriction proposal.

Concerning the exposure assessment, RAC agreed to use one similar exposure scenario for both denaturated alcohol and windscreen washing fluid. In addition, RAC supported the proposal to accept one litre of ingested windscreen washing fluid/denaturated alcohol as a realistic worst case scenario.

Taking into account a 60 kg mass body weight, RAC acknowledged that the maximum concentration of methanol in denaturated alcohol and windshield washing fluids should be 0.1% to ensure adequate protection against severe methanol intoxication.

In summary, RAC agreed on the main elements presented by the Rapporteurs.

b) Conformity check

1) D4/D5

The Chairman welcomed the Dossier Submitters representative from UK and an external expert invited by Cefic. He informed the participants that the restriction dossier on D4/D5 had been submitted by UK on 17 April 2015. The RAC commenting round finished on 25 May with no comments received from RAC Members. The Chairman informed the Committee that as agreed at RAC-32 in March, the Committee would be invited to discuss the key issues identified by the Rapporteurs and considered by them as crucial for further opinion development in this plenary straight after the agreement on conformity.

The Dossier Submitter's representative provided a brief introductory presentation on the dossier. The restriction proposal is aimed specifically at reducing emissions to the aquatic environment and is targeted at uses that lead to the greatest waste water emissions according to the registration CSRs. The dossier proposes that D4 and D5 shall not be placed on the market or used in concentrations equal to or greater than 0.1% by weight of each in personal care products that are washed off under normal conditions of use.

The Rapporteurs presented the outcome of the conformity check and the recommendations to the Dossier Submitter and informed the Committee that the dossier can be considered in conformity from the RAC point of view. The Committee agreed that the dossier conforms to the Annex XV requirements.

The Rapporteurs were then invited to present the key issues identified by them in the dossier. The Rapporteurs mentioned some recommendations on the scope, on information on hazard and risk and on the justification. They then proposed to the Committee that RAC should agree with the recent MSC opinion that both substances are vPvB (and D4 is a PBT because of its human health classification and aquatic toxicity, which was not considered by the MSC), and should not re-open this discussion. The Committee agreed.

The Chairman informed that SEAC will conclude on the conformity of this dossier at SEAC-27. If the dossier will be considered in conformity by both Committees, the public consultation on the Annex XV report will be launched on 18 June and the first draft opinion should be prepared by the Rapporteurs by early August (replacing the previous key issues document).

6.3 Appointment of Rapporteurs for restriction dossiers

According to the procedure for the appointment of Rapporteurs, for AfA, Restriction dossiers and CLH which was revised and agreed at RAC-31, the Secretariat presented the Members who volunteered for RAC rapporteurships for the restriction dossiers on Perfluorooctyl silanes (PFAS) (to be submitted by Denmark) and for the restriction dossiers on Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP) (to be submitted by ECHA). RAC agreed on the pool of Rapporteurs as outlined in the room document RAC/33/2015/07 RESTRICTED. The Chairman announced the selection of the Rapporteurs for the upcoming restriction dossier on Perfluorooctyl silanes (PFAS).

7. Authorisation

7.1 General authorisations issues

a) General authorisation issues

Applications received

The ECHA Secretariat informed the Committee about three applications for authorisation of chromates submitted in the May window. These are currently being checked for their compliance with the ECHA business rules. He also informed that a first application for authorisation of EDC might be received in June.

Addition of a 'succinct summary' to future applications

The Secretariat informed the Committee that in response to concerns from the Members States in the REACH Committee about the enforceability of authorisation decisions, an addition to the application called the 'succinct summary' had been developed. ECHA coordinated an *ad-hoc* working group consisting from the representatives of the Forum, the Member States, the representatives of RAC and the European Commission. The *ad-hoc* working group developed and agreed on a format for the succinct summary. This is meant to summarise the operational conditions and risk management measures and is to be prepared and submitted by the applicants as part of upcoming applications for authorisation with the intention of helping enforcers. As the next step ECHA will publish the format on its website before the summer break. The format will be improved based on the experience and feedback received from the applicants and the national enforcement authorities.

Progress in evaluating applications

The Secretariat also presented an analysis of the RAC and SEAC draft opinions on the 13 applications for authorisation for the 19 uses of trichloroethylene. The analysis focused on the consistency of the opinions with regard to the identified excess risks for both workers and man via environment in relation to the uncertainties observed in the applications, RAC's recommendations on the operational conditions (OC) and risk management measures (RMM), as well as the advice provided to SEAC regarding the length of the review period. It was emphasised that the excess risks in combination with the uncertainties lead to recommendations from RAC and not the risk alone. The presentation was appreciated by the RAC Members. An observer from the Commission noted that the review period reflects not only uncertainties and the excess risks, but also the analysis of alternatives. She also called for continued attention to the consistency of the Committees' opinions, stressing the importance of the application-specific information to be provided to the Commission in the opinions of the Committees. She also reflected on the different approach to be taken by the Committees depending on the threshold or non-threshold nature of the effects of the substance.

In his concluding remarks the Chairman thanked the Secretariat for the detailed presentation and confirmed that for future opinions on applications for authorisation the work of evaluation should be done in the same standardised manner. He also confirmed that a list of agreed standard phrases for recurring issues in the opinions was being prepared. Noting that every application for authorisation is unique, the phrases cannot be standardised in absolute terms but would act as a guide. He also confirmed that the annex to the meeting minutes, containing the conclusions and the action points will reflect the application for authorisation conclusions on each opinion in more detail in order to facilitate their finalisation.

b) Capacity building: RAC reference values

1. DNEL values setting for the reproductive toxicant bis(2-methoxyethyl)ether (diglyme)

The Chairman informed the Committee that during the RAC consultation on the draft note on Diglyme the Secretariat had received comments from four RAC Members. Considering the proximity of the plenary, the Secretariat decided not to request the consultant to update the draft note, but rather to discuss the open issues at the plenary.

For Diglyme the DNELs to be derived need to cover developmental toxicity and fertility (testicular effects), as Diglyme is on Annex XIV for both effects. With respect to testicular toxicity, the Committee discussed the adjustment factor for study duration to be used in calculating the DNELs, given that only 14-day inhalation studies were available. RAC agreed on an assessment factor of 4 for study duration instead of the default of 6, given the relatively short length of the sperm cycle in rats. The Committee then discussed the DNEL reference values via inhalation, oral and dermal routes of exposure, for both type of effects.

Finally, RAC agreed the note on the DNEL reference values to be published on the ECHA website for Diglyme.

The Chairman thanked the Rapporteur, the consultant and the Committee for their work on the note.

2. Carcinogenicity dose-response relationship setting for 1,2-dichloroethane (EDC)

The Chairman informed the Committee that during the RAC consultation on EDC the Secretariat received comments from three RAC Members. Again, considering the proximity of the plenary, the Secretariat decided not to ask the consultant to update the draft note, but rather to discuss the open issues at the plenary.

With regard to dermal exposure, the Rapporteur drew the Committee's attention to the proposed values for the amount of EDC absorbed through the skin. He expressed doubts regarding 100%, which seemed to be too high, considering the volatility of the substance. He also noted difficulties with a 1% value for the opposite reason, finally, proposing 50% which could be used as a default.

After a brief discussion, RAC agreed on the use of 50% absorption as a default value for the dermal route of exposure, unless the applicant could justify another application-specific value by describing specific conditions of use.

RAC agreed the note on the dose-response reference values to be published on the ECHA website for EDC.

The Chairman thanked the Rapporteur, the consultant and the Committee for their work on the note.

7.2 Authorisation applications

a) Authorisation application – third version of RAC draft opinion

1. Trichloroethylene 2a

The Chairman briefly introduced the '2a' application cases, noting that following the last plenary meeting the Rapporteurs had prepared updated versions of the draft opinions taking the discussions held at RAC-32 as well as the comments received during the RAC consultation into account.

Use 1 Use of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist

The Chairman briefly introduced the case noting that following the last plenary meeting the Committee had requested clarifications from the Applicant on the relationship between exposure measurements and the type of degreaser (Types III-V) and had received a reply. The Rapporteurs were of the view that the measured data for inhalation exposure of workers seems to corroborate the results of modelling. Nevertheless, there are significant uncertainties related to the representativeness of the measured data considering the large number of companies that would benefit from the authorisation applied for. Based on these uncertainties and on the relatively high risk level for directly exposed workers, RAC did not consider the risk management measures (RMMs) and operating conditions (OCs) as described in the draft opinion to be appropriate and effective in limiting the risk. Therefore, RAC proposed additional conditions and monitoring arrangements at workplaces for the improvement of the RMM and OCs. RAC also brought to SEAC's attention that the uncertainties related to the exposure assessment coupled with the estimated cancer risk level for workers indicate that anything more than a normal review period would not be appropriate in this case.

RAC agreed on the draft opinion by consensus.

Use 3 Use of tricholoroethylene in packaging

The Chairman noted that use 3 of the TCE2a application is similar to TCE2b use 2 and would be considered in pairs at the plenary. However, the comparison made between the two applications was only for the purpose of clarifying the information presented to the Committee and Members were reminded that each application should be assessed on its own merit.

The Rapporteurs mentioned that in their view the exposure has been appropriately described by the Applicant. However, there were some uncertainties in the exposure assessment for both closed and semi-closed systems. With regard to the risk management measures and operating conditions described in the application, the Rapporteurs were of the view that these were in general appropriate and effective in limiting the risk to indirectly exposed workers and general population. However, there were still uncertainties for directly exposed workers using semi-closed systems; therefore, the Rapporteurs proposed additional monitoring arrangements and improvement of the RMMs and OCs for the review report. With regard to the review period, the Rapporteurs had no recommendation for SEAC.

RAC agreed the draft opinion by consensus.

Use 4 Use of tricholoroethylene in formulation

The Chairman noted that the use 4 of the TCE2a application is similar to TCE2b use 1 and would be considered in pairs at the plenary. However, the comparison made between the two applications was only for the purpose of clarifying the information presented to the Committee and Members were reminded that each application should be assessed on its own merit.

The Rapporteurs mentioned that in their view the exposure has been appropriately described by the Applicant. However, there were some uncertainties in the exposure assessment. With regard to the risk management measures and operating conditions described in the application, the Rapporteurs were of the view that these were in general appropriate and effective in limiting the risk to indirectly exposed workers and to the general population, but there were still uncertainties for directly exposed workers using non-closed systems. The Rapporteurs did not propose any additional monitoring arrangements or conditions. However following discussions with Members it was noted that despite the level of identified risks appearing to be relatively low, a further reduction of exposure (to an as low level as technically and practically possible) seemed possible by the use of closed systems. With regard to the review period, the Rapporteurs had no recommendation for SEAC.

RAC agreed the draft opinion by consensus.

Use 5 Use of Trichloroethylene as Extraction Solvent for Bitumen in Asphalt Analysis

The Rapporteurs presented the draft opinion mentioning that in their view the exposure has been appropriately described by the Applicant. However there are still uncertainties about the representativeness of the inhalation measurements and on the dermal exposure assessment. With regard to the risk management measures and operating conditions described in the application, the Rapporteurs were of the view that these are appropriate, but with some uncertainties about the directly exposed workers. For this, the Rapporteurs were proposing monitoring arrangements and a review and improvement of the RMMs and OCs. With regard to the review period, the Rapporteurs proposed having no recommendation for SEAC, however noted the uncertainties related to the exposure assessment and relatively high risk level for directly exposed workers for the consideration of SEAC.

RAC agreed the draft opinion by consensus.

For all the trichloroethylene 2a opinions above, the Rapporteurs together with the Secretariat will make an editorial check. The Secretariat will send the combined RAC and SEAC draft opinions to the Applicant for their possible comments.

The Chairman thanked the Rapporteurs for their efficient and thorough work.

2. Trichloroethylene 2b:

The Chairman briefly introduced the cases noting that following the last plenary meeting the Rapporteurs prepared the updated versions of the RAC draft opinions considering the discussions held at RAC-32 as well as the comments received during the RAC consultation.

Use 1 Use of Trichloroethylene in formulation

The Chairman noted that the use 1 of the TCE2b application was similar to TCE2a use 4 and would be considered in pairs at this plenary. However, the comparison made between the two applications was only for the purpose of clarifying the information presented to the Committee and Members were reminded that each application should be assessed on its own merit.

The Rapporteurs mentioned that in their view the exposure has been appropriately described by the Applicant. However, there were some uncertainties in the exposure assessment. With regard to the risk management measures and operating conditions described in the application, the Rapporteurs were of the view that these were in general appropriate and effective in limiting the risk to indirectly exposed workers and to the general population, but there were still uncertainties for directly exposed workers using non-closed systems; therefore, the Rapporteurs proposed additional monitoring arrangements and improvement of the RMMs and OCs for the review report. With regard to the review period, the Rapporteurs had no recommendation for SEAC.

RAC agreed the draft opinion by consensus.

Use 2 Use of trichloroethylene in packaging

The Chairman noted that the use 2 of the TCE2b application was similar to TCE2a use 3 and would be considered in pairs at this plenary (see above).

The Rapporteurs mentioned that in their view the exposure has been appropriately described by the Applicant. However, there were some uncertainties in the exposure assessment for both types of systems (closed and semi-closed). With regard to the risk management measures and operating conditions described in the application, the Rapporteurs were of the view that these were in general appropriate and effective in limiting the risk to indirectly exposed workers and general population. However, there were still uncertainties for directly exposed workers using semi-closed systems; therefore, the Rapporteurs were proposing additional monitoring arrangements and improvement of the RMMs and OCs for the review report. With regard to the review period, the Rapporteurs had no recommendation for SEAC.

RAC agreed the draft opinion by consensus.

For both the trichloroethylene 2b opinions, the Rapporteurs together with the Secretariat will make an editorial check. The Secretariat will send the combined RAC and SEAC draft opinions to the Applicant for their possible comments.

The Chairman thanked the Rapporteurs for their efficient and thorough work.

Trichloroethylene 12

Use 1 Industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems

The Chairman briefly introduced the case noting that following the last plenary meeting, the Rapporteurs have prepared the updated version of the RAC draft opinion considering the discussions held at RAC-32, as well as the comments received during the RAC consultation.

The Rapporteurs noted that no measurement data was presented to confirm the exposure estimates and that the modelling results for worker exposure are associated with large uncertainties.. Therefore, the Rapporteurs considered that there was no way of assessing how representative the modelled exposure data is for the workplaces covered by the use applied for. Furthermore, the assessment of exposure of man via environment was considered unrealistic and incomplete. As a consequence, it is not possible to reliably assess the appropriateness and effectiveness of the operational conditions and risk management measures in limiting the risks. Based on the above, the Rapporteurs recommended additional conditions for this application which were discussed and agreed by Members. With regard to the review period, the Rapporteurs recommended a very short review period to SEAC due to the large uncertainties in the exposure assessment and the level of risks.

RAC agreed the draft opinion by consensus. The Rapporteurs together with the Secretariat will carry out an editorial check of the draft opinion and will send the combined RAC and SEAC draft opinion to the Applicant for their possible comments.

The Chairman thanked the Rapporteurs for their efficient and thorough work.

b) Authorisation applications – first version of RAC draft opinion

1. Lead chromate 1:

Use 1 Industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection

The Chairman welcomed the Rapporteur and reported on the state of play of the dossier. At the previous meeting RAC agreed on the conformity of the application and discussed the key issues, as presented by the Rapporteur.

No comments were received during the RAC Consultation on the application. Two comments were received during the public consultation. On 22 April the first dialogue of the RAC and SEAC Rapporteurs took place. On 29 April the WebEx trialogue meeting between the Rapporteurs of the Committees and the Applicant took place.

RAC concluded that the information on exposures provided by the applicant in general appeared to be sufficient for the assessment of the use applied for. Lead biomonitoring data was present and gave some understanding about the level of lead exposure of the worker population. RAC also noted that there were significant uncertainties related to the representativeness of the available monitoring and/or biomonitoring data due to the limited number of measurements taken both for lead and chromium. RAC also concluded that the exposure levels without and with respiratory protective equipment/personal protective equipment were high. However, from the photographic evidence, it became apparent that for at least one of the work stations, exposure to lead chromate was not adequately contained. The necessary risk management measures were therefore apparently not sufficient and not effective in limiting the risk to the workers.

Furthermore RAC recommended that a review report, if any, shall contain an extensive description and valid documentation of the effectiveness of improved RMM, systematic

monitoring for lead and chromate exposures of the employees involved and continued efforts to minimise possible exposures. In case the authorisation is granted, the use of full enclosure with air extraction around the area where the tasks resulting in exposure are performed (such as a glove box) should be considered.

RAC recommended that the information gathered in the monitoring and/or biomonitoring campaigns must be used to review and improve RMM and operational conditions, to further reduce workers' exposure to lead chromate. The hierarchy of control principles must be followed in the selection of RMM. The outcomes and conclusions of such review, including those related to the implementation of the additional RMM, must be documented by the applicant. The results of the monitoring and/or biomonitoring as well as description and valid documentation of the effectiveness of improved technical measures and RMM must be included in any subsequent authorisation review report, if submitted.

RAC brought to the attention of SEAC that the uncertainties related to the exposure assessment coupled with the high estimated cancer risk levels for workers indicate a need for a shorter review period.

The Committee agreed the draft opinion by consensus. The Chairman thanked the Rapporteurs for their work on the application.

7.3 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. Following the Chairman's proposal, RAC agreed to nominate all Members to same pool of Rapporteurs for all substances no 16 to no 22 of Annex XIV. The expanded pool of Rapporteurs, as outlined in the amended restricted room document RAC/33/2015/10 rev 1, was then agreed by RAC. The Chairman appointed Rapporteurs for the upcoming applications for authorisation on the uses of Chromium trioxide 1, Sodium chromate 1 and Sodium dichromate 1.

8. AOB

A RAC Member asked for clarification of the practice for a revision of guidance documents as based on her experience (from the commenting round on the revised Guidance on reproduction (Section R.7.6 of Chapter R.7a of the Guidance on IR&CSA)) highly relevant information from a peer reviewed scientific paper was not accepted with the explanation that the information was not freely available. The RAC Member questioned the possible impact this might have on the current REACH Guidance and asked for further clarification of the procedure. The Secretariat would check the details and provide an explanation to the Committee.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 33 1-5 June 2015

(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/33/2015**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-33 minutes.
4. Report from other ECHA bodies and activities	
a) Report on RAC 32 action points, written procedures and other ECHA bodies SECR presented document **RAC/33/2015/01** and document **RAC/33/2015/02.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes SECR presented the update on the Q3 - Q4/2015 and Q1/2016 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-33 meeting on CIRCABC.
c) General RAC procedures **(closed session)** RAC agreed on the revised general approach on the admission of accredited stakeholder organisations to RAC.	**SECR** to upload the presentation to the confidential folder of the RAC-33 meeting on CIRCABC. **SECR** to inform the other ECHA Committees on the RAC decision and publish the revised document on the ECHA website. **SECR** to apply the revised procedure and propose an updated list of RAC stakeholders for the agreement of RAC in RAC-34.
(open session) RAC agreed on the proposed required competences and the selection procedure for co-opting additional Members to RAC.	**SECR** to upload the presentation to the non-confidential folder of the RAC-33 meeting on CIRCABC.
(open session) RAC agreed on the revised Rules of Procedure of the Committee for Risk Assessment.	**SECR** to upload the presentation to the non-confidential folder of the RAC-33 meeting on CIRCABC.

	SECR to inform the Management Board on the agreement of RAC on the proposed revised Rules of Procedures.
Info point on Article 95	
RAC Members broadly supported the goals of REACH Article 95. RAC agreed to establish a Joint Working Group to solve conflicts of opinions between RAC and SCOEL in relation to NMP.	**SECR** to launch a call for volunteers to join the Joint Working Group for NMP.
5. Harmonised classification and labelling (CLH)	
A. Substances with hazard classes for agreement without plenary debate a) Tefluthrin (ISO): Acute toxicity, Skin corrosion/irritation, Eye damage/irritation, Skin sensitisation, Germ cell mutagenicity, Carcinogenicity, Reproductive toxicity b) Cyanamide: Acute toxicity, STOT SE, Skin corrosion/irritation, Skin sensitisation, Germ cell mutagenicity c) Dichlofluanid: Acute toxicity, Skin sensitisation d) Triadimenol (ISO): Acute toxicity, Skin corrosion/irritation, Eye damage/irritation, STOT RE, Germ cell mutagenicity e) Terbuthylazine (ISO): Acute toxicity, STOT SE, Skin corrosion/irritation, Eye damage/irritation, Skin sensitisation, Germ cell mutagenicity f) Salicylic acid: Acute toxicity, Eye damage g) Quinolin-8-ol; 8-hydroxyquinoline: Acute toxicity, Skin corrosion/irritation, Eye damage/irritation h) Fipronil (ISO): Aquatic Acute and Aquatic Chronic Toxicity	
c) Dichlofluanid (ISO)	
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 (H332), Skin Sens. 1 (H317)]	**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.
h) Fipronil (ISO)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Acute 1 (H400) with M=1000, Aquatic Chronic 1 (H410) with M=10000]	**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.
B. Substances with hazard classes for agreement in plenary session a) Tefluthrin (ISO)	

b) Cyanamide

c) Triadimenol (ISO)

d) Terbutylazine (ISO)

e) Salicylic acid

f) Methylhydrazine

g) Dibutyltin dilaurate

h) Quinolin-8-ol; 8-hydroxyquinoline

i) 2-methyl-1-(4-methylthiophenyl) -2-morpholinopropan-1-one

a) Tefluthrin (ISO)	
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. 2 (H300 and 310), Acute Tox.1 (H310)] [Agreement at RAC-32 on Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with M=10000 for both.]	**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.
b) Cyanamide	
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. 3 (H301 and H311), Skin Corr. 1 (H314), Skin Sens. 1 (H317), STOT RE 2 (H373 (thyroid)), Repr. 2 (H361fd), Carc. 2 (H351), Aquatic Chronic 3 (H412)]	**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.
c) Triadimenol (ISO)	
RAC agreed on hazard class for the harmonised classification and labelling as indicated in Table 2 below. RAC will continue examination of the dossier during RAC-34 in September. [Acute Tox. 4 (H302)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC-33 and to provide it to SECR. [In the event of additional data being provided, **SECR** to launch a new (targeted) public consultation.] [**SECR** to launch a RAC consultation prior to RAC-34 plenary meeting.] **Rapporteur** to revise the opinion in accordance with the comments provided in the RAC consultation.
d) Terbuthylazine (ISO)	
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), STOT RE 2 (H373), Aquatic Acute 1 (H400) with M=10, Aquatic Chronic 1 (H410) with 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.
e) Salicylic acid	
RAC agreed on hazard classes for the harmonised classification and labelling as indicated in Table 2 below. RAC requested further clarification on the relevance to developmental toxicity of the doses in the human epidemiology studies vs. the animal studies. [Acute Tox. 4 (H302), Eye Dam. 1 (H318)]	**SECR** to contact the Dossier Submitter with regard to the relevant epidemiology data. [In the event of additional data being provided, **SECR** to launch a new (targeted) public consultation.] [**SECR** to launch a RAC consultation prior to RAC-34 plenary meeting.] **Rapporteur** to revise the opinion in accordance with the comments provided in the RAC consultation.
f) Methylhydrazine	
RAC agreed to postpone the discussion of the draft opinion to RAC-34.	
g) Dibutyltin dilaurate	
RAC agreed by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Muta. 2 (H341), Repr. 1B (H360FD), STOT RE 1 (H372 (immune system))]	**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.
h) Quinolin-8-ol; 8-hydroxyquinoline	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 3 (H301), Eye Dam. 1 (H318), Skin Sens. 1 (H317), Repr. 1B (H360D), Aquatic Acute 1 (H400) with M=1, Aquatic Chronic 1 (H410) with 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.
i) 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B (H360DF)]	**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.
5.2 Appointment of RAC (co-)rapporteurs for CLH dossiers	
RAC appointed the new (co-)rapporteurs for CLH dossiers.	**SECR** to upload the list of appointed (co-)rapporteurs to CIRCA BC confidential.
6. Restrictions	
6.1 General restriction issues	
RAC took note of the report of the Restrictions workshop held at ECHA on 7-8 May 2015.	
6.2 Restriction Annex XV dossiers	
a) Opinion Development	
1. Isopropylidenediphenol (Bisphenol A) – revised draft opinion Rapporteurs presented and RAC discussed the revised draft of the RAC opinion. RAC adopted the opinion on Bisphenol A by consensus.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs**, together with SECR, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and CIRCABC IG.
2. DecaBDE – revised draft opinion Rapporteurs presented and RAC discussed the revised draft of the RAC opinion. RAC adopted the opinion on decaBDE by consensus.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs**, together with SECR, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and CIRCABC IG.

3. Perfluorooctanoic acid (PFOA) – first draft opinion Rapporteurs presented and RAC discussed the first draft opinion. RAC agreed with supporting the scope of the proposal as proposed by the Rapporteurs (with derogations and the concentration limit to be discussed later). RAC concluded that it is concerned for effects on the mammary gland, but believes that it is currently not possible to set a robust NOAEL as basis for a DNEL and for risk characterisation. RAC noted epidemiological studies suggesting an association between PFOA-exposure and decreased birth weights. Due to unclear adversity and uncertainties in dose-response it cannot be used in the RC. RAC noted epidemiological studies suggesting an association between PFOA-exposure and cholesterolemia. Due to unclear adversity and uncertainties in dose-response it cannot be used in the RC. Substance identity will be further considered.	**Rapporteurs** to take the RAC discussion into account in the revised draft opinion (by early August 2015). Concentration limit and derogations to be fully developed for RAC-33.
4. Methanol – key issues document Rapporteurs presented and RAC discussed the key issues document for the RAC opinion.	**Rapporteurs** to take the RAC discussion and the Dossier Submitter`s clarifications into account in the first version of the draft opinion (by end of July 2015). **SECR** to open a written commenting round on the first version of the draft opinion.
c) Conformity check	
1. D4/D5 – Key issues presentation RAC agreed that the dossier conforms to the Annex XV requirements and took note of the recommendations to the dossier submitter. Rapporteurs presented and RAC discussed the key issues of the dossier.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to CIRCABC. **SECR** to inform the dossier submitter on the outcome of the conformity check. **Rapporteurs** to take the RAC discussion on key issues into account in the preparation of the first draft opinion (by early August 2015).

6.3 Appointment of RAC (co-)rapporteurs for restriction dossiers	
RAC appointed the new (co-)rapporteurs for restriction dossiers.	**SECR** to upload the list of appointed (co-)rapporteurs to CIRCA BC confidential.
7. Authorisation	
7.1 General authorisation issues	
a) General authorisation issues	
b) Capacity building	
1. DNEL values setting for the reproductive toxicant bis(2-methoxyethyl)ether (diglyme) RAC agreed on the DNEL reference values via inhalation, oral and dermal routes of exposure. RAC agreed on a duration assessment factor of 4 to be used for the calculation of the DNEL for testicular effects. RAC agreed on the note on the DNEL reference values setting for Diglyme.	**SECR** to update the agreed note in accordance with the discussion in RAC-33. **SECR** to publish the agreed note on the ECHA website.
2. Carcinogenicity dose-response relationship setting for 1,2-dichloroethane RAC agreed on the use of 50% absorption as a default value for the dermal route of exposure, unless the applicant provides convincing justification for another application-specific value by describing specific conditions of the use. RAC agreed on the note on the carcinogenicity dose-response relationship setting for EDC.	**SECR** to request the consultant to update the agreed note in accordance with the discussion in RAC-33. **SECR** to publish the agreed note on the ECHA website.
7.2 Authorisation applications	
a) Authorisation application – 3rd version of RAC draft opinion	
1. Trichloroethylene 2a: **<u>Use 1:</u>** Use of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist RAC agreed on the draft opinion with the following conclusions: - RAC noted that the air measurements seem to corroborate the worker exposure modelling for inhalation. Nevertheless, there are significant uncertainties related to the representativeness of the air measurements.	Actions: **TCE2a use 1** **Rapporteurs** together with SECR to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline, the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, SECR will make the Applicant's comments available on CIRCABC and will

- Due to the uncertainties related to the representativeness of the worker exposure estimates and to the relatively high risk level, the **RMMs and OCs** as described in the draft opinion are not considered to be appropriate and effective in limiting the risk. - The risk estimates for man via environment as provided by the applicant are considered overly conservative. - RAC requested the following **additional conditions and monitoring arrangements** at workplaces for the improvement of the RMM/OCs of this application: use of TCE for cleaning only where specific requirements (system of use parameters) exist; at the minimum by the end of their service life, ECSA type III machines should be replaced with type IV, or preferably type V machines; the process must be performed under vacuum if possible. Monitoring arrangements at the workplace (air and biomonitoring). - RAC recommended a **no more than a normal review period**.	inform RAC.
Use 3: Use of Trichloroethylene in packaging RAC agreed on the DO with the following conclusions - The exposure has been appropriately described and assessed. However, RAC notes there are some uncertainties in the exposure assessment for both types of systems. - RAC agrees that RMMs and OCs appear to be generally appropriate and effective in limiting the risk to indirectly exposed workers and general population. However there are still uncertainties for directly exposed workers using semi-closed systems. - RAC proposed additional monitoring arrangements and improvement of the RMM/OCs for the review report. - RAC has no advice to SEAC on the review period.	**TCE2a use 3** **Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline, the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, SECR will make the Applicant's comments available on CIRCABC and will inform RAC.
Use 4: Use of Trichloroethylene in formulation RAC agreed on the DO with the following conclusions - The exposure has been appropriately described and assessed. However, RAC notes there are some uncertainties in the exposure assessment. - RAC agrees that RMMs and OCs appear to be generally appropriate and effective in limiting the risk to exposed workers and general population. However there are still uncertainties for directly exposed workers	**TCE2a use 4** **Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline, the RAC Chairman will approve

using non-closed systems. - RAC proposed no additional conditions or monitoring arrangements. However RAC notes that despite the level of identified risks appearing to be relatively low, a further reduction of exposure (to an as low level as technically and practically possible) seems possible by the use of closed systems. - RAC has no advice to SEAC on the review period.	the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, SECR will make the Applicant's comments available on CIRCABC and will inform RAC.
Use 5: Use of Trichloroethylene as Extraction Solvent for Bitumen in Asphalt Analysis RAC agreed on the draft opinion with the following conclusions: - The exposure is appropriately described and assessed, however uncertainties exist on the representativeness of measurements. - The RMMs and OCs as described in the DO are appropriate, but some uncertainties exist about directly exposed workers. - Request for monitoring arrangements and improvement of RMM/OCs. - No RAC recommendation on the review period, however RAC notes the uncertainties related to the exposure assessment and relatively high risk level for directly exposed workers.	**TCE2a use 5:** **Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline, the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, SECR will make the Applicant's comments available on CIRCABC and will inform RAC.
2. Trichloroethylene 2b: **Use 1**: Use of Trichloroethylene in formulation RAC agreed on the DO with the following conclusions - The exposure has been appropriately described and assessed. However, RAC notes there are some uncertainties in the exposure assessment. - RAC agrees that RMMs and OCs appear to be generally appropriate and effective in limiting the risk to exposed workers and general population. However there are still uncertainties for directly exposed workers using non-closed systems. - RAC proposed additional monitoring arrangements and improvement of the RMM/OCs for the review report. - RAC has no advice to SEAC on the review period.	**TCE2b use 1** **Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline, the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, SECR will make the Applicant's comments available on CIRCABC and will inform RAC.
Use 2: Use of Tricholoroethylene in packaging	**TCE2b use 2** **Rapporteurs** together with **SECR** to do

RAC agreed on the DO with the following conclusions - The exposure has been appropriately described and assessed. However, RAC notes there are some uncertainties in the exposure assessment for both types of systems. - RAC agrees that RMMs and OCs appear to be generally appropriate and effective in limiting the risk to indirectly exposed workers and general population. However there are still uncertainties for directly exposed workers using semi-closed systems. - RAC proposed additional monitoring arrangements and improvement of the RMM/OCs for the review report. - RAC has no advice to SEAC on the review period.	the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline, the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, SECR will make the Applicant's comments available on CIRCABC and will inform RAC.
3. Trichloroethylene 12: **<u>Use 1:</u>** Industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems RAC agreed on the draft opinion with the following conclusions: - RAC agreed that the exposure assessment includes significant uncertainties and the assessment of exposure of Man via Environment is unrealistic and incomplete. - RAC noted that workplaces have only been described in modelling terms but no data for any workplace was presented, therefore there was no way of assessing how representative the modelled data is for any specific workplace. - RAC agreed that the OCs and RMM are not appropriate and effective in limiting the risks. - RAC agreed that the available information on alternatives appear to suggest that substitution with alternatives would lead to overall reduction of risk. - Additional conditions were recommended for this application: to reduce environmental releases and prevent sources of emission, including leakage, should be controlled in order to reduce risk; at the minimum by the end of their service life, ECSA type III machines should be replaced with type IV, or preferably type V machines; the process must be performed under vacuum if possible. Monitoring arrangements at the workplace (air and biomonitoring) for further review. - RAC advised SEAC on a very short review period due to the uncertainties in the exposure assessment and risks.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, SECR will make the Applicant's comments available on CIRCABC and will inform RAC.
b) Authorisation application – first version of draft opinion	

1. Lead chromate 1: **<u>Use 1:</u>** Industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection RAC agreed on the DO with the following conclusions: **- The information** on exposures provided by the applicant in general appears to be sufficient for the assessment of the use applied for. Lead biomonitoring data is present and gives some understanding about the level of Pb exposure of the worker population. RAC also notes that there are significant uncertainties related to the representativeness of the available monitoring/ biomonitoring data due to the limited number of measurements taken both for Pb and Cr. - The exposure levels without and with RPE/PPE are high. The necessary RMMs are apparently not sufficient and not effective in limiting the risk to the workers. - In case the authorisation is granted, the use of full enclosure with air extraction around the area where the tasks resulting in exposure are performed (such as glove box) should be considered. - Furthermore RAC sets the conditions that: - A review report (if any) shall contain an extensive description and valid documentation of the effectiveness of improved RMMs, - Systematic monitoring for lead and chromate exposures of the employees involved and further continue efforts to minimise possible exposures, - In case the authorisation is granted, the use of full enclosure with air extraction around the area where the tasks resulting in exposure are performed (such as glove box) should be considered. - The information gathered in the monitoring/ biomonitoring campaigns must be used to review and improve RMMs and OCs, to further reduce workers' exposure to lead chromate: - The hierarchy of control principles must be followed in the selection of RMMs, - The outcomes and conclusions of such review, including those related to the implementation of the additional RMMs, must be documented, - The results of the monitoring/ biomonitoring as well as description and valid documentation of the effectiveness of improved technical measures and RMM must be included in any subsequent authorisation review report, if submitted. - RAC has brought to the attention of SEAC that the uncertainties related to the exposure assessment	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline, the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, SECR will make the Applicant's comments available on CIRCABC and will inform RAC.

coupled with the high estimated cancer risk levels for workers indicate a need for a shorter review period.	
7.3 Appointment of (co-)rapporteurs for authorisation applications RAC agreed on the updated pool of Rapporteurs for the applications for authorisation.	**SECR** to upload the pool of Rapporteurs to CIRCABC restricted.
8. AOB	
9. Action points and main conclusions of RAC-33	
SECR to upload the adopted action points to CIRCA BC.	

Table 1: Classification tables of substances for which RAC adopted the opinion

Tefluthrin (ISO); 2,3,5,6-tetrafluoro-4-methylbenzyl (1*RS*,3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitter's proposal	xxx-xxx-xx-x	tefluthrin (ISO); 2,3,5,6-tetrafluoro-4-methylbenzyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropane carboxylate	-	79538-32-2	Acute Tox. 1 Acute Tox. 2 Acute Tox. 2 STOT-RE 1 Aquatic Acute 1 Aquatic Chronic 1	H330 H310 H300 H372 (nervous system) H400 H410	GHS06 GHS08 GHS09 Dgr	H330 H310 H300 H372 (nervous system) H410		M = 10000 M = 10000	
RAC opinion	xxx-xxx-xx-x	tefluthrin (ISO); 2,3,5,6-tetrafluoro-4-methylbenzyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropane carboxylate	-	79538-32-2	**Acute Tox. 1** **Acute Tox. 2** **Acute Tox. 2** **Aquatic Acute 1** **Aquatic Chronic 1**	**H330** **H310** **H300** **H400** **H410**	**GHS06** **GHS08** **GHS09** **Dgr**	**H330** **H310** **H300** **H410**		**M = 10000** **M = 10000**	
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	tefluthrin (ISO); 2,3,5,6-tetrafluoro-4-methylbenzyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropane carboxylate	-		Acute Tox. 1 Acute Tox. 2 Acute Tox. 2 Aquatic Acute 1 Aquatic Chronic 1	H330 H310 H300 H400 H410	GHS06 GHS08 GHS09 Dgr	H330 H310 H300 H410		M = 10000 M = 10000	

Cyanamide

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 Entry	615-013-00-2	cyanamide; carbanonitril	206-992-3	420-04-2	Acute Tox. 3 * Acute Tox. 4 * Eye Irrit. 2 Skin Irrit. 2 Skin Sens. 1	H301 H312 H319 H315 H317	GHS06 Dgr	H301 H312 H319 H315 H317			
Dossier submitter's proposal	615-013-00-2	cyanamide	206-992-3	420-04-2	**Add:** Repr. 2 STOT RE 1 Aquatic Chronic 1 **Modify:** Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Skin Sens. 1B **Remove:** Eye Irrit. 2	**Add:** H361fd H372 (thyroid)(oral) H410 **Modify:** H311 H301 H314 H317 **Remove:** H319	GHS08 GHS06 GHS05 GHS09 Dgr	**Add:** H361fd H372 (thyroid)(oral) H410 **Modify:** H311 H301 H314 H317 **Remove:** H319		M=1	
RAC opinion	615-013-00-2	cyanamide	206-992-3	420-04-2	**Add:** **Carc. 2** **Repr. 2** **STOT RE 2** **Aquatic Chronic 3** **Modify:** **Acute Tox. 3** **Acute Tox. 3** **Skin Corr. 1** **Remove:** **Eye Irrit. 2** **Retain:** **Skin Sens. 1**	**Add:** **H351** **H361fd** **H373 (thyroid)** **H412** **Modify:** **H301** **H311** **H314** **Remove:** **H319** **Retain:** **H317**	**GHS08** **GHS07** **GHS06** **GHS05** **Dgr**	**Add:** **H351** **H361fd** **H373 (thyroid)** **H412** **Modify:** **H301** **H311** **H314** **Remove:** **H319** **Retain:** **H317**			
Resulting Annex VI entry if agreed by COM	615-013-00-2	cyanamide	EC No or "-"	CAS No or "-"	Carc. 2 Repr. 2 STOT RE 2 Acute Tox. 3 Acute Tox. 3	H351 H361fd H373 (thyroid) H301 H311	**GHS08** **GHS07** **GHS06** **GHS05** **Dgr**	H351 H361fd H373 (thyroid) H301 H311			

					Skin Corr. 1 Skin Sens. 1 Aquatic Chronic 3	H314 H317 H412		H314 H317 H412			

Terbuthylazine (ISO); *N*-tert-butyl-6-chloro-*N*'-ethyl-1,3,5-triazine-2,4-diamine

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	xxx-xxx-xx-x	terbuthylazine (ISO); *N*-tert-butyl-6-chloro-*N*'-ethyl-1,3,5-triazine-2,4-diamine	227-637-9	5915-41-3	Carc. 2 Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H373 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H373 H410		 M=10 M=10	
RAC opinion	xxx-xxx-xx-x	terbuthylazine (ISO); *N*-tert-butyl-6-chloro-*N*'-ethyl-1,3,5-triazine-2,4-diamine	227-637-9	5915-41-3	**Acute Tox. 4** **STOT RE 2** **Aquatic Acute 1** **Aquatic Chronic 1**	**H302** **H373** **H400** **H410**	GHS07 GHS08 GHS09 Wng	H302 H373 H410		 **M=10** **M=10**	
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	terbuthylazine (ISO); *N*-tert-butyl-6-chloro-*N*'-ethyl-1,3,5-triazine-2,4-diamine	227-637-9	5915-41-3	Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	**H302** **H373** **H400** **H410**	GHS07 GHS08 GHS09 Wng	H302 H373 H410		 M=10 M=10	

Dibutyltin dilaurate; dibutyl[bis(dodecanoyloxy)]stannane

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	xxx-xxx-xx-x	dibutyltin dilaurate; dibutyl[bis(dodecanoyloxy)]stannane	201-039-8	77-58-7	Muta. 2 Repr. 1B STOT RE 1	H341 H360FD H372 (immune system)	GHS08 Dgr	H341 H360FD H372 (immune system)			
RAC opinion	xxx-xxx-xx-x	dibutyltin dilaurate; dibutyl[bis(dodecanoyloxy)]stannane	201-039-8	77-58-7	**Muta. 2** **Repr. 1B** **STOT RE 1**	**H341** **H360FD** **H372 (immune system)**	**GHS08** **Dgr**	**H341** **H360FD** **H372 (immune system)**			
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	dibutyltin dilaurate; dibutyl[bis(dodecanoyloxy)]stannane	201-039-8	77-58-7	Muta. 2 Repr. 1B STOT RE 1	H341 H360FD H372 (immune system)	GHS08 Dgr	H341 H360FD H372 (immune system)			

Quinolin-8-ol; 8-hydroxyquinoline

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	xxx-xxx-xx-x	quinolin-8-ol; 8-hydroxychinoline	205-711-1	148-24-3	Repr. 2 Acute Tox. 3 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H361d H301 H318 H317 H400 H410	GHS08 GHS06 GHS05 GHS09 Dgr	H361d H301 H318 H317 H410		 M = 1 M = 10	
RAC opinion	xxx-xxx-xx-x	quinolin-8-ol; 8-hydroxychinoline	205-711-1	148-24-3	**Repr. 1B** **Acute Tox. 3** **Eye Dam. 1** **Skin Sens. 1** **Aquatic Acute 1** **Aquatic Chronic 1**	**H360D** **H301** **H318** **H317** **H400** **H410**	**GHS08** **GHS06** **GHS05** **GHS09** **Dgr**	**H360D** **H301** **H318** **H317** **H410**		 **M = 1** **M = 1**	
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	quinolin-8-ol; 8-hydroxychinoline	205-711-1	148-24-3	Repr. 1B Acute Tox. 3 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H301 H318 H317 H400 H410	GHS08 GHS06 GHS05 GHS09 Dgr	H360D H301 H318 H317 H410		 M = 1 M = 1	

2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one (Irgacure 907)

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 Entry	606-041-00-6	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5	Acute Tox. 4* Aquatic Chronic 2	H302 H411	GHS07 GHS09 Wng	H302 H411			
Dossier submitters proposal	606-041-00-6	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5	**Add:** Repr. 1B	**Add:** H360Df	**Add:** GHS08 **Modify:** Dgr	**Add:** H360Df			
RAC opinion	606-041-00-6	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5	**Add:** **Repr. 1B**	**Add:** **H360FD**	**Add:** **GHS08** **Modify:** **Dgr**	**Add:** **H360FD**			
Resulting Annex VI entry if agreed by COM	606-041-00-6	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	400-600-6	71868-10-5	Repr. 1B Acute Tox. 4* Aquatic Chronic 2	H360FD H302 H411	GHS08 GHS07 GHS09 Dgr	H360FD H302 H411			

Dichlofluanid (ISO); *N*-dichlorofluoromethylthio-*N*',*N*'-dimethyl-*N*-phenylsulfamide

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	616-006-00-7	dichlofluanid (ISO); *N*-dichlorofluoromethylthio-*N*',*N*'-dimethyl-*N*-phenylsulfamide	214-118-7	1085-98-9	Skin Sens. 1 Eye Irrit. 2 Acute Tox. 4 * Aquatic Acute 1	H317 H319 H332 H400	GHS07 GHS09 Wng	H317 H319 H332 H400	-	M=10	-
Dossier submitters proposal	616-006-00-7	dichlofluanid (ISO); *N*-[(Dichlorofluoromethyl)thio]-*N*',*N*'-dimethyl-*N*-phenylsulfamide	214-118-7	1085-98-9	**Modify :** Acute Tox. 4 Skin Sens. 1B	**Retain:** H332 H317	**Retain:** GHS07 Wng	**Retain:** H332 H317	**-**	**-**	**-**
RAC opinion	616-006-00-7	dichlofluanid (ISO); *N*-[(Dichlorofluoromethyl)thio]-*N*',*N*'-dimethyl-*N*-phenylsulfamide	214-118-7	1085-98-9	**Retain :** **Skin Sens. 1** **Modify :** **Acute Tox. 4**	**Retain:** **H317** **H332**	**Retain:** **GHS07** **Wng**	**Retain:** **H332** **H317**	**-**		
Resulting Annex VI entry if agreed by COM	616-006-00-7	dichlofluanid (ISO); *N*-[(Dichlorofluoromethyl)thio]-*N*',*N*'-dimethyl-*N*-phenylsulfamide	214-118-7	1085-98-9	Acute Tox. 4 Skin Sens. 1 Eye Irrit. 2 Aquatic Acute 1	H332 H317 H319 H400	GHS07 GHS09 Wng	H332 H317 H319 H400	-	M=10	**-**

Fipronil (ISO); 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile

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	608-055-00-8	fipronil (ISO); 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile	424-610-5	120068-37-3	Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H301 H311 H331 H372** H400 H410	GHS06 GHS08 GHS09 Dgr	H301 H311 H331 H372** H410		M=10	
Dossier submitters proposal	608-055-00-8	fipronil (ISO); 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile	424-610-5	120068-37-3	**Retain:** Aquatic Acute 1 Aquatic Chronic 1	**Retain:** H400 H410	**Retain:** GHS09 Dgr	**Retain:** H410		**Modify:** M=10000 M=10000	
RAC opinion	608-055-00-8	fipronil (ISO); 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile	424-610-5	120068-37-3	**Retain:** **Aquatic Acute 1** **Aquatic Chronic 1**	**Retain:** **H400** **H410**	**Retain:** **GHS09** **Dgr**	**Retain:** **H410**		**Modify:** **M=1000** **M=10000**	
Resulting Annex VI entry if agreed by COM	608-055-00-8	fipronil (ISO); 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfinyl]-1*H*-pyrazole-3-carbonitrile	424-610-5	120068-37-3	Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H301 H311 H331 H372** H400 H410	GHS06 GHS08 GHS09 Dgr	H301 H311 H331 H372** H410		M=1000 M=10000	

Table 2: Classification tables of substances for which RAC agreed on specified hazard classes

Triadimenol (ISO); α-tert-butyl-β-(4-chlorophenoxy)-1*H*-1,2,4-triazole-1-ethanol

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	xxx-xxx-xx-x	triadimenol (ISO); α-tert-butyl-β-(4-chlorophenoxy)-1*H*-1,2,4-triazole-1-ethanol	259-537-6	55219-65-3	Acute Tox. 4 Repr. 2 Aquatic Chronic 2	H302 H361f H411	GHS07 GHS08 GHS09 Wng	H302 H361f H411			
RAC opinion	xxx-xxx-xx-x	triadimenol (ISO); α-tert-butyl-β-(4-chlorophenoxy)-1*H*-1,2,4-triazole-1-ethanol	259-537-6	55219-65-3	**Acute Tox. 4** Repr. 1B or Repr. 2 Lact. Aquatic Chronic 2 or 1	**H302** H360Fd or H361fd H362 H410 or H411	**GHS07**	**H302**			
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	triadimenol (ISO); α-tert-butyl-β-(4-chlorophenoxy)-1*H*-1,2,4-triazole-1-ethanol	259-537-6	55219-65-3							

Salicylic acid

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	xxx-xxx-xx-x	salicylic acid	200-712-3	69-72-7	Acute Tox. 4 Eye Dam. 1	H302 H318	GHS07 GHS05 Dgr	H302 H318			
RAC opinion	xxx-xxx-xx-x	salicylic acid	200-712-3	69-72-7	Repr. 2 or none **Acute Tox. 4** **Eye Dam. 1**	H361d or none **H302** **H318**	GHS08 **GHS07** **GHS05** **Dgr**	H361d or none **H302** **H318**			
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	salicylic acid	200-712-3	69-72-7							

Part III. List of Attendees of the RAC-33 meeting

1-5 June 2015

RAC Members
BARANSKI Bogusław
BIRO Anna
BJORGE Christine
BRANISTEANU Radu
CARVALHO João
COPIN Stephanie
CZERCZAK Slawomir
Di PROSPERO FANGHELLA Paola
DUNAUSKIENĖ Lina
DUNGEY Stephen
GRUIZ Katalin
GUSTAFSON Anne-Lee
HAKKERT Betty
HUSA Stine
HÖLZL Christine
ILIE Mihaela
JENSEN Frank
KADIĶIS Normunds
KALOGIROU Andreas
KAPELARI Sonja
LEINONEN Riitta
LUND Bert-Ove
MENARD Anja
MULLOOLY Yvonne
MURRAY Brendan
NEUMANN Michael

PARIS Pietro
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SANTONEN Tiina
SCHLÚTER Urs
SCHULTE Agnes
SMITH Andrew
SOGORB Miguel
SOERENSEN Peter
SPETSERIS Nikolaos
STAHLMANN Ralf
STASKO Jolanta
UZOMECKAS Zilvinas
VARNAI Veda Marija
Excuses
PASQUIER Elodie
TADEO José Luis
TSITSIMPIKOU Christina
Commission observers
LUVARA Giuseppina DG GROW
MORRIS Alick DG EMPL
SCAZZOLA Roberto DG GROW
Invited expert
BARTHELEMY-BERNERON Johanna (observing on behalf of Elodie Pasquier)

RAC advisors		**Stakeholders observers**
BARRON Thomasina (Brendan Murray), cyanamide		ANNYS Erwin, Cefic
ESPOSITO Dania (Pietro Paris), terbuthilazyne		BARRY Frank, ETUC
HENSCHEL Susann (Urs Schlueter), AfA TCEs		MUNARI Tomaso, EuCheMS
STOCKMANN-JUVALA Helene (Tiina Santonen)		ROMANO Dolores, EEB
SUUTARI Tiina (Riitta Leinonen)		VEROUGSTRAETE Violaine, Eurometaux
TARVAINEN Ilari (Riitta Leinonen)		ROWE Rocky, ECPA
VÄÄNÄNEN Virpi (Tiina Santonen)		**Dossier submitters**
WINTHER Toke (Peter Hammer Soerensen), tefluthrin		Norwegian dossier submitters:
		GUTZKOW Kristine (PFOA)
		CORRELL MYHRE Ingunn (PFOA)
Industry experts		
BEKHIRIA Sami (Cefic, Dow Corning, D4/D5)		German dossier submitters :
BEYER Dieter (Cefic, Bayer, Bisphenol A)		VIERKE Lena (PFOA)
BOCK Ronald (Cefic, Chemours, PFOA)		
GELBKE Heinz-Peter (ECPA, Alzchem GmbH, Cyanamide)		Industry dossier submitters
HENNINGER Kerstin (ECPA, BCS, Triadimenol)		GARD-FLOC´h Arielle (Novacyl, salicylic acid)
JACOBI Sylvia (Cefic, Arbemarle, DecaBDE)		KLAUS Ana-Maria (Bayer, salicylic acid)
LLOYD Sara (ECPA, Syngenta, tefluthrin and terbutylazine)		STRATMANN Heidi (BASF, 2-methyl-1-(4-methylthiophenyl)

REMOTE PARTICIPANTS		KJUUS Berit Eyde (DecaBDE)
RAC Members		KOPANGEN Marit (PFOA, DecaBDE)
TADEO José Luis		LARSEN Ann Kristin (dibutyltindilaurate)
Advisers :		CORRELL Myhre Ingunn (DecaBDE)
GERAETS Liesbeth (Betty Hakkert)		MYHRE Oddvar (DecaBDE)
MARTIN Sara (Steven Dungey and dossier submitter to D4/D5)		TOLFSEN Christina (DecaBDE)
SEAC Rapporteurs		**PL dossier submitter:**
BRIGNON Jean-Marc (PFOA)		GODALA Mariusz (methanol)
CSERGO Robert (methanol)		
FANKHAUSER Simone (lead chromates)		**UK dossier submitter:**
FIORE Karine (lead chromates)		MARTIN Sara (D4/D5)
GEORGIOU Stavros (BPA)		
KIISKI Johanna (PFOA)		
SLETTEN Thea (BPA)		
THIELE Thiele (DecaBDE)		
		Commission
Dossier submitters		BERTATO Valentina
		FERNANDES-de-BARROS Mariana
DE dossier submitters:		GARCIA-JOHN Enrique
BIEGEL-ENGLER Annegret (PFOA)		RIEPMA Wim
NIEDERSTRASSER Bernd (PFOA)		ROZWADOWSKI Jacek
SCHNEIDER Regina (tefluthrin, cynamide)		
STAUDE Claudia (PFOA)		
STARKE Sue Martina (PFOA)		
THIELE Karen (PFOA)		
		ECHA staff
FR dossier submitters:		BERGES Markus
FIORE Karine (BPA)		BLAINEY Mark
		BOWMER Tim, Chairman
NO dossier submitters:		BROECKAERT Fabrice
BLOM Cecile (PFOA)		DVORAKOVA Dana
CORRELL Myhre Ingunn (dibutyltin dilaurate)		ERICSSON Gunilla
EIDE Marcus (DecaBDE, dibutyltin dilaurate)		GEORGIADIS Nikolaos
FOTLAND Tor Oystein (DecaBDE)		HELLSTEN Kati
HOFER Tim (DecaBDE)		HENNIG Philipp
INSTANES Christina (DBTDL)		HONKANEN Jani

JOVER BUSTILLO Vanessa		
KANELLOPOULOU Athanasia		
KARJALAINEN Ari		
KIOKIAS Sotirios		
KIVELÄ Kalle		
KLAUK Anja		
KOKKOLA Leila		
KOSK-BIENKO Joanna		
KOSTIKA Xenia		
LEGZDIPA Ilze		
LOGTMEIJER Christiaan		
LUDBORŽS Arnis		
MARQUEZ-CAMACHO Mercedes		
MAZZOLINI Anna		
MOTTET Denis		
MULLER Gesine		
NICOT Thierry		
NYGREN Jonas		
ORISPÄÄ Katja		
PELTOLA Jukka		
PERAZZOLA Chiara		
REGIL Pablo		
RODRIGUEZ-IGLESIAS Pilar		
ROGGEMAN Maarten		
SADAM Diana		
SIMPSON Peter		
SMILOVICI Simona		
SOSNOWSKI Piotr		
SPJUTH Linda		
STOYANOVA Evgenia		
VAN HAELST Anniek		

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-33 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-33 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-33 meeting

ANNEX IV Administrative issues and information items

1 June 2015
RAC/A/33/2015

Final Agenda
33rd meeting of the Committee for Risk Assessment

1-5 June 2015

ECHA Conference Centre (Annankatu 18, Helsinki)

1 June starts at 9.00
5 June ends at 12.30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/33/2015
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Report from other ECHA bodies and activities

a) Report on RAC 32 action points, written procedures and an update on other ECHA bodies

RAC/33/2015/01
RAC/33/2015/02 (room document)

b) RAC workplan for all processes

For information

c) General RAC procedures
(closed session)

RAC/33/2015/03
(restricted document)
RAC/33/2015/04
RAC/33/2015/05
For discussion/agreement

d) Request from the European Commission under REACH Article 95 regarding NMP

For information

Item 5 – Harmonised classification and labelling (CLH)

5.1 CLH dossiers

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

a) Tefluthrin (ISO): Acute toxicity, STOT SE, Skin corrosion/irritation, Eye damage/irritation, Skin sensitisation, Germ cell mutagenicity, Carcinogenicity, Reproductive toxicity

b) Cyanamide: Acute toxicity, Skin corrosion/irritation, Skin sensitisation

c) Dichlofluanid: Acute toxicity, Skin sensitisation

d) Triadimenol (ISO): Acute toxicity, Skin corrosion/irritation, Eye damage/irritation, STOT RE, Germ cell mutagenicity

e) Terbuthylazine (ISO): Acute toxicity, STOT SE, Skin corrosion/irritation, Eye damage/irritation, Skin sensitisation, Germ cell mutagenicity, Toxicity to reproduction, Aquatic acute toxicity, Aquatic chronic toxicity

f) Salicylic acid: Acute toxicity, Eye damage

g) Quinolin-8-ol; 8-hydroxyquinoline: Acute dermal toxicity, Skin corrosion/irritation, Eye damage/irritation, Aquatic acute and chronic toxicity

h) Fipronil (ISO)

B. Hazard classes for agreement with plenary debate

a) Tefluthrin (ISO)

b) Cyanamide

c) Triadimenol (ISO)

d) Terbutylazine (ISO)

e) Salicylic acid

f) Methylhydrazine

g) Dibutyltin dilaurate

h) Quinolin-8-ol; 8-hydroxyquinoline

i) 2-methyl-1-(4-methylthiophenyl) -2-morpholinopropan-1-one

For discussion/adoption

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

RAC/33/2015/06
(Restricted room document)
For agreement

Item 6 – Restrictions

6.1 General restriction issues

For information

6.2 Restriction Annex XV dossiers

a) Opinion development

1) Isopropylidenediphenol (Bisphenol A) – revised draft opinion

For adoption

2) DecaBDE – revised draft opinion

For adoption

3) Perfluorooctanic acid (PFOA) – first draft opinion

For discussion

4) Methanol – key issues document

For discussion

b) Conformity check - Key Issues Presentation

i. D4/D5

For agreement/for discussion

6.3 Appointment of (co-)Rapporteurs for restriction dossiers

RAC/33/2015/07
(Restricted room document)
For agreement

Item 7 – Authorisation

7.1 General authorisation issues

a) General authorisation issues

For information and discussion

b) Capacity building:

1. DNEL values setting for the reproductive toxicant bis(2-methoxyethyl)ether (diglyme)[3]
2. Carcinogenicity dose-response relationship setting for 1,2-dichloroethane[4]

[3] If not adopted via written procedure

RAC/33/2015/08
RAC/33/2015/09
For discussion and agreement

7.2 Authorisation applications

a) Authorisation application – third version of RAC draft opinion

3. Four uses of trichloroethylene submitted by *DOW Deutschland Anlagengesellschaft mbH* (Trichloroethylene 2a):

   Use 1: Use of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist
   Use 3: Use of tricholoroethylene in packaging
   Use 4: Use of tricholoroethylene in formulation
   Use 5: Use of Trichloroethylene as Extraction Solvent for Bitumen in Asphalt Analysis

4. Two uses of trichloroethylene submitted by *Richard Geiss GmbH* (Trichloroethylene 2b):

   Use 1: Use of Trichloroethylene in formulation
   Use 2: Use of tricholoroethylene in packaging

5. The use of trichloroethylene submitted by *Chimcomplex SA Borzesti* (Trichloroethylene 12):

   Use 1: Industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems

b) Authorisation application – first version of RAC draft opinion

a. Lead chromate 1:

   Use 1: Industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection

For discussion/agreement

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

RAC/33/2015/10
(Restricted room document)

[4] If not adopted via written procedure

For agreement

Item 8 – AOB

Item 9 – Action points and main conclusions of RAC-33

Table with Conclusions and Action points from RAC-33

For adoption

ANNEX II (RAC-33)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-33 meeting.

Document number	Title
RAC/A/33/2015	Final Draft Agenda
RAC/33/2015/01	Report from other ECHA bodies and activities
RAC/33/2015/02 Room document	Administrative document
RAC/33/2015/03 Restricted	Revised general approach for admission of accredited stakeholder organisations to RAC and SEAC
RAC/33/2015/04	Revised Rules of Procedure of the Committee for Risk Assessment
RAC/33/2015/05	Appointment of co-opted Members to RAC and SEAC
RAC/33/2015/06 Restricted room document	Appointment of Rapporteurs for CLH dossiers
RAC/33/2015/07 Restricted room document	Appointment of Rapporteurs for restriction dossiers
RAC/33/2015/08	Capacity building: DNEL values setting for the reproductive toxicant bis(2-mothoxyethyl)ether (diglyme)
RAC/33/2015/09	Capacity building: carcinogenicity dose-response relationship setting for 1,2-dichloroethane (EDC)
RAC/33/2015/10 Restricted room document	Appointment of Rapporteurs for authorisation applications
RAC/33/2015/11	General authorisation issues – TCE conclusions

ANNEX III (RAC-33)

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 RAC 29, 30, 31 and/or 32		
RESTR: Bisphenol A (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Tiina SANTONEN	Being involved in a study on BPA performed by her employer.
RESTR: DecaBDE (ECHA)	Christine BJØRGE	Working for the CA who collaborated with ECHA on the preparation of the dossier.
RESTR: PFOA	Christine BJØRGE	Working for the CA who collaborated with Germany on the preparation of the dossier.
	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
REST: Methanol (FI & PL)	Riitta LEINONEN	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier.
	Boguslaw BARANSKI	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier.
CLH: Tefluthrin (ISO) (DE)	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		substance - no other mitigation measures applied.
	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

New dossiers

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW		
AfA: TCE12	Radu BRANISTEANU	Previous position of MSCA in REACH Committee in favour of a longer sunset date for TCE.
REST: D4/D5	Steve DUNGEY	Working for the CA submitting the dossier; directly involved in the preparation of the dossier, asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR: DecaBDE (ECHA)	Stine HUSA	Working for the CA who collaborated with ECHA on the preparation of the dossier.
RESTR: PFOA	Stine HUSA	Working for the CA who collaborated with ECHA on the preparation of the dossier.
CLH: Cyanamide (DE)	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		in the event of a vote on this substance - no other mitigation measures applied.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Dichlofluanid (UK)	Andrew SMITH	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.
	Steve DUNGEY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Triadimenol (UK)	Andrew SMITH	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.
	Steve DUNGEY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Terbuthylazine (UK)	Andrew SMITH	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.
	Steve DUNGEY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH:Dibutyltin dilaurate (NO)	Christine BJØRGE	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.
	Stine HUSA	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.

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Helsinki, 26 May 2015

RAC/33/2015/02

ROOM DOCUMENT

33RD MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

1 – 5 June 2015

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-32 Action Points

The RAC-32 action points due for RAC-33 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-32	20 May 2015	Adopted

2.2 RAC consultations on dossiers (status by 26 May 2015)

Subject / Document	Deadline	Status / follow-up
CLH: Tefluthrin (ISO) – HH only	24 April 2015	Closed
CLH: 2-methyl-1-(methylthiophenyl)-2-morpholinopropan-1-one	8 May 2015	Closed
CLH: Dibutyltin dilaurate	4 May 2015	Closed
CLH: Fipronil(ISO)	30 April 2015	Closed
CLH: Quinolin-8-ol (ISO), ENV & HH	8 May 2015	Closed
CLH: Cyanamide, ENV & HH	10 May 2015	Closed
CLH: Dichlofluanid (ISO)	30 April 2015	Closed
CLH: Triadimenol (ISO)	8 May 2015	Closed
CLH: Salicylic acid	8 May 2015	Closed
CLH: Terbutylazine (ISO)	8 May 2015	Closed
CLH: Methylhydrazine	24 April 2015	Closed
AfA: TCE2a (ZG508361-36) use 5	17 May 2015	Closed
AfA: Diglyme DNEL (draft note)	18 May 2015	Closed
AfA: EDC dose-response curves (draft note)	27 April 2015	Closed
REST: D4/D5: Conformity of restriction dossier and draft outcome of conformity	25 May 2015	Closed

Subject / Document	Deadline	Status / follow-up
check		
REST: Bisphenol A: 4th draft opinion	4 May 2015	Closed
REST: Methanol: Restriction dossier	10 April 2015	Closed
REST: Methanol: Key issues	22 May 2015	Closed
REST: PFOA: First draft opinion	22 May 2015	Closed
REST: DecaBDE: Revised draft opinion	22 May 2015	Closed

2.3 Other written consultations of RAC (status by 26 May 2015)

Other written consultations	Deadline	Status / follow-up
RAC consultation on the draft minutes of RAC-32	30 April 2015	Closed
RAC and SEAC consultation on specific issues related to the appointment of co-opted Members to RAC and SEAC	3 May 2015	Closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
AfA: Call for expression of interests for co-opted Members to RAC and SEAC	4 June 2015	Ongoing
CLH: Call for expression of interest for rapporteurship	19 – 30 March 2015	Ten dossiers; volunteers for five dossiers appointed via WP
Restriction: Call for expression of interest for rapporteurship for Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP) restriction proposal	30 March - 30 April 2015	Volunteers to be appointed at the plenary or via WP

2.5 Written procedures for appointment of (co-)rapporteurs

Appointment (co-)RAP	For Substance	Deadline	Outcome

Appointment (co-)RAP	For Substance	Deadline	Outcome
CLH: Written procedure for appointing of (co-) rapporteur(s)	▪ Pyroxsulam ▪ 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich; [1] di-''isononyl'' phthalate [2], (DINP) ▪ margosa extract from the kernels of Azadirachta indica extracted with water and further processed with organic solvents	30 March 2015	Closed No comments were received from RAC Members on the recommendation of the Chairman; the RAC (co-)rapporteurs were appointed with tacit agreement.
	▪ disodium 4-amino-6-((4-((4-(2,4-diaminophenyl)azo)phenylsulfamoyl)phenyl)azo)-5-hydroxy-3-((4-nitrophenyl)azo)naphthalene-2,7-disulfonate, Acid Black 210 Na ▪ pyridazine-3,6-diol, maleic hydrazine ▪ flutianil (ISO) ▪ flumioxazin (ISO) ▪ (R)-p-mentha-1,8-diene	17 April 2015	Closed No comments were received from RAC Members on the recommendation of the Chairman; the RAC (co-)rapporteurs were appointed with tacit agreement.
CLH: Written procedure for appointing of (co-) rapporteur(s)	▪ Amisulbrom (ISO) ▪ Spiroxamine (ISO)	17 May 2015	Closed No comments were received from RAC Members on the recommendation of the Chairman; the RAC (co-)rapporteurs were appointed with tacit agreement.

2.6 Other written procedures

Other written procedures	Deadline	Status / follow-

		up
AfA: Adoption of the draft RAC Note Establishing a Reference Dose-Response Relationship for Carcinogenicity of 1,2-dichloroethane (EDC).	18 May 2015	Closed