RAC/M/26/2013
Final
22 November 2013

Minutes of the 26th Meeting of the Committee for Risk Assessment (RAC-26)

10-13 September 2013

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 26th meeting of the Committee for Risk Assessment (RAC). Apologies were received from four members. The participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed after the adoption of the minutes. 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 week's agenda, highlighting some of the more challenging dossiers and pointing out the joint session with the Committee for Socio-Economic Analysis (SEAC) in which general restriction issues, the recommendation of the review period in applications for authorisation, and the first conformity check on an authorisation application would be considered. He informed the Committee that Agenda Item 9 under AOB "*Report from the project on economic valuation of environmental impacts*" would not go ahead at this meeting and that a project report and presentation had been uploaded to RAC CIRCABC.1

The Final Draft Agenda (RAC/A/26/2013) was adopted without further modifications. The agenda and the list of all meeting documents 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 and one adviser declared potential conflicts of interest, or had this declared for them by the Chairman each to specific agenda items. In the event of a vote, these meeting participants were requested to refrain from voting on the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

Two RAC Members questioned the practice of declaring a potential conflict of interest when the dossier is submitted by a Member State Competent Authority or executing agency by whom the member is employed and when this member has not been personally involved in the preparation of the dossier. In their view, excluding the member from voting in case there is a potential conflict of interest declared on any dossier submitted by the respective Competent Authority would not be in line with the request towards the Competent Authorities to provide support to their nominated Committee Members.

The Secretariat responded that the practice of member's declaring a potential conflict of interest in dossiers submitted by the respective Competent Authority where they are employed had been in place for a long time and that these declarations are always listed in the minutes[1]. The Chairman proposed to have a more extensive discussion on the issue at a forthcoming meeting.

4. Report from other ECHA bodies and activities

a) Report on RAC 25 action points, written procedures and other ECHA bodies

The Chairman informed the Committee that all action points of RAC-25 had been completed or were on-going. Three opinions on organic acids still needed to be published.

The Chairman also informed the Committee that the written procedure on harmonised classification of Pyridaben had ended on 23 August. The secretariat received 25 positive votes from the Members having voting rights (with a required quorum of 22 votes) and in addition two supportive responses from the Norwegian Members of the Committee. The Chairman thanked the Members, who responded in the written procedure.

He also informed the Committee that the final minutes of RAC-25 had been adopted via written procedure and were uploaded to CIRCABC and on the ECHA website on 16 August and thanked those Members, who had provided comments.

The Chairman then updated the Committee about the discussion on the functioning of the ECHA Committees that took place at the Management Board meeting on 19-20 June, and the following meeting of the Management Board Working Group on Planning and Reporting which took place on 5 September. The topics discussed were the Committee's increasing workload and the need for more members to take on the role of rapporteur, clearer information to the Competent Authorities on what is expected in terms of support for an active member and the balance between the Committee's efficiency and the use of resources.

The Chairman also reminded the meeting that the regular Report on the activities of other ECHA bodies (RAC/26/2013/01) was available for information.

b) RAC work plan for all processes

The Chairman presented the updated RAC work-plan for the remaining part of 2013, 2014 and the first half of 2015, covering the three processes of restriction, authorisation and harmonised classification and labelling of substances. He emphasised the oncoming workload from REACH authorisations and the current and continuing need for volunteers as rapporteurs for these dossiers.

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[1] **Note from the Secretariat.**

Declarations of interest, including those of Committee members working for MSCAs submitting dossiers were discussed at RAC's first meeting (Jan. 2008) and such interests were considered at that time by the Secretariat to be relevant. Since the 5th meeting (Feb. 2009), Committee members working for MSCAs or Institutes that had prepared dossiers have declared such interests on a regular basis.

In order to better document interest management by the Committee, and in line with a recommendation of the European Court of Auditors, a table of members declaring interests and the following specific description was included in the minutes as from RAC 17/18 onwards: "*…declared potential conflicts of interest to the substance – related discussions due to their participation and/or participation of their institutions in the preparation of the dossiers submitted by the MS-CAs*".

5. Harmonised classification and labelling (CLH)

5.1 CLH dossiers

a) Lead

The Chairman welcomed an expert accompanying the Eurometaux stakeholder observer. He reported that lead had a variety of uses, both for industrial purposes as well as in consumer products. The legal deadline for adoption of the opinion is 22 April 2014.

Metallic lead has currently no harmonised classification in Annex VI to the CLP Regulation. The dossier submitter (Sweden) had proposed to classify the substance, including all physical forms of lead, as Repr. 1A (H360FD), with a specific concentration limit of 0.03%.

The Chairman clarified that the dossier was being tabled for a first discussion at a RAC plenary meeting. He invited the Rapporteurs to present the draft opinion and the comments received during the public consultation and the RAC consultation.

The subsequent discussions focussed on the bioavailability of different forms of lead, justification for classification of metallic lead for fertility and development, on a potential classification for lactation and on the setting of specific concentration limits based on human data.

Where bioavailability is concerned, it was recognised by the Committee that ingestion of metallic lead can elevate blood lead levels in both rodents and humans as stated in the CLH report (e.g. measured elevated blood lead levels after oral ingestion of a piece of metallic charm bracelet containing 99,1 % lead in human) and during public consultation (a study on the absorption of lead particles of different sizes from the gastrointestinal tract of the rat). It was also pointed out that lead oxide is formed on the surface of metallic lead that can become systemically available via hand-to-mouth behaviour. Although the summarised animal studies were conducted with soluble lead acetate, and human epidemiological and case studies often do not report the specific form of lead which patients are exposed to, elevated blood lead levels are clearly associated with adverse effects on fertility or development. RAC agreed that classification into category 1A for fertility and developmental toxicity was warranted. One RAC member reserved the right to express a minority opinion in case the final wording of the justification for category 1A for both hazard classes was not adequately supported.

With regard to lactation, the evidence presented by the Rapporteur was considered sufficient for classification and Lact. (H362) was agreed by the RAC.

Where the setting of specific concentration limits is concerned, the Co-rapporteur presented a rationale and calculation based on an adverse effect level in humans of 100µg/l for development. The method took into account relative absorption of lead from metallic particles compared with lead acetate and distribution in the body. Although calculations could justify a theoretical setting of very low specific concentration limits, the co-Rapporteur proposed the specific concentration limit of 0.03% for developmental effects and no specific concentration limits for fertility and lactation effects. However, some RAC members considered the rationale to be based on many assumptions, and considered that a specific concentration limit should only be set if the available data allow this. An alternative way of setting specific concentration limits based on animal data was suggested by one RAC member. It was recognised though that adequate and reliable animal data were not provided in the CLH report nor were they made available during the public consultation. One RAC member expressed reservations as to the applicability of the specific concentration limit of 0.03% to all forms of lead, and to metallic lead in bulk form in particular. The Eurometaux stakeholder expert offered to provide kinetic models, which might assist in the setting of specific concentration limits.

The Chairman concluded that the discussion on setting specific concentration limits would be rescheduled at the RAC-27 and thanked the Rapporteurs for their presentation of the arguments and the Committee for their participation in the discussions.

b) Dodemorph

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that dodemorph is an active substance used in plant protection products, where it is used in the form of its acetate. The CLH dossier was submitted by the Netherlands. The legal deadline for adoption of the opinion is 17 June 2014.

Dodemorph is already included in Annex VI to the CLP Regulation, where it is classified as Skin Irrit. 2 (H315), Eye Irrit. 2 (H319), STOT SE 3 (H335, respiratory tract irritation), and as Aquatic Chronic 2 (H411). The dossier submitter (The Netherlands) had proposed to remove the current harmonised health hazard classifications, to add Repr. 2 for developmental effects (H361d) and to add Aquatic Acute 1 with an M-factor of 1 and to replace Aquatic Chronic 2 by Aquatic Chronic 1 with an M-factor of 1.

The Chairman noted that the dossier was being tabled for a first discussion at a RAC plenary meeting and invited the Rapporteur to present the draft opinion and the comments received during both the public consultation and the RAC consultation.

The Committee recognised that dodemorph and dodemorph acetate displayed the same toxicological properties while the studies provided in the dossier were actually conducted using dodemorph acetate. Following discussion on which classification would apply in practice, it was concluded that both substances should have the same human health classification for both local and systemic effects. For dodemorph it was therefore decided to allocate the same harmonised classifications as for the acetate, namely to remove the current health hazard classifications from the Annex VI to the CLP Regulation and to add harmonised classifications as Skin Corr. 1C (H314), Skin Sens. 1A (H317), Repr. 2 (H361d), and STOT RE 2 (H373, liver), as well as the supplemental labelling, 'corrosive to the respiratory tract' (EUH071). As to the environmental classification, it was agreed to allocate both Aquatic Acute 1 and Aquatic Chronic 1 with the M-factors of 1 for both aquatic hazard classes.

The Secretariat clarified that dodemorph and dodemorph acetate would have two separate entries in the Annex VI to the CLP Regulation because they have a different classification for the aquatic hazard.

RAC adopted the opinion on dodemorph by consensus. The Chairman thanked the Rapporteur(s) for their presentation of the arguments and the Committee for their participation in the discussions.

c) Dodemorph acetate

The Chairman Referred to the preceding discussion on dodemorph by way of introduction, noting that this CLH dossier for the acetate was also submitted by the Netherlands and that the legal deadline for adoption of the opinion is also 17 June 2014.

A with dodemorph, dodemorph acetate currently has no harmonised classification in Annex VI to the CLP Regulation. The dossier submitter had proposed harmonised classification as Skin Corr. 1 (H314), Skin Sens. 1A (H317), Repr. 2 for developmental effects (H361d) and as Aquatic Chronic 1 (H410) with an M-factor of 1.

The Chairman invited the Rapporteur to present the draft opinion and the comments received during both the public consultation and the RAC consultation.

The Secretariat reminded the Committee that the CLP Regulation currently has no provision for classifying skin corrosion without a sub-categorisation as 1A, 1B or 1C. After some discussion of the available data, which showed that the substance was corrosive to

rabbit skin after a 4 hour exposure period, with no information on shorter exposure periods, RAC agreed to classify dodemorph acetate as Skin Corr. 1C.

Regarding effects on the respiratory tract, RAC concluded on EUH071 as supplemental labelling, as was proposed by the dossier submitter.

With regard to reproductive toxicity, the Committee, in agreement with a range of comments provided during the public consultation, concluded on Repr. 2 (H361d). Discussion centred on the effect on pup viability which occurred mainly during lactation on days 1 to 4. The Rapporteurs noted that they had consulted the original study reports for the two relevant studies and concluded that there was evidence to suggest the possibility that the reduced viability was due to maternal toxicity and therefore the data justified classification as Repr. 2, and not Repr. 1B. The Committee agreed with their proposal.

RAC also agreed to classify dodemorph acetate as STOT RE 2 with the hazard statement specifying effects on the liver (H373, liver), although it had not been included in the proposal by the dossier submitter.

In relation to aquatic toxicity, the RAC confirmed the proposal by the dossier submitter to classify for Aquatic Chronic 1 with an M-factor of 1.

RAC adopted the opinion for dodemorph acetate by consensus. The Chairman thanked the Rapporteur(s) for their presentation of the arguments and the Committee for their participation in the discussions.

d) Phenol, dodecyl-, branched (tetrapropenylphenol (TPP))

The Chairman welcomed a representative of the industry dossier submitter from the United Kingdom. He reported that phenol, dodecyl, branched is a UVCB substance, i.e. a complex mixture of branched alkyl-substituted phenols which is widely used by the chemical industry for the synthesis of polymers from monomers. The legal deadline for adoption of the CLH opinion is 17 June 2014.

Phenol, dodecyl, branched has currently no harmonised classification in Annex VI to the CLP Regulation. The Chairman noted that a harmonised classification would apply to any substance which predominantly contain C12 (branched) alkyl-substituted phenols.

The dossier submitter had proposed to classify the substance for Skin Irrit. 2 (H315), Eye Irrit. 2 (H319), Repr. 2 (H361f), and for Aquatic Acute 1 (H400) with an M-factor of 1, and Aquatic Chronic 1 (H410) with an M-factor of 10.

The Chairman informed the Committee that the dossier was being tabled for the first discussion at the RAC plenary meeting and that another company from France had submitted a CLH dossier for the same substance, proposing classification as Repr. 1B (H360F). To coordinate the evaluation of reproductive toxicity for both dossiers, this endpoint would be considered for both submissions at RAC-27. He indicated that the discussion of the other hazard classes proposed only by the UK dossier submitter would take place at RAC-26.

As to skin corrosion/irritation, some RAC members considered that corrosion could not be excluded since there was a consistent pattern of necrosis in five different studies. Other members argued that the lesions were not described in detail, nor was the observation period in the studies long enough to conclude whether the lesions were reversible or not, and that they would hence be in favour of skin irritation rather than skin corrosion. It was however concluded that the description of the lesions as necrosis by the study director could be relied on and since necrosis is by definition irreversible, RAC proposed to classify the substance as Skin Corr. 1C (H314).

With regard to severe eye damage/eye irritation, RAC agreed with the dossier submitter's proposal to classify for Eye Irrit. 2 (H319). It was recognised, however, that on the basis

of the current CLP guidance, an explicit classification for Eye Irrit. 2 would not be required because of the proposed classification for Skin Corr. 1C.

RAC agreed to the proposal by the dossier submitter on the aquatic hazards, but concluded on an M-factor of 10 for the acute aquatic classification based on the selection of a different key study than the one chosen by the dossier submitter.

For RAC-27, it was agreed that the rapporteurs will include the evaluation of reproductive toxicity in the draft opinion, and circulate the this to the Committee for comments. The Chairman thanked the Rapporteur(s) for their presentation of the arguments and the Committee for their participation in the discussions.

d) Imidazole

The Chairman reported that industry had submitted a dossier for imidazole which indicated that the use of the substance was confidential. The substance has no harmonised classification in the Annex VI to the CLP Regulation. The legal deadline for adoption of the opinion is 18 June 2014.

The dossier submitter proposed to classify Imidazole as Repr. 1B (H360D), Acute Tox. 4 (H302), Skin Corr. 1C (H314) and Eye Dam. 1 (H318). During the public consultation, comments from four Member State Competent Authorities' were received and were addressed in the second draft opinion.

The Chairman stated that all hazard classes proposed in the dossier would be discussed in the meeting and invited the adviser to the Rapporteur to present the draft opinion and the comments received during the public consultation.

RAC agreed to classify Imidazole for Acute Tox. 4 (H302) based on the LD_{50} values in one key study (on 100% Imidazole) and one supporting study (on 95% Imidazole) respectively. Both LD_{50} values were within the range of the appropriate guidance values ($300 < LD_{50} \leq 2000$).

RAC agreed that the reported observations after 1-hour exposure did not meet the definition of a corrosive substance, i.e. no full thickness destruction was seen, whereas after 4-hour exposure the criteria were met, and therefore agreed to classify imidazole as Skin Corr. 1C (H314).

The RAC agreed with the dossier submitter that the criteria for Eye Dam. 1 (H318) were met because the observed effects were not fully reversed by the end of the 8-day observation period. The new draft guidance on the application of the CLP criteria states that once the substance is classified as Skin Corr.1 then serious damage to eyes is implicit and the substance is classified for serious eye damage but there is no need to label as such. However, the current guidance and practice applies no classification for serious eye damage once the substance is classified as Skin Corr. 1 and RAC agreed to follow this until the new guidance is adopted. Accordingly, the RAC agreed not to classify Imidazole for serious eye damage.

The RAC concluded that there was not sufficient data to allow a conclusion on classification for fertility and agreed to classify Imidazole as Repr. 1B (H360D) based on clear foetotoxicity and teratogenic effects in the rat prenatal developmental toxicity study (OECD 414), with only minimal and transient maternal toxicity and no data to suggest that developmental effects were not relevant to human.

The Committee adopted the opinion on Imidazole by consensus. The Chairman thanked the Rapporteur(s) for their presentation of the arguments and the Committee for their participation in the discussions.

e) Spirotetramat

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that spirotetramat is an active substance intended for use as an insecticide on a range of crops. The CLH dossier was submitted by Austria and the legal deadline for adoption of the opinion is 24 March 2014.

Spirotetramat currently has no harmonised classification in the Annex VI to the CLP Regulation. The DS (Austria) had proposed to classify the substance as Skin Sens. 1A (H317), Eye Irrit. 2 (H319), Repr. 2 (H361fd), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with an M-factor of 1 for both aquatic hazard classes.

The Chairman informed that the dossier was being tabled for second discussion at a RAC plenary meeting. He reported that at RAC-25 in June 2013, the Committee had already agreed to classify spirotetramat for skin sensitisation (Skin Sens. 1A), eye irritation (Eye Irrit. 2) and respiratory tract irritation (STOT SE 3). The Committee had also concluded that classification for STOT RE, mutagenicity, carcinogenicity or for physical hazards was not warranted. However, in relation to toxicity to reproduction, and in particular fertility, the RAC had not finalised the discussions, pending the provision of further toxicokinetic information by the expert accompanying the ECPA stakeholder observer.

The Chairman noted that at the present meeting, the discussion on fertility should be continued and that the classification proposal for developmental effects and for the aquatic hazards should be completed. He then invited the Rapporteur to present the draft opinion in relation to these hazards and the proposal for classification, based on the information in the dossier, the comments received during the public consultation and more recently from industry

The subsequent discussions on fertility focused on the question of whether the effects on fertility seen in rats were relevant for humans. Clear effects on fertility were observed in male rats, while in mice similar effects are not observed. The industry representative argued that this is due to toxicokinetic differences between rats (especially male rats) and mice in e.g. the amount of the metabolite which has been identified as the main toxic entity, and in quantitative differences in elimination of this metabolite. The industry representative further argued that based on *in vitro* data using human hepatocytes, the toxicokinetics in humans indicates that the effects seen in rats are not relevant to humans. It was further argued that although according to the *in vitro* data the toxic metabolite (s-enol) is formed in higher amounts in humans compared to rats, the fertility effects seen in rats would not occur, because in humans saturation of the elimination pathway would not be reached due to a more efficient metabolism and elimination.

The discussion in RAC focused on the information and argumentation provided by industry and whether it was convincing enough to raise doubt about the relevance of the effects to humans and whether classification in category 2 instead of category 1B would be more appropriate. Some RAC members argued that they did not find the toxicokinetic data and the argumentation by industry convincing enough and were in favour of category 1B due to the clear effects on male fertility in rats. However, other RAC members thought that the data and the justification provided were sufficiently convincing and did raise doubt about the relevance of the effect to humans and the potential of Spirotetramat to pose a hazard to human reproduction; they considered that Repr. 2 would therefore be more appropriate. After a thorough discussion, a majority of RAC members were in favour of category 2 and it was concluded that the substance should be classified in category 2 for reproductive toxicity in relation to effects on sexual function and fertility.

As to developmental toxicity, after the Rapporteur's presentation of the available data, RAC agreed to classify the substance as category 2. Overall, the reproductive toxicity classification was therefore agreed to be Repr. 2 (H361fd).

With regard to aquatic toxicity, RAC agreed on classification as Aquatic Acute 1 (based on data for the mollusc *Crassostrea virginica* as the most sensitive species tested) and

Aquatic Chronic 1 (based on the surrogate approach) with an M-factor of 1 for both hazard classes.

RAC adopted the opinion on spirotetramat by consensus. The Chairman thanked the Rapporteur(s) for their presentation of the arguments and the Committee for their participation in the discussions.

f) Sulfoxaflor

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that sulfoxaflor was a new insecticide with a novel functional group acting as an agonist to nicotinic acetylcholine receptors of insects. The CLH dossier was submitted by Ireland and in parallel, the active substance is under peer review by EFSA. The legal deadline for adoption of the CLH opinion is 6 August 2014.

Sulfoxaflor currently has no harmonised classification in Annex VI to the CLP Regulation. The dossier submitter had proposed to classify the substance as Acute Tox. 4 (H302), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with an M-factor of 1 for both aquatic hazard classes.

The Chairman noted that the dossier was being tabled for first discussion at a RAC plenary meeting. As the CLH opinion development needed to be aligned with the peer review of sulfoxaflor by EFSA, he asked the Secretariat to update the Committee about the status of the alignment and the next steps. The Secretariat clarified that at RAC-26 all hazards except carcinogenicity and reproductive toxicity, would be discussed. This is due to (i) additional information to be provided by the applicant, as requested by EFSA in accordance with Art. 12(3), and (ii) the outcome of an EFSA expert consultation planned before RAC-27on effects potentially relevant for classification. For these reasons, the consideration of carcinogenicity and reproductive toxicity are foreseen for RAC-27. The Chairman then invited the Rapporteur to present the draft opinion, based on the information in the dossier and the comments received during the public consultation.

RAC agreed to the proposal by the dossier submitter to classify the substance as Acute Tox. 4 (H302), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with an M-factor of 1 for both aquatic hazard classes, in addition agreeing not to classify sulfoxaflor for other health hazards which were reviewed or for physical hazards. The Aquatic Chronic classification was based on a long-term sediment toxicity test, supported by the surrogate approach.

Finally the Chairman announced that the complete draft opinion including an evaluation of carcinogenicity and reproduction would be circulated to the Committee during October 2013 for comments. The Chairman thanked the Rapporteur(s) for their presentation of the arguments and the Committee for their participation in the discussions.

g) 1,2- Epoxybutane

The Chairman reported that the substance is used as an intermediate for the synthesis of other substances and as a monomer in a polymerization process, and that it has currently a harmonised classification for human health hazards and aquatic toxicity in Annex VI to the CLP Regulation. The CLH dossier was submitted by Germany and the legal deadline for the adoption of the opinion is 7 August 2014.

The dossier submitter (Germany) proposed to remove Aquatic Chronic 3 (H412) from the classification of the substance because of new experimental results showing that the substance is readily biodegradable.

The Chairman then invited the Rapporteurs to present the revised draft opinion and the comments received during the public consultation and the RAC consultation.

RAC agreed that the new data show that 1,2-epoxybutane is readily biodegradable. It is also not likely to bioaccumulate. In the absence of valid toxicity data, QSAR data were used to support the evaluation of acute aquatic hazards. This was not possible for the chronic data set as no reliable QSAR data were available, leaving only the surrogate approach. Based on that, RAC agreed with the proposal of the dossier submitter to remove the environmental classification. While QSAR was used to support the poor quality acute data set, it was not considered appropriate to use it to estimate chronic toxicity in this case.

RAC adopted the opinion on 1,2-epoxybutane by consensus. The Chairman thanked the Rapporteur(s) for their presentation of the arguments and the Committee for their participation in the discussions.

h) Anti-coagulant rodenticides – general discussion

i) Chlorophacinone

j) Bromadiolone ketone

k) Difenacoum

l) Difethialone

m) Flocoumafen

n) Warfarin

o) Brodifacoum

p) Coumatetralyl

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and reported that the eight dossiers submitted by eight different dossier submitters (Ireland, Italy, the Netherlands, Sweden, Norway, Denmark, Spain, Finland) would be dealt with in this meeting as a group. The substances belong to a group of anticoagulant rodenticides, i.e. those with an anti-vitamin K mode of action (AVKs) and are used mainly as the active substances in the biocidal products for pest control of rats and mice and other rodents. The legal deadline for the adoption of opinions is 4 September 2014.

Some substances already have a harmonised classification in Annex VI to the CLP Regulation, however only Warfarin is classified for toxicity to reproduction as Repr. 1A (H360D), since it is a recognised human teratogen.

The Chairman noted that this was the first discussion on this group of CLH dossiers and introduced for a proposal as to how to proceed. Before a detailed discussion on classification and labelling of individual substances was held, a number of important issues on the principles, which are common to the group, were identified. They were summarised in a paper on general issues related to the assessment of developmental toxicity of the AVKs, drafted by the Rapporteur (RAC/26/2013/02). More specifically, the aim of the current discussion was to agree on a general approach on how to proceed with the proposals for classification of AVKs for developmental toxicity as well as to have an initial discussion on how to set specific concentration limits for acute toxicity, specific target organ toxicity after repeated exposure and toxicity to reproduction. The Chairman then invited the Rapporteur to present the general issues paper.

The Rapporteur presented the general issues paper summarising the main aspects that needed to be addressed in relation to developmental toxicity before the detailed discussion on individual substances. He provided an overview of the human data available for warfarin and the animal data available for the other substances. The Chairman then presented an overview of the regulatory background incl. CLP classification criteria and weight of the evidence (WoE) approach recommended by the Regulation.

In the subsequent discussion, RAC agreed to consider the AVKs in a detailed, scientific, substance-by-substance analysis with reference to warfarin, taking all available data into account in a WoE approach in accordance with the CLP criteria. The RAC agreed that while read across might be appropriate, it should be secondary as part of the weight of evidence approach.

One RAC member pointed out that not only the anticoagulation effect, which is common to all the substances under discussion, but also other consequences of an antivitamin K mode of action in the foetus should be explored, when discussing the developmental toxicity. Some RAC members expressed the view that in spite of the lack of positive data from animal studies using the conventional developmental toxicity model (without vitamin K supplement), other AVKs than Warfarin may be regarded as potential human teratogens. Human case reports on other anticoagulants such as phenprocoumon (a coumarin related drug) in addition to recent data on similar developmental toxicity findings to warfarin as a consequence of a genetic disorder leading to the same mode of action, would also need to be considered.

The ECPA expert appreciated the general issues paper drafted by the Rapporteur, and with regard to development, provided further details on the different periods of nasal development between humans and rats since post-natal exposure is needed in order to show a shortened snout in rats while nasal hypoplasia occur after exposure to warfarin in the first trimester in humans. The expert claimed that a study by Kubaszky *et al* (2009) on warfarin showed that the standard developmental toxicity study in the rat can appropriately reflect the developmental toxic effects of the human teratogen.

RAC agreed with the dossier submitter's proposal not to re-open the already existing harmonised classification for developmental toxicity of Warfarin (Cat. 1A; H360D).

Following an introductory presentation from the Secretariat, a brief discussion was held on setting of specific concentration limits for Warfarin based on the DS's proposal. It was mentioned that ideally, human data should be compared with human cut-off values in order to estimate the potency for developmental toxicity. However, in the absence of human cut off values, RAC preliminarily agreed to compare human data with the cut-off values based on animal data, as a starting point.

RAC agreed on the appointment of two Members as additional Rapporteurs, owing to the resignation of one of the previous Rapporteurs.

The Chairman concluded that the draft opinions on the eight individual dossiers would be rescheduled at RAC-27. The Chairman thanked the Rapporteur(s) for their presentation of the arguments and the Committee for their participation in the discussions.

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

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

5.3 General and procedural CLH issues

Skin corrosion

In relation to the skin corrosion hazard class, the Secretariat informed the Committee that currently the CLP Regulation does not allow for classification without a sub-categorisation as either of 1A, 1B or 1C. The Secretariat reported that this option would only be available once the eighth ATP to the CLP Regulation was adopted, implementing the fifth revision of the UN GHS. Therefore, the Committee would need to decide for each substance classified as a skin corrosive on which sub-category to allocate.

The Secretariat informed the Committee that in two opinions adopted by the RAC in the recent past, namely for acrolein and for dimethyltin dichloride, a sub-category had not been allocated. Therefore, ECHA in cooperation with the Rapporteur proposed to draft an amendment to both opinions justifying sub-category 1B (as default) for both substances. The amendments would be submitted for the approval of the RAC via written procedure.

Handling of late information

The Secretariat presented the "Lines to take on information arriving after public consultation" summarising main aspects of handling information provided after the public consultation.

6. Restriction

6.1 General restriction issues (joint RAC/SEAC session)

The Committees were provided with an update on intended restriction dossiers. The Secretariat had informed the Committees earlier about cadmium and its compounds in plastics and paints, chrysotile asbestos in industrial diaphragms (both to be submitted by ECHA at the request of the Commission, with an expected submission date of 17 January 2014) and bisphenol-A in thermal paper (by France, with an expected submission date of 17 January 2014)., The Committee was informed that the following new intentions have been included into the Registry of Intentions:

- Cadmium and its compounds in artist paints. This intention was submitted by Sweden and the expected submission date is also 17 January 2014. The scope of this intention has recently been modified, so that it does not include the use of cadmium and its compounds in pigments for enamel, ceramics and glasses.
- The Commission has requested ECHA to prepare a proposal for a restriction on the manufacture, use and placing on the market of bis(pentabromophenyl) ether (DecaBDE) and of mixtures and articles containing it. The expected submission date is 1 August 2014. The call for rapporteurs for this dossier will be launched shortly after SEAC 20 and RAC-26.

6.2 Restriction Annex XV dossiers

a) Lead in consumer articles – second version of the draft opinion

The Chairman welcomed the dossier submitter's representative from the Swedish Member State Competent Authority who followed the discussions remotely as an observer.

He then introduced the state of play with the development of the opinion for the proposed restriction, on the placing on the market of lead and its compounds in articles intended for consumer use. He restated that the proposal is targeted at consumer articles that could be placed in the mouth by children, considering that children are the most vulnerable group when exposed to lead. Lead compounds (but not elemental lead) are classified as toxic to reproduction, category 1 and 2. Lead, however, has been shown to be a non-threshold substance for neurotoxic and neurodevelopmental effects. The main route through which small children (between ages of 6 and 36 months) are exposed to lead from consumer articles is by mouthing. The key negative effect from such exposure is the impairment of the development of the Central Nervous System. This health risk cannot be adequately controlled with the existing EU legislative measures.

The second version of the RAC draft opinion was provided to the Committee on 16 August 2013 together with the Rapporteurs' responses to the comments by the RAC members on the first version of the opinion (ORCOM), and the responses by the dossier submitter and the Rapporteurs to early comments from the public consultation. The dossier submitter, as well as the RAC and SEAC (Co-)rapporteurs provided answers to the draft Forum advice

which was submitted on 7 June 2013. The updated background document was delivered by the dossier submitter in early July 2013 and the updates to the background document were included by the Secretariat on 16 August 2013.

Following this introduction, the RAC Rapporteurs were invited to present the second version of the draft RAC opinion, with a focus on mouthing times, a proposed migration/content limit for brass alloys as well as the proposed derogations.

The RAC discussed and supported the proposal by the Rapporteurs for the **realistic daily mouthing time** of 20 minutes for all age groups. Furthermore, RAC agreed on a **realistic worst case mouthing time** (based on the 95-percentile) of one hour for all age groups. More specifically, RAC was provided with the calculations based on the data contained in the four studies used (Juberg et al (2001), DTI (2002), RIVM/Groot (1998) and Greene (2002)) in support of these values, for the category of articles most representative of the articles intended to be restricted.

It was noted that previously, RAC had supported different mouthing times in its opinion on the ECHA assessment on DINP and DIDP in toys and childcare articles and that the reasons for this difference should be clearly explained (same studies, but different category of articles chosen because for DINP/DIDP the restriction concerned toys and childcare articles) in the opinion. One RAC member suggested that as the issue of mouthing time keeps coming up in restriction dossiers the RAC should try to consolidate its view on mouthing times applicable to future dossiers.

In the context of assessing comments received during the public consultation, RAC also discussed the relationship between lead content and migration rate. A derogation for brass alloys with a restriction limit of 1.7% rather than 0.05% had been requested by industry during the public consultation based on additional migration data which was provided to support the request. The RAC Rapporteurs provided the Committee with an evaluation of lead migration rates of three sample alloys with different lead contents. Since the average lead concentration at which the release rate was 0.05 µg/h x cm^2 per hour was 0.47%, they proposed a tolerable lead content in such material of 0.5%.

Migration studies and other relevant information received during the public consultation confirm that lead ions migrate from both metal and polymeric material. It was however concluded that the limited data available do not allow the setting of a generic migration rate for all materials, nor a link with a generic content limit. In the absence of further information, RAC therefore considered a concentration limit of 0.05% to be protective for all materials concerned in the present restriction, in line with the DS proposal and with the lead in jewellery restriction.

RAC then proceeded to discuss the various derogations proposed from the point of view of assessing the risks. One proposal by the dossier submitter to derogate locks was supported by the RAC, however, they considered that there was a potential risk from keys and padlocks. For musical instruments, the dossier submitter had proposed that a derogation is no longer considered necessary as they are unlikely to be accessible to children. RAC concluded that considering normal use or foreseeable misuse they would fall outside the scope of the proposed restriction.

RAC concluded in response to a further derogation proposed by the dossier submitter that second hand articles in general terms would have a similar risk profile to new articles and should therefore not be considered as being different. Likewise, articles made of recycled material were considered to pose similar risks to articles made of virgin materials.

When addressing the proposals for exemptions received so far during the public consultation (closing on 21 September 2013), RAC considered them all in the context of the possibility for mouthing taking place, focusing on the size of the articles/article groups and their accessibility. RAC also assessed the possibility for children to come into contact with the various article groups during normal or a foreseeable misuse i.e. for those consumer articles not directly targeted at children.

In addition, RAC also discussed the issue of coated articles, and considered that the potential risk depends on the effectiveness of the coating (in reference to the agreed migration limit). RAC also considered some risk associated with outdoor articles (such as garden hoses lying on the ground etc.), since foreseeable misuse can be expected.

In addition, RAC agreed on the following derogations proposed for the dossier: locks, musical instruments, ball pen tips. However adult shoe soles, diving weights, ammunition, fishing sinkers and weights, fixed furnishing, screws and internal hinge mechanisms were not discussed due to lack of time and the Chairman noted that they would be consulted on in the 3rd version of the opinion and the conclusion reflected in the fourth version.

In conclusion, the Rapporteurs were invited to take comments received into account in the third version of the draft opinion which is due by the end of September 2013. Furthermore, the Rapporteurs together with the Secretariat were invited to update the background document to bring it into line with the opinion. The Secretariat was then requested to arrange a written consultation with the RAC prior to the 27th meeting in December, 2013 on the remaining list of derogations. The Chairman thanked the Rapporteur(s) for their presentation of the arguments and the Committee for their participation in the discussions.

b) 1-Methylpyrrolidin-2-one (NMP) - outcome of the conformity check

The Chairman welcomed the dossier submitter's representative from the Netherlands (via WebEx).

The Chairman reminded the Committee that the restriction dossier on 1-Methyl-2-pyrrolidone (NMP) was first submitted to ECHA in April 2013. In June this year, RAC concluded that the submitted dossier did not conform to the Annex XV requirements as it did not present sufficient information to allow an independent assessment of the hazards, the toxicity studies being described quite briefly in the report. SEAC considered the dossier to be in conformity. The Netherlands resubmitted their proposal on 9 August 2013 and the conformity check in RAC and SEAC was launched on 15 August.

The representative of the dossier submitter then presented the main changes to the revised proposal. A restriction on the manufacture and use of NMP by professional and industrial workers is proposed. NMP may only be manufactured and used, if the exposure (as an 8-hr TWA) will remain below 5 mg/m³. Peak exposures (15 min. STEL) must also remain below 10 mg/m³. Furthermore, NMP may only be manufactured and used, if dermal exposure is avoided by the use of preventive measures. NMP is classified as a skin, eye and possible respiratory irritant but also is classified as a toxic to reproduction in category 1B, based on developmental toxicity. The dossier explains how data from animal studies provide a concern that the exposure of pregnant women to sufficiently high levels of NMP may result in reduced birth weight of the newborns or stillbirth. The aim of the restriction proposal is therefore to control the risks resulting from the exposure of expecting mothers. The dossier argues that the risks resulting from the exposure of pregnant women to the substance cannot be adequately controlled with legislative provisions currently in place in EU.

The RAC Rapporteur presented the outcome of the RAC conformity check and recommended that the dossier should be considered in conformity. He explained that the dossier now contains quantitative information on developmental toxicity studies, relevant to the derivation of the DNEL, which was previously missing from the report and was the main reason for non-conformity from the RAC standpoint.

The Commission representative noted the use of a DNEL in this case, effectively as a binding Occupational Exposure Limit (OEL).

RAC agreed that the NMP dossier conforms to the requirements of Annex XV and the Chairman then informed the participants that following the conclusion of SEAC on conformity, the Secretariat would communicate the results of the conformity check and

recommendations to the dossier submitter. The Chairman thanked the Rapporteur(s) for their presentation of the arguments and the Committee for their participation in the discussions.

c) Nonyl phenol – outcome of the conformity check

The Chairman welcomed the SEAC Rapporteur and the dossier submitter representatives; the latter followed the discussion remotely via WebEx.

The Chairman reminded the Committee that the restriction dossier on nonylphenol (NP) and nonylphenol ethoxylates (NPE) was first submitted by Sweden to ECHA in August 2012. In September 2012, both RAC and SEAC concluded that the dossier did not conform to the requirements of Annex XV. The dossier submitter resubmitted their proposal in November 2012. In March this year, RAC considered the dossier to be in conformity while SEAC again concluded that the dossier was not in conformity. Sweden again submitted their dossier in July 2013 as a new restriction proposal and the conformity check was launched in RAC and SEAC on 15 August.

The representative of the dossier submitter provided an introductory presentation on the proposal. The Annex XV dossier proposes a restriction on the placing on the market of NP and NPE in textile clothing, fabric accessories and interior textile articles that can be washed in water, if they contain these substances alone or in combination in concentrations equal or higher than 100 mg/kg textile. The RAC Rapporteurs presented the outcome of the conformity check to the Committee and again recommended that the dossier be considered in conformity.

The Commission observer asked for clarification of the recommendation of the RAC Rapporteurs under question B5 of the Recommendations document, where it was noted that the risk characterisation ratios indicate a risk from NP for the marine environment and for certain countries also to the freshwater compartment, and that further monitoring data might change this picture. The Rapporteurs replied that there is no explanation in the dossier on what this monitoring data actually represents, adding that they were aware that more monitoring data may be available. One participant asked whether linear NP is also included in the restriction, to which the rapporteurs responded that it is.

RAC again agreed that the dossier conforms to the requirements of the Annex XV to the REACH Regulation. The Chairman thanked the Rapporteur(s) for their presentation of the arguments and the Committee for their participation in the discussions.

6.3 Appointment of (co-) rapporteurs for restriction dossiers

The Secretariat presented the recommendation of the Chairman for the pools of Rapporteurs for the restriction dossiers on Cadmium and its compounds in artist paints (to be submitted by Sweden), and bisphenol-A (by France) as outlined in the meeting document RAC/26/2013/05 CONFIDENTIAL. RAC took note on the pools for (Co-)rapporteurs as proposed in the recommendation.

The Chairman then informed the meeting that as four restriction dossiers are expected to be submitted in January 2014, the agreement on the recommendation of the Chairman for the appointment of the (Co-)rapporteurs for these restriction dossiers will be arranged via written procedure before the December meeting.

Furthermore, RAC was informed that shortly after the RAC-26 meeting, the Secretariat will launch a call for the appointment of (Co-)rapporteurs for the restriction dossier on Bis(pentabromphenyl) ether (DecaBDE).

7. Authorisation

7.1 Authorisation application on phthalates – outcome of the conformity check and introductory presentation on the application

The Chairman provided an introductory presentation, recalling some key aspects concerning the processing of applications for authorisation, i.e. confidentiality rules, dissemination of confidential documents, stakeholders in an observed (open) session, establishment of conformity, questions from the Committees to the applicant and the Committee's role in evaluating the application.

One stakeholder observer suggested making the presentation of the Chairman available on the ECHA website. Another Stakeholder observer asked for clarification on how the Secretariat decides on the confidentiality classification of the information being considered. The Secretariat reassured them that the general transparency policy of ECHA will be followed, noting that a large amount of the information is made available for the public consultation process in order to make it meaningful. The confidential information in the applications for authorisation is necessary for the opinion making but not necessarily for discussions in the plenary. However, if the confidential content needs to be discussed, this will be done in the non-observed (closed) session.

The Chairman welcomed the RAC and SEAC Rapporteurs for the first application for authorisation and reminded the Committees that this application concerned the use of DEHP in the processing of a stop-off formulation containing the substance during the diffusion bonding and manufacture of aero-engine fan blades. The public consultation and also the Committees consultation were launched on 14 August. He mentioned that the discussion on the conformity check would take place in RAC and SEAC separately and then gave the floor to the RAC Rapporteurs to present the first application for authorisation. Following these presentations, the Chairman then gave the floor to the SEAC rapporteur for his presentation on the socio-economic aspects of the first application for authorisation.

For better understanding of the use of the substance, two RAC Members suggested to request the applicant to submit a video clip which demonstrated the particular use. The Secretariat responded that the first Dialogue and the Trialogue are designed for the purpose of providing this type of information and RAC Members may take part in the meetings, if they so desire. The Rapporteur, however, noted that visualisation of the exposure would be beneficial to the understanding of each case. The Chairman noted the request by the two Members and its support by the Rapporteur.

In the separate RAC session which followed, the Rapporteurs presented the draft Conformity Report, acknowledging that the application for authorisation can be considered in conformity with the requirements of the REACH Regulation. They also reported on some of their findings in the exposure calculations and risk assessment which could be relevant for the formulation of the draft Opinion of RAC. The Rapporteurs will formulate a set of questions to the applicant for further clarifications, which will be addressed at a later stage during the development of the RAC Opinion.

RAC agreed on the conformity of the first application for authorisation. The Secretariat will upload the Conformity Report to the non-confidential part of CIRCABC and will send it to the applicant. The Chairman thanked the Rapporteurs for their presentation of the arguments and the Committee for their participation in the discussions.

7.2 Recommendation of the review period in applications for authorisation

In the joint RAC/SEAC session the Secretariat presented a revised note on the Committees' recommendation of the review period in applications for authorisation. The overall aim is to build an efficient opinion making process and to achieve consistent and transparent opinions. Following the discussion at the RAC-25 and SEAC-19, the Commission had provided comments which proposed a "normal" duration of the review period of seven years, a "long" duration of 12 years and the possibility of a shorter duration (without specifying the number of years). The review period could also be extended under exceptional circumstances.

Several members agreed with the general idea of the proposed review period as a starting point when considering each application. They underlined that this would be a learning process for both Committees and there would be a need for a case by case approach but that a clear indication as to where to begin such considerations would be useful. Some were of the opinion that the review period is a policy issue and the scientific Committees are not the correct bodies to make such decisions. The secretariat pointed out that the Committees, in particular SEAC, would be the only body in possession of appropriate information on this issue to be able to advise the Commission and that this was therefore a scientific and technical issue within the Committees mandate. Some members thought that the proposed timing did not adequately reflect the normal range of investment cycles of industry; others thought that it did.

The proposed approach was thought to be balanced and was generally supported by the stakeholders representing industry associations. Other stakeholders representing NGOs were of the opinion that the normal review period is too long, considering that substances have been on the candidate list already for a long time and their use is still possible until the sunset date.

Given that the discussion on RAC related issues were very different from those related to SEAC, the Chairman thanked the members of the joint session for a very productive debate and concluded that the Committees would continue to a conclusion on the revised note (which was agreed to be a SEAC-document only) in separate sessions. In the subsequent discussion, RAC agreed to the following sentence in the note on its role/remit: "Procedurally, RAC would provide SEAC with its opinion on the remaining risk and – as appropriate – on the risks from possible alternatives as well as any considerations to be taken into account by SEAC in setting the length of the review period."

7.3 .Capacity building

a. DNEL setting (BBP)

The ECHA Secretariat presented a document on establishing reference DNELs for benzyl butyl phthalate (BBP) and informed the Committee that the DNEL for BBP is based on an oral 2-generation study in rat (Tyl et al., 2004) with a NOAEL of 50 mg/kg body weight per day and on the RAC conclusion that reduced anogenital distance in male rats was the most sensitive endpoint. In the commenting round, 5 Members and 1 stakeholder organisation provided comments. The RAC agreed on the document setting the reference DNEL values for BBP and the Secretariat will upload it on the ECHA website.

b. ECHA project on carcinogenicity dose-response analysis of Cr(VI)- and As-containing substances

The Chairman welcomed the invited expert representing the contractor carrying out the ECHA sponsored project entitled: "*Services to support the assessment of remaining cancer risks related to the use of chromium- and arsenic-containing substances in Applications for*

Authorisation" and asked him to present a progress report and the preliminary findings of the project.

The RAC Members acknowledged the usefulness and importance of the project and made several recommendations for the final report, including:

- more details to justify the threshold values and the importance of the information on the dose-response during setting of those values,
- whether large particles of Cr cause gastro-intestinal cancer,
- the relationship between the frequency of the observed hyperplasia and the frequency of the cancer as well as information about the spontaneous occurrence of the cancer in the population
- clarity of the description of the relevant toxic entity of arsenic for each substance; i.e. is "As" meant to represent elemental arsenic or the ion, and if it is the ion, which valence applies?

The Secretariat then informed the RAC about the plans for completion of the project and that the outcome would be scheduled for discussion and possible agreement by the RAC at its 27th and/or 28th meetings in December 2013 and March 2014.

7.4 Appointment of (co-)rapporteurs for authorisation applications

During the plenary meeting the Committee members expressed their interest by applying to the pool of Rapporteurs and by indicating the absence of conflict of interest. The pool of Rapporteurs as outlined in the amended confidential room document RAC/26/2013/08 Rev.1 had been agreed by the plenary without discussion.

8. AOB

No any other business items have been discussed at the RAC plenary meeting.

13 September 2013

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 26, 10-13 September 2013

(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/26/2013**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-26 minutes.
4. Report from other ECHA bodies and activities	
4a. Report on other ECHA bodies **SECR** presented document **RAC/26/2013/01.** containing the reports from MB-30 (19-20 June), SEAC-19 (5-6 June 2013), MSC-30 (11-14 June 2013), BPC-2 (May 29-30 May 2013), Forum-15 (18 - 20 June 2013 and its working groups.	**SECR** to upload the document to the CIRCABC non-confidential website.
4b. RAC work plan for all processes **SECR** presented update on the 2013-2014 work plan for RAC covering Classification and Labelling, Restriction and Authorisation processes.	**SECR** to upload the presentation to non-confidential folder of the RAC-26 meeting on CIRCABC.
5. Harmonised classification and labelling (CLH)	
5.1.a) Lead	
RAC agreed on the classification and labelling for the hazard classes as indicated in bold in Table 2 below. Discussions on specific concentrations limits will be continued to RAC-27. [Repr. 1A (H360FD); Lact. (H362)]	**Rapporteurs** to revise the opinion in accordance with the discussions in RAC. **SECR** to launch RAC consultation on the revised document. **Rapporteurs** to accommodate any changes to the opinion following RAC consultation in time before RAC-27.
5.1.b) Dodemorph	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Corr. 1C; EUH071; Skin Sens. 1A; STOT RE 2 (liver); Repr. 2 (H361d); Aquatic Acute 1 and Chronic 1; M=1 both]	**Rapporteurs** to revise the opinion in accordance with the discussions in RAC and to provide it to the SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

5.1.c) Dodemorph acetate	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in Table 1 below. [Skin Corr. 1C; EUH071; Skin Sens. 1A; STOT RE 2 (liver); Repr. 2 (H361d); Aquatic Chronic 1; M=1]	**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 to publish it on the ECHA website.
5.1.d) Phenol, dodecyl-, branched (SI submission)	
RAC agreed on the classification and labelling for the hazard classes as indicated in bold in Table 2 below. [Skin Corr. 1C; Aquatic Acute 1 and Chronic 1; M=10 both] Discussions on reproductive toxicity will be postponed to RAC-27.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to include an evaluation for reproductive toxicity. **SECR** to launch RAC consultation on the revised document. **Rapporteurs** to accommodate any changes to the opinion following RAC consultation in time before RAC-27.
5.1.e) Imidazole	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B (H360D), Acute Tox. 4 (H302); Skin Corr. 1C]	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur if necessary. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1.f) Spirotetramat	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [classifications agreed at RAC-26: Repr. 2 (H361fd); Aquatic Acute 1 and Chronic 1; M=1 both]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to the SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1.g) Sulfoxaflor	
RAC agreed on the classification and labelling for the hazard classes as indicated in bold in Table 2 below. [Acute Tox. 4 (H302); Acute Aquatic 1 and Chronic 1; M=1 both] Discussions on carcinogenicity and reproductive toxicity will take place at RAC-27.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to include an evaluation for carcinogenicity and reproductive toxicity. **SECR** to launch RAC consultation on the revised document. **Rapporteurs** to accommodate any changes to the opinion following RAC consultation in time before RAC-27.

5.1.h) 1.2 Epoxybutane	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Removal of classification Aquatic Chronic 3 (CLP) and R52-53 (DSD)] [please add the adopted C&L – to be consistent with other action points]	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1.i) Anti-coagulant rodenticides	
RAC Rapporteur presented the general issues paper summarising some important issues of principle related to developmental toxicity. RAC agreed upon the approach for classification of developmental toxicity of anticoagulant rodenticides by taking a detailed analysis on substance-by-substance basis looking at all data available and using the WoE approach. RAC agreed to use human data as the basis for calculating SCLs for Repro for warfarin as a starting point.	**Rapporteurs** to prepare the draft opinions for each AVK dossier reflecting the outcome of the discussion and forward it to ECHA. **SECR** to launch the RAC consultation on 8 AVKs draft opinions ahead of the detailed discussion at RAC 27.
5.2 Appointment of RAC (co-)rapporteurs for CLH dossiers	
Call for expression of interest of (co-) rapporteur volunteerships for CLH dossiers listed in document **RAC/26/2013/02 (CONFIDENTIAL room document)**.	**SECR** to upload the list of appointed (co-)rapporteurs to CIRCABC confidential.
5.3 General and procedural CLH issues	
SECR presented for the information of RAC 'Lines for late information' paper summarising main aspects of handling information provided after the PC.	
6. Restrictions	
6.2 Restriction Annex XV dossiers	
6.2a. Lead in consumer articles – 2nd version of the RAC draft opinion	
RAC Rapporteurs presented the second version of the RAC draft opinion.	**Rapporteurs** to take RAC discussion into account in the third version of the draft opinion (by end of September 2013). **Rapporteurs** in cooperation with the Secretariat to update the Background document to be in line with the RAC draft opinion. **SECR** to arrange a written consultation on the remaining list of derogations (after the end of public consultation).

6.2b. 1-Methylpyrrolidin-2-one (NMP) - outcome of the conformity check	
RAC agreed that the dossier conforms to the Annex XV requirements and took note of the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC. **SECR** to inform the Dossier Submitter on the outcome of the conformity check.
6.2c. Nonylphenol - outcome of the conformity check	
RAC agreed that the dossier conforms to the Annex XV requirements and took note of the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC. **SECR** to inform the Dossier Submitter on the outcome of the conformity check.
6.3 Appointment of (co-)rapporteurs for restriction dossiers	
RAC took note of the pool of (co-)rapporteurs in line with the room document **RAC/26/2013/05 CONFIDENTIAL**).	SECR to organise the written procedure for the agreement on the appointment of (co-)rapporteurs for the four restriction dossiers to be submitted to ECHA in January 2014 (before December 2013 plenary).
7. Authorisation	
7.1 Authorisation application on phtahalates – outcome of the conformity check and introductory presentation on the application	
Co-Rapporteurs presented the first DEHP application for authorisation and the draft conformity report. RAC agreed on the conformity of the application for authorisation.	**SECR** to upload the adopted Conformity Report for the first application for authorisation on CIRCA BC. **SECR** to send the updated Conformity Report to the Applicant.
7.2 Recommendation of the review period in applications for authorisation (document RAC/26/2013/06)	
RAC discussed the recommendation for setting the review period. **RAC** agreed on its role in the setting of the review period.	**SECR** to inform SEAC and allow them to include relevant information on RAC responsibilities in the SEAC document. **SECR** to include text in the RAC 26 minutes.
7.3 Capacity building	
7.3a) DNEL setting (BBP) (document RAC/26/2013/07)	
RAC discussed and agreed the document setting the reference DNEL values for benzyl butyl phthalate (BBP).	**SECR** to upload the document on ECHA website.

7.4 Appointment of (co-) Rapporteurs for authorisation applications (closed session) (document RAC/26/2013/08 CONFIDENTIAL)	
RAC agreed on the pool of rapporteurs for the applications for authorisation.	**SECR** to upload the document on confidential folder on CIRCA BC.
9. AOB	
9a) Report from the project on economic evaluation of environmental impacts	
10. Action points and main conclusions of RAC-26	
	SECR to upload the adopted action points to CIRCABC.

Table 1. Adopted by RAC proposed new or revised classification in Annex VI, CLP and DSD

1. Spirotetramat

Classification and labelling in accordance with the CLP Regulation

	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	-	-	-	-	-	-	-	-	-	-	-
Dossier submitters proposal		spirotetramat (ISO)	-	203313-25-1	Repr. 2 Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H361fd H319 H317 H400 H410	GHS08 GHS07 GHS09 Wng	H361fd H319 H317 H410	-	 M = 1 M = 1	-
RAC opinion	607-711-00-0	spirotetramat (ISO); (5s,8s)-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate	-	203313-25-1	Repr. 2 STOT SE 3 Eye Irrit. 2 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H361fd H335 H319 H317 H400 H410	GHS08 GHS07 GHS09 Wng	H361fd H335 H319 H317 H410	-	 M = 1 M = 1	-
Resulting Annex VI entry if agreed by COM	607-711-00-0	spirotetramat (ISO); (5s,8s)-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate	-	203313-25-1	Repr. 2 STOT SE 3 Eye Irrit. 2 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H361fd H335 H319 H317 H400 H410	GHS08 GHS07 GHS09 Wng	H361fd H335 H319 H317 H410	-	 M = 1 M = 1	-

Classification and labelling in accordance with DSD

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	-	-	-	-	-	-	-	-
Dossier submitters proposal		spirotetramat (ISO)	-	203313-25-1	Repr. Cat. 3; R62 – 63 Xi; R36 R43 N; R50-53	Xn; Xi; N R: 36-43-50/53-62-63 S: 2, 13, 20/21. 24/25, 27/28, 36/37/39, 56, 66, 60. 61	-	-
RAC opinion	607-711-00-0	spirotetramat (ISO); (5s,8s)-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate	-	203313-25-1	Repr. Cat. 3; R62-63 Xi; R36/37 R43 N; R50-53	Xn; N R: 36/37-43-50/53-62-63 S: (2-)36/37-46-60-61	Xi; R43: C ≥ 0.1% N; R50-53: C ≥ 25% N; R51-53: 2,5% ≤ C < 25% R52-53: 0.25% ≤ C < 2,5%	-
Resulting Annex VI entry if agreed by COM	607-711-00-0	spirotetramat (ISO); (5s,8s)-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate	-	203313-25-1	Repr. Cat. 3; R62-63 Xi; R36/37 R43 N; R50-53	Xn; N R: 36/37-43-50/53-62-63 S: (2-)36/37-46-60-61	Xi; R43: C ≥ 0.1% N; R50-53: C ≥ 25% N; R51-53: 2,5% ≤ C < 25% R52-53: 0.25% ≤ C < 2,5%	-

2. Sulfoxaflor

Classification and labelling in accordance with the CLP Regulation

	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	-	-	-	-	-	-	-	-	-	-	-
Dossier submitters proposal		sulfoxaflor (ISO); [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ6-sulfanylidene]cyanamide	-	946578-00-3	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410	-	 M=1 M=1	-
RAC opinion		sulfoxaflor (ISO); [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ6-sulfanylidene]cyanamide	-	946578-00-3	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410	-	M=1 M=1	-
Resulting Annex VI entry if agreed by COM		sulfoxaflor (ISO); [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ6-sulfanylidene]cyanamide	-	946578-00-3	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410	-	M=1 M=1	-

Classification and labelling in accordance with DSD

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	-	-	-	-	-	-	-	-
Dossier submitters proposal		sulfoxaflor (ISO); [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ6-sulfanylidene]cyanamide	-	946578-00-3	Xn; R22 N; R50-53	Xn; N R: 22-50/53 S: tbd	N; R50/53: C ≥ 25%; N; R51/53: 2.5% ≤ C < 25%; R52/53: 0.25% ≤ C < 2.5%	-
RAC opinion		sulfoxaflor (ISO); [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ6-sulfanylidene]cyanamide	-	946578-00-3	Xn; R22 N; R50-53	Xn; N R: 22-50/53 S: tbd	N; R50/53: C ≥ 25%; N; R51/53: 2.5% ≤ C < 25%; R52/53: 0.25% ≤ C < 2.5%	-
Resulting Annex VI entry if agreed by COM		sulfoxaflor (ISO); [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ6-sulfanylidene]cyanamide	-	946578-00-3	Xn; R22 N; R50-53	Xn; N R: 22-50/53 S: tbd	N; R50/53: C ≥ 25%; N; R51/53: 2.5% ≤ C < 25%; R52/53: 0.25% ≤ C < 2.5%	-

3. Lead

Classification and labelling in accordance with the CLP Regulation

	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	-	-	-	-	-	-	-	-	-	-	-
Dossier submitters proposal		lead	231-100-4	7439-92-1	Repr. 1A	H360DF	GHS08 Dgr	H360DF	-	Repr. 1A; H360DF: C ≥ 0.03 %	-
RAC opinion		lead	231-100-4	7439-92-1	Repr. 1A Lact.	H360DF H362	GHS08 Dgr	H360DF H362	-	Repr. 1A; H360D: C ≥ 0.03 %	-
Resulting Annex VI entry if agreed by COM		lead	231-100-4	7439-92-1	Repr. 1A Lact.	H360DF H362	GHS08 Dgr	H360DF H362	-	Repr. 1A; H360D: C ≥ 0.03 %	-

Classification and labelling in accordance with DSD

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	-	-	-	-	-	-	-	-
Dossier submitters proposal		lead	231-100-4	7439-92-1	Repr. Cat. 1; R60-61	T R: 60-61 S: (1/2-)13-35-45-53	Repr. Cat. 1; R60-61: C ≥ 0.03 %	-
RAC opinion		lead	231-100-4	7439-92-1	Repr. Cat. 1; R60-61 R64	T R: 60-61-64 S: (1/2-)13-35-36/37-45-53	Repr. Cat. 1; R61: C ≥ 0.03 %	-
Resulting Annex VI entry if agreed by COM		lead	231-100-4	7439-92-1	Repr. Cat. 1; R60-61 R64	T R: 60-61-64 S: (1/2-)13-35-36/37-45-53	Repr. Cat. 1; R61: C ≥ 0.03 %	-

4. Dodemorph

Classification and labelling in accordance with the CLP Regulation

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-057-00-7	dodemorph (ISO); 4-cyclododecyl-2,6-dimethylmorpholine	216-474-9	1593-77-7	Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Aquatic Chronic 2	H319 H335 H315 H411	GHS07 GHS09 Wng	H319 H335 H315 H411	-	-	-
Dossier submitters proposal	613-057-00-7	dodemorph (ISO); 4-cyclododecyl-2,6-dimethylmorpholine	216-474-9	1593-77-7	**Add** Repr. 2 Aquatic Acute 1 **Modify** Aquatic Chronic 1 **Remove** Eye Irrit. 2 STOT SE 3 Skin Irrit. 2	**Add** H361d H400 **Modify** H410 **Remove** H319 H335 H315	**Retain** GHS09 **Add** GHS08 **Modify** Dgr **Remove** GHS07	**Add** H361d **Modify** H410 **Remove** H319 H335 H315	-	**Add** M=1 M=1	-
RAC opinion	613-057-00-7	dodemorph (ISO); 4-cyclododecyl-2,6-dimethylmorpholine	216-474-9	1593-77-7	**Add** Repr. 2 STOT RE 2 Skin Corr. 1C Skin Sens. 1A Aquatic Acute 1 **Modify** Aquatic Chronic 1	**Add** H361d H373 (liver) H314 H317 H400 **Modify**	**Retain** GHS07 GHS09 **Add** GHS05 GHS08 **Modify**	**Add** H361d H373 H314 H317 **Modify** H410	**Add** EUH071	**Add** M=1 M=1	-

					Remove Eye Irrit. 2 STOT SE 3 Skin Irrit. 2	H410 **Remove** H319 H335 H315	Dgr	**Remove** H319 H335 H315			
Resulting Annex VI entry if agreed by COM	613-057-00-7	dodemorph (ISO); 4-cyclododecyl-2,6-dimethylmorpholine	216-474-9	1593-77-7	Repr. 2 STOT RE 2 Skin Corr. 1C Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H361d H373 (liver) H314 H317 H400 H410	GHS05 GHS07 GHS08 GHS09 Dgr	H361d H373 H314 H317 H410	EUH071	M=1 M=1	-

Classification and labelling in accordance with DSD

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	613-057-00-7	dodemorph (ISO); 4-cyclododecyl-2,6-dimethylmorpholine	216-474-9	1593-77-7	Xi; R36/37/38 N; R51-53	Xi; N R: 36/37/38-51/53 S: (2-)26-61	-	-
Dossier submitters proposal	613-057-00-7	dodemorph (ISO); 4-cyclododecyl-2,6-dimethylmorpholine	216-474-9	1593-77-7	**Add** Repr. Cat.3; Xn; R63 **Modify** N; R50-53 **Remove** Xi; R36/37/38	**Add** Repr. Cat.3; Xn; R63 **Modify** N; R50-53 **Remove** Xi; R36/37/38	**Add** N; R50-53: C ≥ 25 % N; R51-53: 2,5% ≤ C < 25% R52-53: 0.25 % ≤ C < 2,5 %	-
RAC opinion	613-057-00-7	dodemorph (ISO); 4-cyclododecyl-2,6-dimethylmorpholine	216-474-9	1593-77-7	**Add** Repr. Cat. 3; R63 C; R34 R43 **Modify** N; R50-53 **Remove** Xi; R36/37/38	**Add** Repr. Cat.3; Xn; R63 **Modify** N; R50-53 **Remove** Xi; R36/37/38	**Add** N; R50-53: C ≥ 25 % N; R51-53: 2,5% ≤ C < 25% R52-53: 0.25 % ≤ C < 2,5 %	-
Resulting Annex VI entry if agreed by COM	613-057-00-7	dodemorph (ISO); 4-cyclododecyl-2,6-dimethylmorpholine	216-474-9	1593-77-7	Repr. Cat. 3; R63 C; R34 R43 N; R50-53	C; N R: 34-43-63-50/53 S: (1/2)-26-36/37/39-45-46-60-61	N; R50-53: C ≥ 25 % N; R51-53: 2,5% ≤ C < 25% R52-53: 0.25 % ≤ C < 2,5 %	-

5. Dodemorph acetate

Classification and labelling in accordance with the CLP Regulation

	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	-	-	-	-	-	-	-	-	-	-	-
Dossier submitters proposal		dodemorph acetate (ISO); 4-cyclododecyl-2,6-dimethylmorpholin-4-ium acetate	250-778-2	31717-87-0	Repr. 2 Skin Corr. 1 Skin Sens. 1A Aquatic Chronic 1	H361d H314 H317 H410	GHS05 GHS07 GHS08 GHS09 Dgr	H361d H314 H317 H410	EUH071	M = 1	-
RAC opinion		dodemorph acetate (ISO); 4-cyclododecyl-2,6-dimethylmorpholin-4-ium acetate	250-778-2	31717-87-0	Repr. 2 STOT RE 2 Skin Corr. 1C Skin Sens. 1A Aquatic Chronic 1	H361d H373 (liver) H314 H317 H410	GHS05 GHS07 GHS08 GHS09 Dgr	H361d H373 H314 H317 H410	EUH071	M = 1	-
Resulting Annex VI entry if agreed by COM		dodemorph acetate (ISO); 4-cyclododecyl-2,6-dimethylmorpholin-4-ium acetate	250-778-2	31717-87-0	Repr. 2 STOT RE 2 Skin Corr. 1C Skin Sens. 1A Aquatic Chronic 1	H361d H373 (liver) H314 H317 H410	GHS05 GHS07 GHS08 GHS09 Dgr	H361d H373 H314 H317 H410	EUH071	M = 1	-

Classification and labelling in accordance with DSD

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry		dodemorph acetate (ISO); 4-cyclododecyl-2,6-dimethylmorpholin-4-ium acetate	250-778-2	31717-87-0	Repr. Cat. 3; R63 C; R34 Xi; R43 N; R51-53	C; N R: 34-43-63-51/53 S: (1/2)-26-28-36/37/39-45-61	-	-
Dossier submitters proposal		dodemorph acetate (ISO); 4-cyclododecyl-2,6-dimethylmorpholin-4-ium acetate	250-778-2	31717-87-0	Repr. Cat. 3; C; R34 Xi; R43 Xn; R63 N; R51-53	C; N R: 34-43-63-51/53 S: (1/2)-26-28-36/37/39-45-61	-	-
RAC opinion		dodemorph acetate (ISO); 4-cyclododecyl-2,6-dimethylmorpholin-4-ium acetate	250-778-2	31717-87-0	Repr. Cat. 3; R63 C; R34 Xi; R43 N; R51-53	C; N R: 34-43-63-51/53 S: (1/2)-26-28-36/37/39-45-61	-	-
Resulting Annex VI entry if agreed by COM		dodemorph acetate (ISO); 4-cyclododecyl-2,6-dimethylmorpholin-4-ium acetate	250-778-2	31717-87-0	Repr. Cat. 3; R63 C; R34 Xi; R43 N; R51-53	C; N R: 34-43-63-51/53 S: (1/2)-26-36/37/39-45-46-61	-	-

6. Phenol, dodecyl-, branched

Classification and labelling in accordance with the CLP Regulation

	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	-	-	-	-	-	-	-	-	-	-	-
Dossier submitters proposal		Phenol, dodecyl-, branched [1]; Phenol, 2-dodecyl-, branched; Phenol, 3-dodecyl-, branched; Phenol, 4-dodecyl-, branched; Phenol, (tetrapropenyl) derivatives [2];	310-154-3 [1]	121158-58-5 [1] 74499-35-7 [2]	Repr. 2**[RAC-27]** Skin Irrit. 2 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H361f **[RAC-27]** H315 H319 H400 H410	GHS08**[RAC-27]** GHS07 GHS09 Wng	H361f**[RAC-27]** H315 H319 H410		 M = 1 M = 10	-
RAC opinion		Phenol, dodecyl-, branched [1]; Phenol, 2-dodecyl-, branched; Phenol, 3-dodecyl-, branched; Phenol, 4-dodecyl-, branched; Phenol, (tetrapropenyl) derivatives [2];	310-154-3 [1]	121158-58-5 [1] 74499-35-7 [2]	Skin Corr. 1C Aquatic Acute 1 Aquatic Chronic 1	H314 H400 H410	GHS05 GHS09 Dgr	H314 H410		 M = 10 M = 10	-
Resulting Annex VI entry if agreed by COM		Phenol, dodecyl-, branched [1]; Phenol, 2-dodecyl-, branched; Phenol, 3-dodecyl-, branched; Phenol, 4-dodecyl-, branched; Phenol, (tetrapropenyl) derivatives [2];	310-154-3 [1]	121158-58-5 [1] 74499-35-7 [2]	Skin Corr. 1C Aquatic Acute 1 Aquatic Chronic 1	H314 H400 H410	GHS05 GHS09 Dgr	H314 H410		 M = 10 M = 10	-

Classification and labelling in accordance with DSD

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	-	-	-	-	-	-	-	-
Dossier submitters proposal		Phenol, dodecyl-, branched [1]; Phenol, 2-dodecyl-, branched; Phenol, 3-dodecyl-, branched; Phenol, 4-dodecyl-, branched; Phenol, (tetrapropenyl) derivatives [2];	– 310-154-3[1]	– 121158-58-5 [1] – 74499-35-7 [2]	– Repr. Cat. 3; R62 **[RAC-27]** – Xi; R36/38 – N; R50-53	– Xn; N – R: 36/38-62-50/53 – S: 26-36/37/39-60-61	– N; R50-53: C ≥ 25 % – N; R51-53: 2.5% ≤ C < 25% – R52-53: 0.25 % ≤ C < 2.5 %	-
RAC opinion		Phenol, dodecyl-, branched [1]; Phenol, 2-dodecyl-, branched; Phenol, 3-dodecyl-, branched; Phenol, 4-dodecyl-, branched; Phenol, (tetrapropenyl) derivatives [2];	– 310-154-3[1]	– 121158-58-5 [1] 74499-35-7 [2]	– C; R34 – N; 50-53	– C; N – R: 34-50/53 – S: (1/2-)-26-36/37/39-45-60-61	– N; R50-53: C ≥ 2.5 % – N; R51-53: 0.25% ≤ C < 2.5% – R52-53: 0.025 % ≤ C < 0.25 %	-
Resulting Annex VI entry if agreed by COM		Phenol, dodecyl-, branched [1]; Phenol, 2-dodecyl-, branched; Phenol, 3-dodecyl-, branched; Phenol, 4-dodecyl-, branched; Phenol, (tetrapropenyl) derivatives [2];	– 310-154-3[1]	– 121158-58-5 [1] 74499-35-7 [2]	–	–	–	-

7. 1.2-epoxybutane (2-ethyloxirane)

Classification and labelling in accordance with the CLP Regulation

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling		
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)
Current Annex VI entry	603-102-00-9	1,2-epoxybutane	203-438-2	106-88-7	Flam. Liq. 2; Carc. 2; Acute Tox. 4*; Acute Tox. 4*; Acute Tox. 4*; Eye Irrit. 2; STOT SE 3; Skin Irrit. 2; Aquatic Chronic 3	H225 H351 H332 H312 H302 H319 H335 H315 H412	GHS02 GHS08 GHS07 Dgr	H225 H351 H332 H312 H302 H319 H335 H315 H412	
Dossier submitters proposal					Removal of Aquatic Chronic 3;	Removal of H412		Removal of H412	
RAC opinion					Removal of Aquatic Chronic 3;	Removal of H412		Removal of H412	
Resulting Annex VI entry if agreed by COM					Flam. Liq. 2; Carc. 2; Acute Tox. 4*; Acute Tox. 4*; Acute Tox. 4*; Eye Irrit. 2; STOT SE 3; Skin Irrit. 2;	H225 H351 H332 H312 H302 H319 H335 H315	GHS02 GHS08 GHS07 Dgr	H225 H351 H332 H312 H302 H319 H335 H315	

Classification and labelling in accordance with the DSD

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits
Current Annex VI entry	603-102-00-9	1,2-epoxybutane	203-438-2	106-88-7	F; R11 Carc. Cat. 3; R40 Xn; R20/21/22 Xi; R36/37/38 R52-53	F; Xn R: 11-20/21/22-36/37/38-40-52/53 S: (2-)9-16-29-36/37-61	
Dossier submitters proposal					Removal of R52-53	Removal of: R52/53 S61	
RAC opinion					Removal of R52-53	Removal of: R52/53 S61	
Resulting Annex VI entry if agreed by COM					F; R11 Carc. Cat. 3; R40 Xn; R20/21/22 Xi; R36/37/38	F; Xn R: 11-20/21/22-36/37/38-40 S: (2-)9-16-29-36/37	

8. Imidazole

Classification and labelling in accordance with the CLP Regulation

	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	-	-	-	-	-	-	-	-	-	-	-
Dossier submitters proposal		Imidazole	206-019-2	288-32-4	Repr. 1B Acute Tox. 4 Skin Corr. 1C Eye Dam. 1	H360D H302 H314 H318	GHS05 GHS07 GHS08	H360D H302 H314 Dgr	**-**	**-**	-
RAC opinion		Imidazole	206-019-2	288-32-4	Repr. 1B Acute Tox. 4 Skin Corr. 1C	H360D H302 H314	GHS05 GHS07 GHS08	H360D H302 H314 Dgr	-	-	-
Resulting Annex VI entry if agreed by COM		Imidazole	206-019-2	288-32-4	Repr. 1B Acute Tox. 4 Skin Corr. 1C	H360D H302 H314	GHS05 GHS07 GHS08	H360D H302 H314 Dgr	-	-	-

Classification and labelling in accordance with DSD

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	-	-	-	-	-	-	-	-
Dossier submitters proposal		Imidazole	206-019-2	288-32-4	Repr. Cat 2; R61 Xn; R22 C; R34	T; C R: 61-22-34 S: 26-36/37/39-45-53	-	-
RAC opinion		Imidazole	206-019-2	288-32-4	Repr. Cat 2; R61 Xn; R22 C; R34	T; C R: 61-22-34 S: 26-36/37/39-45-53	-	-
Resulting Annex VI entry if agreed by COM		Imidazole	206-019-2	288-32-4	Repr. Cat 2; R61 Xn; R22 C; R34	T; C R: 61-22-34 S: 26-36/37/39-45-53	-	-

Part III. List of Attendees of the RAC-26 meeting

(10-13 September 2013)

RAC members	**ECHA staff**
BARANSKI Bogusław	ATLASON Palmi
BARRON Thomasina	BARMAZ Stefania
BJORGE Christine	BOWMER Tim
BRANISTEANU Radu	BROECKAERT Fabrice
CARVALHO João	DE BRUIJN Jack
Di PROSPERO FANGHELLA Paola	DVORAKOVA Dana
DUNAUSKIENĖ Lina	ERICSSON Gunilla
DUNGEY Stephen	FUHRMANN Anna
GREIM Helmut	HELLSTEN Kati
GRUIZ Katalin	HONKANEN Jani O.
HAKKERT Betty	KIOKIAS Sotirios
JENSEN Frank	KLAUK Anja
KADIĶIS Normunds	KOKKOLA Leila
KAPELARI Sonja	KOSK-BIENKO Joanna
KORATI Safia	LOGTMEIJER Christiaan
LEINONEN Riitta	LUDBORŽS Arnis
LUND Bert-Ove	MAGGIORE Angelo
MULLOOLY Yvonne	MERKOURAKIS Spyridon
PARIS Pietro	MOSSINK Jos
PASQUIER Elodie	MYÖHÄNEN Kirsi
PINA Benjamin	NICOT Thierry
POLAKOVICOVA Helena	NYGREN Jonas
PRONK Marja	ORISPÄÄ Katja
RUCKI Marian (12-13/09/2013)	RODRÍGUEZ IGLESIAS Pilar
RUPPRICH Norbert	ROGGEMAN Maarten
SCHLÜTER Urs	SADAM Diana
SCHULTE Agnes	SOSNOWSKI Piotr
SMITH Andrew	SPJUTH Linda
SOERENSEN Peter	STOYANOVA Evgenia
STOLZENBERG Hans-Christian	THUVANDER Ann
TADEO José Luis	VAINIO Matti
Van der HAGEN Marianne	Van HAELST Anniek
VIVIER Stéphanie	ÖBERG Tomas

Invited expert		**Remote participants**
DEWHURST Ian (invited expert for capacity building authorisation)		**RAC members**
Dossier submitters		BARRON Thomasina
MÜLLER Severin (industry dossier submitter for TPP)		**Dossier submitters**
Advisers (to the RAC members)		EKOKOSKI Elina (FI DS for AVKs)
JANONYTE Agne, adviser to L. Dunauskiene (imidazole)		GAUSTAD Astrid (NO DS for AVKs)
KORHONEN Hanna, adviser to R. Leinonen		MÜLLER Andre (NL DS for AVKs)
NÚÑEZ Laura, adviser to J.L.Tadeo (dodemorph and dodemorph acetate)		RUBBIANI Maristella (IT DO for AVKs)
PAPPONEN Hinni, adviser to R. Leinonen		BEEKMAN Andre (NL DS for NMP)
PECZKOWSKA Beata adviser to B. Baranski (TPP and AVK)		HENRIKSSON Jörgen (SE DS for nonylphenol)
ROMOLI Debora, adviser to P. Paris		VASS Anne Marie (SE DS for lead restriction)
SMITH Helen, adviser to A.Smith (imidazole and dodemorph)		
TIESJEMA Gitte, adviser to B. Hakkert		**Commission observers:**
TOBIASSEN Lea Stine, adviser to P. Soerensen (AVK)		De BARROS FERNANDES Mariana
Commission observers		BERTATO Valentina
LUVARA Giuseppina		BORRAS HERRERO Anna
SCAZZOLA Roberto (DG ENTR)		GARCIA JOHN Enrique
LEFEVRE Remi (DG ENV)		GIRAL-ROEBLING Anne
Stakeholder observers		PIRSELOVA Katarina
ROWE Rocky (ECPA)		POPOVA Temenuzhka
POOLE Alan (ECETOC)		ROZWADOWSKI Jacek
ANNYS Erwin (CEFIC)		
BARRY Frank (ETUC)		**Advisers:**
BUONSANTE Vito		GOMEZ-CONTRERAS Jeannette (adviser to RAC member Marja Pronk)
DOLORES Romano (EEB)		McGARRY Helen (adviser to RAC member Andrew Smith)
MUNARI Tomaso (EuCheMS)		STARKE Sue-Martina (adviser to RAC member Hans-Christian Stolzenberg)
REGO Laura (ECEAE)		
VEROUGSTRAETE Violaine		**Excuses**

(Eurometaux)		
<u>Other observers</u>		BARRON Thomasina (RAC member)
VARNAI Veda, Croatian observer		LOSERT Annemarie (RAC member on maternity)
BOREIKO Craig, ILZRO (an observer acting as an expert to an observer representing Eurometaux for Lead CLH and Lead restriction)		STAŠKO Jolanta (RAC member)
BILLINGTON Richard, DAS (an observer acting as an expert to an observer representing ECPA for sulfoxaflor)		TSITSIMPIKOU Christina (RAC member)
TEMEROWSKI Michael, Bayer CropScience (an observer acting as an expert to an observer representing ECPA for spirotetramat)		MORRIS Alick (SCOEL)
WARREN Simon, Exponent (an observer acting as an expert to an observer representing ECPA for AVK)		MERCKEL Dan (OECD)

The following participants (in addition to the list of attendees above) attended the Joint Session on Thursday 12.9.2013

SEAC members
BENDL Jiri
BOUSTRAS Georgios
BRIGNON Jean-Marc
CSERGO Robert
DANTINNE Catheline
FANKHAUSER Simone
FEYAERTS Jean-Pierre
FIORE-TARDIEU Karine
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
KIISKI Johanna
KNOFLACH Georg
LUTTIKHUIZEN Cees
RODRIGUEZ DE SANCHO Maria Jesus
SCHUCHTAR Endre
SIMON Franz Georg
SLEZAK Zbigniew
THIELE Karen
THORS Åsa

Advisors & invited experts
CASTELLI Stefano (invited expert, IT)
CAVALIERI Luisa (advisor to K. Fiore-Tardieu)
COGEN Simon (advisor to J-P. Fayaerts)
D'AMICO Flaviano (advisor to S. Grandi)
HENNIG Philipp (advisor to K. Thiele)
KORHONEN Hanna (advisor to J. Kiiski)
PALOTAI Zoltan (invited expert, HU)
SLETTEN Thea Marcelia (invited expert, SE)

Stakeholder observers
BUONSANTE Vito (EEB)
HOLLAND MIKE (EAERE)
JANOSI Amaya (CEFIC)
MOUCHEBOEUF Jean (UEAPME)
WATERSCHOOT Hugo (EUROMETAUX)

Representative of the European Commission
BENGYUZOV Manol (DG ENTR, via webex)
GALLEGO Mateo (DG ENV)
KUBICKI Michal (DG ENTR)
Remote participants
DALTON Marie (SEAC member)
VERHOEVEN Julia (adviser to SEAC member C. Luttikhuizen)
ECHA staff
JACQUEMIN Katline
ORISPÄÄ Katja
ÖBERG Tomas
SADAM Diana

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-26 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-26 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-26 meeting

10 September 2013
RAC/A/26/2013

Final Agenda

26th meeting of the Committee for Risk Assessment

10-13 September 2013
ECHA Conference Centre (Annankatu 18, Helsinki)
10 September: starts at 9:00
13 September: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/26/2013
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 25 action points, written procedures and other ECHA bodies

RAC/26/2013/01
For information

b) RAC workplan for all processes

For information

Item 5 – Harmonised classification and labelling (CLH)

5.1 CLH dossiers

a) Lead
b) Dodemorph
c) Dodemorph acetate
d) Phenol, dodecyl-, branched (tetrapropenylphenol (TPP))
e) Imidazole

f) Spirotetramat

g) Sulfoxaflor

h) 1.2-Epoxybutane

For discussion/adoption

i) Anti-coagulant rodenticides – general discussion

RAC/26/2013/02

For discussion/agreement

a. Chlorophacinone
b. Bromadiolone ketone
c. Difenacoum
d. Difethialone
e. Flocoumafen
f. Warfarin
g. Brodifacoum
h. Coumatetralyl

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

RAC/26/2013/03 (room document)

For agreement

5.3 General and procedural CLH issues

For information

Item 6 – Restrictions

6.1 General restriction issues

For information

6.2 Restriction Annex XV dossiers

a) Lead in consumer articles – 2nd version of the draft opinion

For discussion

b) 1-Methylpyrrolidin-2-one (NMP) – outcome of the conformity check

For agreement

c) Nonyl phenol – outcome of the conformity check

For agreement

6.3 Appointment of (co-)rapporteurs for restriction dossiers

RAC/26/2013/05 (confidential room document)

For information

Item 7 – Authorisation

7.1 Authorisation application on phthalates – outcome of the conformity check and introductory presentation on the application

For agreement

7.2 Recommendation of the review period in applications for authorisation

RAC/26/2013/06

For agreement

7.3 Capacity building

a) DNEL setting (BBP)

RAC/26/2013/07

For discussion/agreement

b) ECHA project on carcinogenicity dose-response analysis of Cr(VI)- and As-containing substances

For information

7.4 Appointment of (co-) rapporteurs for authorisation applications

(*Closed session*)

RAC/26/2013/08 (confidential document)

For agreement

Item 9 – AOB

a) Report from the project on economic evaluation of environmental impacts

For information

Item 10 – Action points and main conclusions of RAC-26

Table with Conclusions and Action points from RAC-26

For adoption

ANNEX II (RAC-26)

Documents submitted to the members of the Committee for Risk Assessment for the RAC-26 meeting.

Number	**Title**
RAC/A/26/2013	Final Draft Agenda
RAC/26/2013/01	Report on RAC 25 action points, written procedures and other ECHA bodies
RAC/26/2013/02	Anticoagulant rodenticides – general issues
RAC/26/2013/03 Room document	Appointment of RAC (co-)rapporteurs for CLH dossiers
RAC/26/2013/05 Room document	Appointment of (co-)rapporteurs for restriction dossiers
RAC/26/2013/06	Recommendation of the review period in application for authorisation + Commission Note
RAC/26/2013/07	Capacity building – DNEL setting (BBP)

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)

RAC members		
Potential conflict of interest in relation to:	**Name of participant**	**Reason**
Difenacoum	Riitta LEINONEN	Working for the CA, partial involvement in the preparation and review of the environmental part of the CLH dossier – may intervene but not allowed to join in closing arguments or to vote.
Difethialone	Christine BJOERGE	Working for the CA submitting the CLH dossier only; from Norway and prevented from voting in any case - no other mitigation measures applied.
Flocoumafen	Betty HAKKERT	Working for the CA submitting the CLH dossier only; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Coumatetralyl	Frank JENSEN	Working for the CA submitting the CLH dossier only; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Bromadiolone	Bert-Ove LUND	Working for the CA submitting the CLH dossier only; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Flocoumafen	Marja PRONK	Working for the CA submitting the CLH dossier only; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Brodifacoum	Paola di PROSPERO	Working for the CA submitting the CLH dossier only; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Coumatetralyl	Peter Hammer SOERENSEN	Working for the CA submitting the CLH dossier only; asked to refrain from voting in the event of a vote on this substance - no

		other mitigation measures applied.
Difethialone	Marianne van der HAGEN	Working for the CA submitting the CLH dossier only; from Norway and prevented from voting in any case - no other mitigation measures applied.
Lead in consumer articles	Bert-Ove LUND	Working for the CA submitting the CLH dossier only; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Lead CLH	Bert-Ove LUND	Working for the CA submitting the CLH dossier only; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Nonylphenol	Bert-Ove LUND	Working for the CA submitting the CLH dossier only; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
ECHA project on carcinogenicity dose-response analysis of Cr(VI) and AS-containing substances	Andrew SMITH	Working in the same agency as a contractor to ECHA active on this issue.

RAC advisers and dossier submitters		
Potential conflict of interest in relation to:	**Name of participant**	**Reason**
Coumatetralyl	Lea-Stine TOBIASSEN (adviser to Peter Hammer Soerensen; DK dossier submitter)	Dossier submitter for this substance. Asked not to intervene.

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