RAC/M/25/2013
Final
16 August 2013

Minutes of the 25th Meeting of the Committee for Risk Assessment (RAC-25)

04-07 June 2013

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 25th meeting of the Committee for Risk Assessment (RAC). He informed the meeting that a RAC member, Gera Troisi, has resigned as a member in April 2013. Apologies were received from five members. One RAC member was absent.

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) on Thursday in which the 'review period' and the a revised working procedure for appointment of (co-) rapporteurs for authorisation applications would be considered. He informed the Committee about the on-going written procedure for the adoption of a RAC opinion based on an Article 77(3)(c) request in support of the work of the member State Committee (MSC) on the specific target organ toxicity of two benzotriazoles (UV-320 and UV-328).

The Final Draft Agenda (RAC/A/25/2013) 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. Five members declared potential conflicts of interest, each to specific agenda items. These meeting participants did not participate in voting under 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.

In answer to questions raised by some RAC members in the context of the RAC consultation on the RAC 24 draft minutes, the Chairman further explained the handling of potential conflicts of interest of RAC members in relation to CLH dossiers:

- Where a Member State Competent Authority (MSCA) (organisation / agency) submits a dossier to ECHA, it is considered good administrative practice that the RAC member employed in that MSCA or an organisation controlling that MSCA and / or processing the dossier declares the concurrent occupation as an interest which could be considered prejudicial to her/his independence.
- Where a RAC member comes from another organisation than a CA preparing a dossier and has nothing to do with its preparation, the concurrent occupation needs not to be declared.

4. Report from other ECHA bodies and activities

a) Report on RAC 24 action points, written procedures and other ECHA bodies

The Secretariat informed the Committee on administrative issues as set out in room document RAC/25/2013/01, which included an overview of the adoptions, consultations, and agreements undertaken by written procedure since the last RAC meeting and on the reports from the last meetings of the ECHA bodies namely the Management Board, the Member State Committee, the Committee for Socio- Economic Analysis and the Forum for Exchange of Information on Enforcement (Forum).

The Chairman informed the Committee about the re-nomination of about half of the RAC members which would be considered by the upcoming Management Board meeting in June

and in December 2013. In addition, a paper on the progress of all Committees is being prepared by the Secretariat for the attention of the Management Board in June. In relation to the RAC, the paper highlights the current workload of the Committee and gives projections for 2014. The Secretariat is aware of an increasing workload and the Chairman pointed out that in the coming years this would mainly be determined by applications for authorisation as well as a potential need for an alignment with the PPP (Plant Protection Products) process. In relation to this, the paper proposes number of measures including a plea to MSCAs for nomination of 2nd RAC members. The issue of co-opted members (discussed at the last RAC meeting) will also be addressed by the Management Board in June.

The Chairman briefly summarised the state of play of an Article 77(3)c dossier on the toxicity to reproduction of gallium arsenide. Following agreement at RAC 24, the draft opinion was prepared, subject to a RAC consultation and in accordance with the mandate was opened for a concluding public consultation (PC). The Chairman underlined that the PC was strictly limited to the text of the opinion only and that after it had been closed, the opinion would be sent for the final agreement by the Committee via written procedure and followed by the publication and the transmission to the Commission in the usual way. Minority statements to the opinion will be published at the same time.

b) RAC work plan for all processes

The Chairman drew the attention of the Committee to a presentation on the work plan for all processes which the RAC deals with (classification and labelling, REACH authorisation and restrictions) prepared by the Secretariat. He pointed out that the aim was to plan for 2-3 meetings ahead and to update this work plan regularly before each meeting. The presentation provides a summary of current and expected restriction dossiers including the timeline, an overview of 'submission windows' for applications for authorisation and an indicative planning of CLH dossiers for RACs 26-28 meetings. In this context, the Chairman reminded the RAC of three main groups of CLH dossiers which will be dealt with in upcoming meetings; namely 8 dossiers on anticoagulant rodenticides, a dossier on boric acid and 2 borate salts as the first part of a larger group of borates and, later in 2014, 10 dossiers on copper compounds. Given the complexity of these groups of dossiers a well-advanced planning of the RAC plenary meetings is vital.

5. Harmonised classification and labelling (CLH)

5.1 Sensitisation criteria following the 2nd ATP to the CLP Regulation

The Secretariat presented information from the draft update of the Guidance on the Application of the criteria following the 2nd ATP to the CLP Regulation, focussing on the draft texts on skin sensitisation, in particular the criteria and data requirements for sub-division into category 1A and 1B. During the subsequent discussions, the members agreed that in the absence of convincing test data which supports the unambiguous application of the sub-categories, the substance should be classified simply as Category 1 without further subdivision.

5.2 CLH dossiers

a) Etridiazole

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and reported that etridiazole is an active substance which is used as a fungicide in the treatment of glasshouse grown fruits and ornamentals. The CLH dossier was submitted by the Netherlands. The legal deadline for adoption of the opinion is 27 August 2013.

Etridiazole has a harmonised classification in Annex VI as Carc. 2, H351, Acute Tox. 3*, H331 (inhalation), Acute Tox. 4*, H312 (dermal), Acute Tox. 4*, H302 (oral), Aquatic Acute 1, H400, Aquatic Chronic 1, H410. The dossier submitter (DS) had proposed to remove the classifications: Acute Tox. 3*, H331 and Acute Tox. 4*, H312, to remove the "*" in Acute Tox. 4*, H302 (i.e. remove the minimum classification), to add STOT SE 3,

H335, and Skin Sens. 1B, H317, and finally, to add multiplication factors (M-factors) of 1 to the Aquatic Acute and Aquatic Chronic classifications (CLP).

The Chairman reminded the Committee that this was the second plenary discussion of this dossier and that at RAC-24 they had already agreed to remove the classifications Acute Tox. 3*, H331 and Acute Tox. 4*, H312, to remove the "*" in Acute Tox. 4*, H302 and to add Skin Sens. 1B, H317. The RAC had not supported the DS proposal to classify for STOT-SE 3, as it had not considered the observed effects sufficient for classification. The discussion of carcinogenicity, reproductive toxicity and environmental hazards had been continued by written consultation due to the limited time available at RAC-24 and bearing the legal deadline in mind would be concluded at this meeting.

The Chairman reported that ECHA had arranged a second, targeted public consultation on carcinogenicity and reproductive toxicity in order to strengthen the information base and because these hazard classes were not specifically addressed in the list for which comments had been requested during the previous public consultation. Comments on these two hazard classes were invited in writing by 3 June 2013. The Chairman then invited the Rapporteurs to present the draft opinion, taking into account the comments received during the aforementioned targeted public consultation.

The RAC based their discussion of carcinogenicity on two available studies, a 104-week study in rats and an 18-month study in mice. The neoplastic lesions observed in the liver at mid and high dose groups in the mouse study were considered to be questionable for classification as both doses were concluded to exceed the maximum tolerable dose (MTD) due to high mortality rates. Regarding the rat study, the RAC concluded that the MTD was not exceeded at any dose. Evident increases in tumour incidences were observed in the liver, thyroid and testes. However, female rats were more sensitive for liver tumours than male rats and liver tumours in male rats were mainly benign. The thyroid tumours were markedly increased in males of mid and high dose groups whereas the tumour response in females was weaker and predominantly benign. Because of preferences for one sex for a tumour type in the rat, the RAC considered the carcinogenic potential of etridiazole as not sufficient for Cat 1B. The existing classification of etridiazole as Carc. 2; H351 according to the CLP Regulation was confirmed by the RAC as appropriate.

In relation to reproductive toxicity, the RAC discussed the observed developmental effects seen in the teratogenicity study on rabbits which occurred at the highest dose (45 mg/kg bw) in the presence of maternal mortality (3/17 pregnant dams). The RAC shared the view of the Rapporteur not to classify, given that the CLP criteria state that maternal mortality greater than 10% is considered excessive and the data for that dose level shall not normally be considered for further evaluation. It was also noted by the rapporteur that the dose selection for the main study was not appropriate as one out of the four pregnant dams (25 %) died in the dose range finding study already at 30 mg/kg and the doses selected for the main study were 45, 15 and 1.7 mg/kg bw. At 15 mg/kg bw no developmental or maternal toxicity were noted.

The RAC also discussed whether the high mortality rates seen at 45 mg/kg bw in the rabbit teratogenicity study would support classification for STOT RE, but agreed not to propose such a classification as it was not known at which time-point during the 13-day treatment the dams died and because no serious adverse effects occurred below the guidance values in the oral 90-day rat study or in the inhalation 28-day rat study.

With regard to skin sensitisation, the RAC modified the agreement from RAC-24, in line with the outcome of the general discussion on sensitisation reported above and decided to classify etridiazole as Skin Sens. 1, without further subdivision.

In relation to aquatic toxicity, the RAC discussed the validity of the reported algae studies and decided to apply the surrogate approach for the chronic classification as the available study did not meet the validity criteria as specified in the OECD TG 201 for 72h for longer exposure times. The RAC agreed to classify etridiazole as Aquatic Acute 1 with an M-factor 1 and Aquatic Chronic 1 with an M-factor 1, in line with the DS's proposal.

Finally, the RAC adopted the opinion on etridiazole by consensus. The Chairman thanked all parties for their efforts in concluding this dossier and pointed out that final revision to reflect the discussions at RAC-25 and an editorial check would be performed before the opinion was published on ECHA's website.

b) Metosulam

The Chairman reported that the substance is used as a herbicide intended to be used in potatoes, wheat, apples/pears and peaches and that it has currently no entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of the opinion is 11 November 2013.

The DS (France) proposed to classify the substance as STOT RE 2; H373, Carc. 2; H351, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 according to the CLP Regulation. As it is an active substance, in accordance with Art. 36(2) of the CLP Regulation, all physical and chemical properties, human health and environmental endpoints are considered in the CLH report.

The Chairman reported that the substance was being discussed at a RAC plenary meeting for the first time and invited the Rapporteurs to present the draft opinion.

The Rapporteurs agreed with the DS proposal for the harmonised classification for specific target organ toxicity after repeated exposure based on the evidence from 90-day studies in dogs and rats where ocular (dog) and renal (dog and rat) lesions were observed at doses below or equal to 100 mg/kg bw/day.

The Rapporteurs agreed with the DS proposal to classify metosulam as carcinogen in category 2 based on findings from a 2-year chronic dietary toxicity study in rats where higher frequency of non-neoplastic renal lesions was observed at 30 and 100mg/kg bw/day as well as higher frequency of malignant tumours in high-dose males and renal neoplasms in both males and females. The classification is proposed on the basis of single species (rats are generally more sensitive to renal toxicity than mice), the substance does not have genotoxic potential and available mechanistic data show that kidney damage probably leads to the formation of renal tumours.

The Rapporteurs agreed with the DS proposal for environmental hazards, including the higher chronic M-factor of 100 that was proposed by the DS following comments received during PC.

The RAC supported the Rapporteurs' conclusions on both human health and environmental hazard classes and the opinion on metosulam was adopted by consensus.

c) Organic acids (octanoic, nonanoic and decanoic acid)

The Chairman noted that three related dossiers for linear fatty acids (octanoic, nonanoic and decanoic) were being discussed for the first time at a RAC plenary meeting.

He reported that the CLH dossiers were submitted by Austria and that the three substances are used in biocidal and pesticidal products. The legal deadline for adoption of the opinion is 20 December 2013.

Out of these three substances, only nonanoic acid already had a harmonised classification on Annex VI to the CLP Regulation, as Skin Corr. 1B, H314. The DS had proposed the following harmonised classifications for the three substances:

> Octanoic acid: Skin Corr. 1C, H314, with a specific concentration limit of 70%, and Aquatic Chronic 3, H412;
>
> Nonanoic acid: Skin Irrit. 2, H315, Eye Dam. 1, H318, and Aquatic Chronic 3, H412 and;
>
> Decanoic acid: Skin Irrit. 2, H315, Eye Dam. 1, H318, and Aquatic Chronic 3, H412, for decanoic acid.

The Chairman invited the Rapporteurs to present the draft opinion, taking into account the comments received during the PC and RAC consultation. During the subsequent discussions, the RAC members agreed that the database for the irritation/corrosion properties of the substances was limited and that some grouping was therefore justified, based on the structural and physico-chemical similarities of the substances. One RAC member and the EFSA representative present pointed out that corrosion / irritation of linear fatty acids was considered to decrease with increasing chain length. The RAC members agreed to classify octanoic acid as Skin Corr. 1C, H314, based primarily on the results from Wetering (1984) but agreed that decanoic acid and nonanoic acid should be classified as Skin Irrit. 2, H315. The results from Leoni and Riedel (2011), an OECD 405 eye irritation study on 70% octanoic acid submitted during PC were read-across to nonanoic and decanoic acids to assign Eye Irrit. 2, H315. As octanoic acid is proposed to be classified as Skin Corr. 1C, no classification for eye irritation is needed. The RAC members agreed that the database was not sufficient to determine specific concentration limits for skin irritation/corrosion or eye irritation for any of the three substances.

The RAC agreed that the data did not warrant classification for respiratory tract irritation (STOT SE 3, H335) for decanoic acid, as brought up during PC.

In relation to the aquatic hazards, the RAC members decided to classify all three substances as Aquatic Chronic 3, H412, based on measured concentrations in the algal tests for nonanoic and decanoic acid and read-across for octanoic acid.

Finally, the RAC adopted the opinions for octanoic, nonanoic and decanoic acid by consensus. The Chairman pointed out that final revisions to reflect the discussions at RAC-25 and an editorial check would be performed before the opinions are published on ECHA's website.

d) 1,2-benzenedicarboxylic acid, dihexylester, branched and linear

The Chairman reported that the substance is used as a lubricant in steering fluid and as a plasticizer. The CLH dossier was submitted by Sweden and the legal deadline for adoption of the opinion was 6 February 2014.

The Chairman clarified that the chemical name "1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear (CAS no. 68515-50-4, EC no. 271-093-5)" had been correctly indicated as the IUPAC name in the CLH dossier, and that therefore the correct substance had been considered. He pointed out that while the name diisohexylphthalate (DIHP) is not strictly correct, it could be used to mean CAS no. 68515-50-4 / EC no. 271-093-5 for the purposes of the discussion.

The substance currently has no harmonised classification in Annex VI to the CLP Regulation. The DS had proposed a harmonised classification as Repr. 1B, H360, without further specifying fertility or developmental effects in the hazard statement.

The Chairman invited the Rapporteurs to present the draft opinion, taking into account the comments received during the PC and the RAC consultation. During the subsequent discussions the RAC members recognised that DIHP also contained a proportion of linear D-n-hexyl phthalate which was previously recommended by the RAC to be classified as Repr. 1B, H360FD in Annex VI of CLP. In addition, they noted that the category approach for the substance had been well elaborated in the dossier, grouping 1,2-benzenedicarboxylic acid, dihexylester, branched and linear together with a range of other, similar C4 to C8 dialkylphthalates that all show effects on fertility and development. Accordingly, the RAC members agreed to classify the substance as Repr. 1B, H360FD, further specifying fertility and developmental effects in the hazard statement.

Finally, the RAC adopted the opinion for 1,2-benzenedicarboxylic acid, dihexylester, branched and linear by consensus. The Chairman pointed out that final revisions to reflect the discussions at RAC-25 and an editorial check would be performed before the opinions are published on ECHA's website.

e) Imazalil

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and reported that imazalil is an active substance mainly for post-harvest use on fruits. The CLH dossier was submitted by Germany. The legal deadline for adoption of the opinion is 20 February 2014.

Imazalil already has a harmonised classification as Acute Tox. 4*, H302, Acute Tox. 4*, H332, Eye Dam. 1, H318, Aquatic Acute 1, H400, and Aquatic Chronic 1, H410. The DS had proposed to add Carc. 2, H351, to upgrade the acute oral classification into Acute Tox. 3, H301, and to delete Aquatic Acute 1. They also proposed an M-factor = 10 for the remaining Aquatic Chronic 1 classification.

The Chairman, noting that the dossier was being tabled for a first discussion at a RAC plenary meeting, invited the Rapporteurs to present the draft opinion and the proposal for classification, based on the information in the dossier and the comments received during the PC.

The DS had included an acute toxicity study in the CLH dossier with LD_{50} values justifying classification as Acute Tox. 3 by the oral route. During the PC, an industry representative submitted data from two additional acute toxicity studies. The ECPA expert stated that these two studies had a Klimisch reliability score of 1 and indicated a classification of Acute Tox. 4 due to higher LD_{50} values, while the study referred to in the CLH dossier had a lower reliability. Hence, the two studies submitted during PC should determine the classification. The Rapporteur pointed out that IND had stated a reliability score of 1 for all studies in their IUCLID file submitted during PC, and hence there is no reason to dismiss the lowest LD_{50} value, justifying classification as Acute Tox. 3, H301. This was agreed by the RAC and Acute Tox. 3, H301, was concluded.

The RAC confirmed the Rapporteur's view on carcinogenicity that there was limited evidence in the dossier to warrant classification as Carc. 1B. The majority of the members agreed that the thyroid tumours seen do not warrant classification, since humans are less susceptible than rats to the mode of action (MoA) behind these tumours (liver enzyme induction). One member pointed out that there is a quantitative but not a qualitative difference between rats and humans, so these tumours could not be completely dismissed, but they are of low relevance to humans. In relation to the observed liver tumours and the postulated phenobarbital like MoA, the RAC concluded that this MoA could not be proven and that the relevance of the tumours seen in mice and rats could not be convincingly excluded. This conclusion was based on the information provided in the CLH dossier, including several in vitro and in vivo mechanistic studies, and also by assessing the new information submitted during the PC. It was further stated that there is no framework for evaluating possible phenobarbital like MoA, nor how to judge the relevance to humans of tumours known to be caused by such an MoA. The RAC asked ECHA for support on this, and it was agreed that ECHA would look into the possibility of producing a short review document for the use of the Committee. The RAC agreed on a classification into Carc. 2, H351, as proposed by the DS.

In relation to the aquatic hazard the RAC agreed with Germany to delete the aquatic acute classification, and to assign an M-factor of 10 to the Aquatic Chronic 1 classification

In relation to eye corrosion/irritation, the RAC re-confirmed the current classification for Eye Dam. 1, H318.

As Imazalil is an active substance in plant protection products, the Rapporteur also provided a review of the available information for other hazard classes than those considered above. For many hazard classes, i.a. reproductive toxicity, there was a lack of detailed information in the dossier and a conclusion on the classification could therefore not be drawn. While the RAC shared the view that further classifications could not be assigned for Imazalil based on the data provided in the CLH dossier, some RAC members expressed their dissatisfaction about not being able to conclude on a hazard class due to a lack of detailed information in the dossier. The Chairman responded that the Secretariat

would ensure a suitable phrasing for the hazards concerned in this opinion and for future opinions in order to ensure that a 'missing classification' could not be interpreted as a conclusion based on the proper evaluation of data.

Finally, the RAC adopted the opinion for Imazalil by consensus. The Chairman pointed out that final revisions to reflect the discussions at RAC-25 and an editorial check would be performed before the opinion was published on ECHA's website.

f) Tebuconazole

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and reported that tebuconazole is an active substance used as a fungicide for foliar and seed treatment applications on a wide range of different crops as well as in biocidal preparations. The CLH dossier was submitted by Netherlands. The legal deadline for adoption of the opinion is 20 February 2014.

Tebuconazole already has a harmonised classification as Repr. 2, H361d***, Acute Tox. 4* (minimum classification, H302), and Aquatic Chronic 2, (H411). The DS (the Netherlands) had proposed to convert the minimum classification into a regular classification for Acute Tox. 4, H302, and to change the aquatic classification into Aquatic Acute 1 and Aquatic Chronic 1, with an acute M-factor of 1 and a chronic M-factor of 10. Information on other hazard classes was not contained in the dossier and the RAC therefore limited its discussion to those indicated by the DS.

The Chairman invited the Rapporteurs to present the draft opinion and the proposal for classification, based on the information in the dossier and the comments received during the PC.

During the subsequent discussions, the RAC agreed with the DS proposal, i.e. to classify tebuconazole as Acute Tox. 4, H302, and Aquatic Acute 1 and Aquatic Chronic 1, with an acute M-factor of 1 and a chronic M-factor of 10.

One RAC member pointed out that additional detail on the chronic effects described in the fish sexual development test (FSDT) study provided in the context of the PC and its use as supportive information would need to be included in the RAC opinion. The Rapporteurs agreed to include this information in the Opinion.

The RAC adopted the opinion for tebuconazole by consensus. The Chairman pointed out that final revisions to reflect the discussions at RAC 25 and an editorial check would be performed before the opinion is published on ECHA's website.

g) Spirotetramat

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and reported that spirotetramat was 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 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 classifications.

The Chairman clarified that the dossier was being tabled for a first discussion at a RAC plenary meeting and that the Committee should agree on as many of the hazard classes as possible. He then invited the Rapporteurs to present the draft opinion and the proposal for classification, based on the information in the dossier and the comments received during the PC.

The subsequent discussion was mainly devoted to fertility. While there was agreement that clear effects which are not secondary to other toxic effects, could be seen in the male reproduction system in rats, the relevance to humans of the observed effects could not be clarified. Some RAC members expressed a preference for Repr. 1B based on the fertility effects observed, while others favoured Repr. 2. According to the ECPA expert, the effects

seen in rats are species specific due to differences in the toxicokinetics and metabolism of the substance between rat, mice and human. He considered that the unique rat metabolite profile causes a saturation of elimination pathways at very high doses, which is due to specific metabolite interactions at organic anion transporter proteins and due to an inefficient conjugation of the enol. Both features increase the steady state concentrations of the testicular toxicant (i.e. the enol) in rats, whereas mice and humans did not demonstrate these metabolic characteristics. Several RAC members requested time to look further into this data as well as more details on test conditions, concentrations/doses used etc. The expert accompanying the ECPA stakeholder observer was requested by the RAC members and agreed to summarise the relevant mechanistic information, preferably by the end of July, in order to make it available prior to further RAC consultations and discussion at RAC-26.

As to other hazards, the RAC agreed to classify spirotetramat for respiratory tract irritation (STOT SE 3, H335), for eye irritation (Eye Irrit. 2, H319) and for skin sensitisation (Skin Sens. 1A, H317). The RAC also concluded that classifications for STOT RE, for mutagenicity, for carcinogenicity as well as for physical hazards were not warranted.

The Chairman proposed to postpone the discussions about development and the aquatic hazards to the RAC-26 plenary, at which time the discussions on fertility would be continued. The RAC agreed to this proposal.

h) Dimethenamid-P

The Chairman provided a short summary noting that this active substance is used as a herbicide. He noted that the effects of racemic (R,S)-Dimethenamid had been tested extensively prior to the discovery of the superior properties of the S-isomer which is now used for its herbicidal properties. The deadline for adoption of the opinion is 22 April 2014 and it has currently no entry in Annex VI of the CLP Regulation.

The DS (Germany) had proposed to classify the substance as Skin Sens. 1B; H317, Acute Tox. 4; H302, Aquatic Acute 1 and Aquatic Chronic 1; H400 and H410; M=10 for both. During the PC general support had been provided in favour of the DS proposal. However, the Rapporteurs came to the conclusion that classification for skin sensitisation category 1 would be more appropriate. During the RAC consultation some comments had been received from the members of RAC regarding the need to discuss the possible reproductive effects (developmental toxicity) of dimethenamid-P. The Rapporteurs included an evaluation of reproductive toxicity in the 2nd version of the ODD.

The Chairman invited the Rapporteurs to present the draft opinion and reply to the RAC comments and then opened the discussion. The RAC agreed to classify the substance as Skin Sens. 1, H317; Acute Tox. 4; H302; Aquatic Acute 1, H400; M=10 and Aquatic Chronic 1, H410; M=10. The Committee also decided that the available data sufficiently justified no classification for developmental toxicity.

The RAC adopted the opinion on dimethenamid-P by consensus.

i) Carvone

Carvone is a terpenoid composed of two enantiomers with slightly varying fragrances. Carvone (d/l) is found naturally in many essential oils and is used as a flavouring agent in food and a fragrance in personal care products. D-Carvone is used as a plant growth regulator, e.g. to prevent or regulate the sprouting of dormant starch potatoes. L-Carvone on the other hand is used as a mosquito repellent. The Annex VI entry will cover both the d/l mixture and individual d and l enantiomers.

This CLH dossier was submitted by the Netherlands and the legal deadline for the adoption of the opinion is 22 April 2014. The substance currently has no entry in Annex VI of the CLP Regulation. The DS (the Netherlands) had proposed to classify the substance as Skin Irrit. 2; H315 and Skin Sens. 1B; H317. During the PC comments received from industry disagreed with the proposed classification for irritation to the skin and the Rapporteurs

came to a similar conclusion. During the RAC consultation two comments were received in favour of no classification.

In addition, the Rapporteurs evaluated toxicity to reproduction (using the original study reports provided by the DS on the Rapporteur's request) and carcinogenicity, coming to the same conclusion as the DS (no classification). With regard to toxicity to reproduction however, the Rapporteur pointed out that the CLH report did not contain dose-response data and in this context he raised a question on how to interpret negative study observations, resp. how to summarise negative data adequately. The Secretariat agreed to consider the matter of interpreting negative study observations in a consistent manner and to inform the Committee afterwards.

One RAC member commented on the use of measured vs. nominal concentrations reported for environmental toxicity.

The RAC decided to classify the substance as Skin Sens. 1; H317 and also concluded that the criteria for classification of the substance as skin irritant were not fulfilled. Thorough examination of the substance for other endpoints also indicated that no classification was warranted.

The RAC adopted the opinion on carvone by consensus.

j) Tembotrione

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and reported that the substance is used as a herbicide against grasses and broad leaved weeds and that it currently has no entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of the opinion is 11 November 2013.

The DS (Austria) proposed to classify the substance for Skin sens. 1B; H317, STOT RE 2; H373, Aquatic Acute 1; H400 M=10 and Aquatic Chronic 1; H410, M=10 according to the CLP Regulation. As it is an active substance, in accordance with Art. 36(2) of the CLP Regulation, all physical and chemical properties, human health and environmental endpoints are considered in the CLH report.

The Chairman reported that this is the second discussion of the dossier and that the substance had been discussed at RAC 24 in March 2013, where the environmental classification had been agreed (i.e. Aquatic Acute 1; H400 M=100 and Aquatic Chronic 1; H410, M=10). Based on the discussion at RAC 24 related to specific target organ toxicity, more specifically the relevance to humans of tyrosinaemia in the rat, the draft opinion had been revised and subject to a 2nd RAC consultation. The Chairman invited the Rapporteur to present the revised draft opinion.

The Rapporteur briefly reminded the RAC of the discussion on skin sensitisation at RAC 24 and confirmed the proposed classification in category 1 (based on a study in Guinea pigs - Magnusson and Kligman Maximisation test performed in accordance with the OECD guideline 406). The Committee agreed to Skin Sens. 1 without further specification of the sub-category.

In accordance with the conclusions at RAC 24 the Rapporteur further assessed the available information on the relevance to humans of tyrosinaemia (the drug NTBC[1] causes tyrosinaemia and eye effects in some human patients). Concerning human sensitivity in relation to the animal data, this may be intermediate to that of the very sensitive rat and the insensitive mouse. The RAC therefore considered the rat data with some reservation due to the expected lower sensitivity of humans. Based on this assessment, it is proposed to classify tembotrione as STOT RE 2 based on the observed eye, kidney and liver effects.

Some RAC members commented that when considering NTBC, classification should not be based on this evidence alone as the effects had been observed in genetically pre-disposed human patients and data for the general population as a whole was absent. In response,

[1] (2-(2-nitro-4-trifluoromethylbenzoyl)-1,3-cyclohexanedione)

the Rapporteur explained that the effects of NTBC had been studied in many different species and in all of them tyrosinaemia was observed. In addition, one RAC member suggested that eye damage could not be dismissed only because of the pre-disposition of patients, while another RAC member explained that there was no direct dependence on genetic disorders and the occurrence of the effects. The ECPA expert recalled two position papers providing more detailed information on the concept of different types of tyrosinaemias, and on the special use of NTBC, an orphan drug administered to children from their first weeks of age to ensure survival and prevent formation of hepatocellular carcinomas. Moreover, ECPA expert explained that in humans, indications of eye effects have only been observed in children, not because children are more sensitive than adults, but because only children have been treated so far.. The RAC agreed to classify tembotrione as STOT RE 2 for eye, kidney and liver effects.

In addition to STOT RE 2, it was proposed to classify tembotrione for developmental toxicity based on effects on growth rate and skeletal findings. Tembotrione affects skeletal development in rats (variations) and rabbits (anomalies and variations), and decreases pre- and postnatal growth rates in rats, the likely MoA being tyrosinaemia. The ECPA expert questioned the relevance of the proposed classification as the effects were observed in the presence of maternal toxicity. One RAC member reminded the RAC of another study in which the effects had been observed in the absence of maternal toxicity. The RAC supported the Rapporteur's proposal for classification for reproductive toxicity (Repr. 2, H361d).

The opinion on tembotrione was adopted by consensus.

Flonicamid

The Chairman reported that flonicamid is an insecticide used on e.g. potatoes, wheat and apples. The substance does not currently have an entry in Annex VI of the CLP Regulation. He summarised the state of play with this dossier and reminded the Committee that at RAC-24 they had agreed on the following classifications proposed by the DS (France): Acute Tox. 4 and no classification for environment, leaving carcinogenicity for discussion at this meeting. There was also a request from members for additional clarification on the environmental classification and for historical control data (HCD) related to carcinogenicity to be provided by the DS and industry. This latter information was received and included in the revised draft opinion which was then opened for a RAC commenting round until 22 April 2013, a total of 4 RAC members providing comments.

In his presentation, the Rapporteur presented the key data relevant to support the conclusion for no classification for carcinogenicity. In the rat study there was no evidence of carcinogenic properties of flonicamid. An increased frequency of benign lung tumors (adenomas) was seen in CD1-mice. There is however a high spontaneous frequency of lung tumors in the CD1 mice strain, and it was noted that the spontaneous incidence was just below the incidence in flonicamid-treated CD-1 mice. The incidences of lung carcinomas in flonicamid treated CD-1 mice were within HCD. The RAC concluded that only the increased incidence of lung adenomas was statistically significant, and these tumours were concluded to be a strain specific effect and that the mechanism behind is not relevant to humans.

After taking into account the weight of evidence analysis the Rapporteur concluded that the low increase in frequency of benign lung tumors in a highly susceptible mice strain with a mechanism which is not relevant for other strains of mice or for rats does not constitute even limited evidence of carcinogenicity of flonicamid in animals. Since flonicamid was also shown to not increase frequency of benign and malignant tumours in rats, the Rapporteur concluded that there is not sufficient evidence to classify flonicamid as Carc. 2; H351 according to CLP.

The RAC members agreed with the conclusion proposed by the Rapporteur not to classify flonicamid as Carc. 2 although they proposed some additions to the justification contained

in the opinion. They proposed to reduce the importance of the references to the test results on isoniazid and the genetic susceptibility of CD-1 mouse.

The RAC agreed to the redrafted text of the opinion concerning the environmental classification ('no classification' as agreed at RAC-24) without further discussion.

The Chairman concluded that the RAC agreed classification of flonicamid as Acute Tox. 4 – H302 (Harmful if swallowed). Pending final editorial changes by the Rapporteur as requested by the RAC, the opinion on flonicamid was adopted by consensus and the Chairman thanked the DS and industry for providing the additional data in a timely manner.

5.3 Requests under Article 77(3)(c) – CLH dossiers

a) Phenolic benzotriazoles (UV-320 and UV-328)

The opinion was adopted via the written procedure (see AP.2 above).

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

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

5.5 General and procedural CLH issues

a) Alignment of the CLH opinion development process with the EFSA process

The Secretariat provided an update on the ongoing cooperation with EFSA on the alignment of the CLH process with the pesticide active substance approval process. The update focused on the pilot dossier (sulfoxaflor), which is currently subject to the ECHA CLH process and at the same time, to the approval process under Regulation (EC) No 1107/2009 (Pesticide Regulation). The Secretariat stressed that the alignment of the timing of the (public) consultations, of the information base for hazard assessment and of further steps during the evaluation phase would be crucial.

During the subsequent discussion, the ECPA stakeholder observer noted that industry would be interested to follow the alignment more closely. He indicated that Member State Competent Authorities (MSCAs) needed to consider further how to best deal with the alignment of the two processes in the case of pesticide active substances under the review programme.

The Chairman informed the Committee that the Secretariat would carry on updating the members about the progress of the pilot project.

b) Introduction of the Biocidal Products Committee

The Chairman of the RAC introduced the Chairman of the Biocidal Products Committee (BPC) Erik van de Plassche and asked him to inform the RAC members of the progress made in setting up the new Committee.

In relation to the alignment of the CLH opinion development process with the biocidal products active substance approval process, the Chairman of the BPC made clear that strict timelines apply throughout the process. He reported that contrary to pesticide active substances, a PC is only foreseen in exceptional cases (if the active substance is a potential candidate for substitution) under the Biocides Regulation[2]. As to the review programme for biocidal active substances, he pointed out that the Commission has recently proposed that in the future a CLH opinion for an active substance covered by the review programme would have to be adopted before the active substance enters the review process, requiring significant resources from the Member States to compile the CLH dossiers. This view was shared by some RAC members.

[2] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

The Chairman of the RAC indicated that the secretariat would update the Committee on any potential changes in workload for the RAC due to the biocides review programme.

6. Restriction

6.1 General restriction issues (joint RAC/SEAC session)

The Secretariat provided an update on upcoming restriction dossiers. There are currently two new substances in the Registry of Intentions (RoI):

- Sweden has submitted a new intention on Nonylphenol and Nonylphenol ethoxylates. Although Nonylphenol (NP) is not used in the manufacturing of the textile it could be unintentionally added to the textile in low concentrations from the degradation of Nonylphenol ethoxylate (NPE) in the manufacturing process. NPE is used for various purposes in the production of textile. It is a surfactant used for dispersion, emulsification, cleaning, etc. NPE degrades to NP mainly in the waste water treatment plant but this can thus also occur somewhere in the manufacturing process. The use of NPE within the textile sector in EU is restricted in concentrations equal or higher than 0,1% (if not used in closed systems) since 2005. The major part of textiles consumed within EU is however imported from suppliers outside the Union. The expected submission date is 2 August 2013.
- France has submitted an intention on Bisphenol A (BPA). The opinion from Anses published in April 2013 confirmed the health effects of BPA, particularly for pregnant women in terms of potential risks to the unborn child. Some exposure situations, mainly related to the handling of thermal paper (cash register receipts, credit card receipts, etc.), leading to potential risk for human health have been identified. Therefore, the scope of the restriction will be the use of BPA in thermal paper. The expected submission date is 17 January 2014.

The Chairman mentioned that the calls for (co-)rapporteurs for the Bisphenol A restriction dossier would be launched shortly after RAC-25/SEAC-19.

The Chairman informed the Committees that the Secretariat had done the editorial revision of the opinion template for restrictions and had included a possibility to describe uncertainties following the recommendation of SEAC in the template. The revised opinion template had been uploaded to CIRCABC Interest Groups of both Committees.

6.2 Restriction Annex XV dossiers

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

The Chairman welcomed the DS representatives from the Swedish MSCA (one representative followed the discussions in person at the meeting and others remotely as observers).

The Chairman introduced the current stage of the opinion development for the restriction proposal on the placing on the market of lead and its compounds in articles intended for consumer use, submitted to ECHA in December 2012. The proposal is targeted at consumer articles that could be placed in the mouth by children, considering that children are the most vulnerable group. Lead compounds (but not elemental lead) are classified as toxic to reproduction, category 1 and 2. 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 and this health risk cannot be adequately controlled with the existing EU legislative measures. Following the RAC conclusion in March 2013 by the RAC that the dossier was in conformity, PC was launched on 21 March 2013. The RAC commenting round on the dossier closed on 10 May 2013, with three comments received. The first version of the RAC draft opinion was provided to the Committee on 17 May 2013, with the written commenting round finishing by 7 June 2013. The aim of the discussion at this meeting was to agree on the main elements presented in the first version of the RAC opinion.

The RAC Rapporteurs presented the first version of the draft RAC opinion by mainly focusing on the definition of 'placing in mouth', possible derogations, lead content in articles as well as appropriate mouthing times.

In general terms, the RAC agreed with the hazard assessment in the restriction proposal for neurotoxicity from the repeated lead exposure as the key effect to be protected against.

More specifically, the RAC supported the general approach taken based on the scientific principles laid down by the previous RAC opinion on lead in jewellery (2010) as well as the risk assessment of European Food Safety Agency (2010) in which a lower benchmark dose level (BMD(01)) of 0.5 µg Pb/kg bw/d was derived as a dose descriptor for the potential adverse effects of lead on children. The most sensitive end-point is the related negative impact on IQ levels from repeated lead exposure. It was considered that IQ impairment from the exposure is well justified, and the Rapporteurs recommended it would not be justified to change this unless new data were available. However, members pointed out that further assessment of the impact of the current restriction is needed.

Furthermore, the Committee supported that the concept of placing in the mouth (based on the technical guideline in the entry 52 of Annex XVII to REACH Regulation 1907/2006) can be helpful to define the articles covered by the proposed restriction, as also noted by the Rapporteurs. A stakeholder expert reminded the Committee that the impact of the proposed restriction on the lead industry is greater compared to the previous lead in jewellery case. The stakeholder expert also challenged the impact of the proposed restriction considering the validity of IQ test results and high lead content in blood levels due to the total exposure of lead which mainly originates from other sources (such as food and water intake).

To sum up, the Chairman concluded that the committee agreed on the basis for the hazard assessment as presented by the Rapporteurs in the first version of the RAC opinion.

The Rapporteurs then presented the mouthing times used in the exposure analysis for both realistic and reasonable worst case, based on the available studies. The RAC discussed the studies and concluded that they would not be directly inter-comparable due to their different nature. A few RAC members supported the use of a mouthing time of sixty-five minutes (this value being closer to that previously agreed for lead in jewellery), whereas others, including the Rapporteurs pleaded for a two hour mouthing time in line with the value concluded in the recent RAC discussions on DINP/DIDP.

Following further discussion of the different options for key mouthing times chosen in previous RAC opinions as well as the possibility of different mouthing times depending on the type of articles involved, the RAC proposed to take two hours as the mouthing time for all types of articles mouthed by children of all ages as a more conservative estimate. However, several RAC members called for the possibility to deviate from this mouthing time should a better justification be provided at a later stage of the opinion development. The Secretariat clarified that the mouthing times (both realistic and reasonable worst estimates) will be further elaborated together with the dossier submitter and the Rapporteurs. The most appropriate values will then be used in the exposure estimations and presented at the September plenary. In conclusion, the Chairman asked the Rapporteurs to provide a stronger justification for a suitable mouthing time in the second version of the draft opinion.

Considering the wide scope of the restriction proposal, the RAC discussed the wide range of articles as well as the various categories of articles in relation to the DTI (2002) study and the ProdCom databases[3] in order to better define what is included. Requested by the Committee, the DS clarified the type of articles included in the assessment and explained that plastic material (e.g. prints, buttons) on or in textile articles are included in the scope of the proposed restriction. Therefore, it was concluded that primarily consumer articles based on either metal alloys or plastics that can be placed in the mouth by children are

[3] Statistics on the production of manufactured goods, Prodcom Annual Sold (NACE Rev. 2).

included in the scope. Clothes and textiles as such are therefore excluded from the scope of the proposal. Furthermore, given the lack of more solid evidence for the time being and considering that the public consultation is still on-going, the RAC supported the proposed average lead content of one per cent in lead containing articles as well as the proposed market share of 10% of consumer articles containing lead or lead compounds (values based on the reported tests of selected articles).

The Commission representative requested clarification as to whether articles covered by other legislation are exempted from the proposal. The Secretariat clarified that the Background document will soon be updated by the DS, including among other matters, a clarification that articles covered by other legislation that regulate lead (i.e. food contact materials, toys, electric and electronic devices etc.) are excluded from the scope of the proposed restriction.

Furthermore, the RAC took note of the limit value of 0,05% which would be applied to metallic and non-metallic articles which can be placed in the mouth of children by the restriction. To this end, the DS had indicated their willingness to scrutinize the migration data and to summarise this on a material by material basis in the Background document.

In this context, the Commission representative drew RAC's attention to developments under the toy safety legislation where decreases in the currently applied migration limit of lead are expected, as well as to the lower limit values of lead in food contact materials under the food safety legislation, both of which should be taken into account.

A stakeholder observer pointed out that there is new migration data available from industry for some brasses and tin, suggesting that migration rates as well as the nature of migration (i.e. processes of different materials) differ per material and can be much lower than that used in the lead in jewellery restriction. This comment had also been submitted via PC. The stakeholder observers were encouraged to invite third parties to provide any additional information in the public consultation which will close by 21 September 2013.

In conclusion, the Rapporteurs were invited to take comments received into account in the second version of the draft opinion which is due by mid-August 2013.

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

The Chairman welcomed the DS representative from the Netherlands and informed the Committee that the DS would be allowed to briefly present the proposal before the (co)rapporteurs report on the outcome of the conformity check.

The Chairman reminded the Committee that the restriction dossier on NMP was submitted by the Netherlands to ECHA on 19 April 2013. The conformity check process was launched in RAC and SEAC on 10 May and the Committees were expected to reach a conclusion on conformity by 8 June 2013 at the latest.

The representative of the DS provided an introductory presentation on the proposal. The Annex XV dossier proposes a restriction on the manufacture and use of NMP in professional and industrial applications. According to the proposal, NMP may only be manufactured and used if it can be guaranteed that the exposure (as an 8-hr time weighted average, TWA) would remain below 5 mg/m³; peak exposure would remain below 10 mg/m³ and protective clothing and gloves would be used. Consumer use is not included. NMP is classified as a reprotoxic substance category 1B based on developmental toxicity, but is also classified as skin, eye and respiratory irritant. The aim of the restriction proposal is to control the risks resulting from exposure of expecting mothers and the dossier describes that exposure to NMP may result in reduced birth weight of the newborns or stillbirth. The risk resulting from the exposure of pregnant women to the substance cannot be adequately controlled with legislative provisions currently in place in EU.

The representative of the Commission asked whether the DS had any data from MSs related to observed health effects resulting from exposure to NMP, to which the DS replied that they had no information on evidence of risk in any MS. The Commission

representative also pointed out the possible need to differentiate between industrial and professional use, as the exposure might be different. The DS responded that they had considered a possibility to differentiate while preparing the proposal, however, it was not clear what exactly is considered as professional and as industrial use and it would also cause difficulties for enforcement authorities to control compliance with such a restriction.

The RAC stakeholder observer from EEB suggested that the combination of a ban of some uses and a lowering of the OEL may be considered as well, as some SMEs may have a problem with compliance with such a low OEL. The DS responded that such an option could be considered, but there are alternatives available and this should be kept in mind.

The RAC (co-)rapporteurs presented the outcome of the RAC conformity check and recommended that the dossier would be considered not in conformity. This was due to the fact that the Annex XV report does not appear to present sufficient information to allow an independent assessment of the hazards. The RAC (co-)rapporteurs explained that the toxicity studies are generally described quite briefly in section B5.9 of the report, with the effects described as increases or decreases without indicating the magnitude of the effect, thus not allowing an independent assessment of the data. For the worker DNELs, there is quantitative information for 2 out of 7 studies for which DNELs have been calculated. For the pregnant worker DNELs, there is quantitative information for 3 out of 5 studies for which DNELs have been calculated. Looking at the 4 studies that have led to the 4 final DNELs, quantitative dose-response information is missing for 1 study (BASF 1994), this being the basis for the worker inhalation DNEL. Minimum requirements would be to add such information for the BASF study (1994), resulting in the inhalation worker DNEL, and for the Solomon study (1995), which is the basis for a DNEL, which is supporting the DNEL driving the exposure level in the restriction proposal and also seems to be the basis for the current OEL. The recommendations from the RAC (co-) rapporteurs to the DS related to the wording of the proposed restriction, hazards, exposure and enforceability were briefly listed. Considering the fact that the restriction proposal is based on the value of DNEL, it is very important that the derived value is well justified in the proposal, and closely scrutinised by the Committee.

One RAC member expressed the view that the RAC should not demand that well known studies are incorporated into the Annex XV report, but providing the references should be sufficient. Another member, however, pointed out that if data is not included in the dossier, it might take several days from the (co-)rapporteurs to prepare the data sets – he therefore expressed support to the (co-)rapporteurs' decision to consider the dossier not in conformity and ask the DS to include all necessary data in the dossier. The (co-)rapporteurs highlighted that the BASF study is not publicly available. Several RAC members indicated support to the (co-)rapporteurs' conclusions on non-conformity of this restriction proposal.

The RAC agreed that the dossier on NMP thus does not conform to the requirements of Annex XV. The Chairman informed the participants that following the discussion and the conclusion of SEAC on conformity, the Secretariat would communicate the results of the conformity check and recommendations to the DS.

6.3 Appointment of (co-) rapporteurs for restriction dossiers

The Secretariat presented and the RAC took note of the pool of (co-)rapporteurs for the restriction dossier on chrysotile (to be submitted by ECHA by 17/01/2014). The Chairman encouraged interested RAC members to come forward as volunteers to be included in the pool.

The Secretariat presented and the RAC agreed on the recommendation of the Chairman (RAC/25/2013/03 confidential) for the appointment of (co-) rapporteurs for the nonylphenol restriction dossier which will be submitted by Sweden by 2/08/2013.

7. Authorisation

7.1 Capacity building

The Chairman invited the Secretariat to present to the Committee the tasks of the RAC in evaluating Applications for Authorisation (AfA) as a further reminder of the upcoming work concerning the AfA process. The presentation summarised the tasks of the RAC and the need for continuous cooperation between the RAC and SEAC, highlighted the essential supporting role of the Secretariat foreseen in the whole process and referred to the time schedules.

The members then asked the Secretariat a series of questions : a) how new information will be included in the process (an annex to the application, a new submission of the application or an update of the application), b) if there is any analysis of how much time Rapporteurs will need to prepare one opinion, c) how the Secretariat is going to support them in understanding the technical aspects of the application and all the uses involved, d) how the 8 weeks PC period can be used to build sufficient knowledge about cases among the Rapporteurs and e) the issue of consistency between different opinions on the same substance was also raised.

The independence of the Committee's opinions was also briefly discussed; some members asked for clarification on how the Committee can prepare independent opinions while at the same time it is not recommended that the members will do their own literature search especially on the analysis of alternatives.

Closing this discussion, the Chairman thanked the Secretariat for their presentation and then invited the invited expert on the ECHA sponsored project "Services to support the assessment of remaining cancer risks related to the use of chromium- and arsenic-containing substances in Applications for Authorisation" to provide an introductory presentation on this capacity building project. The invited expert informed the Committee about dose-response characterisation for cancer, the quantification of risk of cancer, the mathematical models which could be selected, the tasks defined in the project and the anticipated key issues. The project initiated in May. The main part of the project will be done in June-August. At RAC-26 a presentation is scheduled of the results and/or proposals provided to the Committee. After refinement and finalisation, the project will be completed in November 2013.

After the presentation a RAC member informed the Committee about the publication of the report on dose-response curves for non-threshold carcinogens[4]. He informed also that on national level a discussion on dose-response curves was being held. One of the RAC stakeholders advised that a similar project on inorganic arsenic had been carried out by the United States Environmental Protection Agency[5]. Another RAC member noted that the problem for many years is that there is no new epidemiological data available. At the Chairman's request the invited expert confirmed that for the RAC meeting in September there would be sufficient material available for discussion in the Committee.

7.2 Recommendation of the review period in applications for authorisation

[4] Seidler A. et al., (2012). Systematic review and quantification of respiratory cancer risk for occupational exposure to hexavalent chromium, Int Arch Occup Environ Health, DOI 10.1007/s00420-012-0822-0

Pesch B. et al., (2013). Re: Seidler A, Jänichen S, Hegewald J et al. Systematic review and quantification of respiratory cancer risk for occupational exposure to hexavalent chromium, Int Arch Occup Environ Health, DOI 10.1007/s00420-013-0887-4

Seidler A. et al., (2013). Reply to: Pesch B, Weiss T, Pallapies D, Schlüter G, Brüning T. Letter to the editor. Re: Seidler A, Jähnichen S, Hegewald J, Fishta A, Krug O, Rüter L, Strik C, Hallier E, Straube S. Systematic review and quantification of respiratory cancer risk for occupational exposure to hexavalent chromium, Int Arch Occup Environ Health, DOI 10.1007/s00420-013-0888-3

[5] http://www.epa.gov/iris/publicmeeting/arsenic/arsenicmtg_agenda.htm, http://www.epa.gov/iris/publicmeeting/arsenic/iAs%20Workshop%20Session%203%20Slides.pdf

The Secretariat presented the note on the Committees' recommendation of the review period in AfA to a joint session of the RAC and SEAC. "Normal", "short" and "long" review periods were proposed as the starting point for the recommendation. The Secretariat had intended to propose 8, 4 or 12 year review periods for agreement at this meeting. However, due to the link between the opinions of the Committees and the Commission decision, the Commission services had requested more time to review the note in order to ensure that the review period recommended in the opinions matches with their own considerations.

The representative of the Commission confirmed their support for the general idea of the recommendation and the proposal to differentiate between "normal", "short" and "long" review periods.

One representative from an industry stakeholder organisation (Cefic supported by Eurometaux) remarked that the ECHA proposal recognised differences in the industrial world and would discourage rumours about the length of review periods. He also recognised the recommendation to be helpful for industry in undertaking an analysis of alternatives, and expressed industry's preference for a four year review period as a minimum, taking into consideration the time needed for switching to alternative substances and actions/permits which may be required under other legislation. A representative of another stakeholder organisation (ETUC) expressed the opinion that eight and 12 year periods were too long for granting an authorisation.

The Committee members supported the principal proposal of "normal", "short" and "long" review periods. For some, the starting point might be the "short" as opposed to the "normal". Concerning the length of the review periods, members had different views. Several members thought that the proposed review periods were too long and would not give enough pressure for substitution. Others considered the lengths reasonable. There was some discussion about whether the length of the review period should be based on socio-economic or political considerations. It was noted that any political elements would be taken up by the Commission at the decision making stage, while the Committees needed to base their recommendation on the review period on scientific evaluation of the socio-economic considerations set out in the application.

The Commission confirmed that it expects to receive a clear recommendation by the Committees on the review period based on scientific reasoning.

The Chairman concluded that the Committees agreed on the overall approach for setting the review period. The Committees will reflect on the appropriate number of years for the "normal", "short" and "long" review periods, and if there are exceptional circumstances to justify deviating from these. It was agreed that the Secretariat would table the revised document for discussion and agreement at September 2013 plenary meetings.

7.3 Working Procedure for the RAC and SEAC on appointment of (co-)rapporteurs for applications for authorisation

The Secretariat presented to the Committees the revised working procedure for appointment of (co-)rapporteurs for AfA by RAC and SEAC. The Committees agreed on the revised working procedure as proposed.

7.4 Appointment of (co-)rapporteurs authorisation applications

Following adoption of the Working Procedure for the RAC and SEAC on appointment of (co) rapporteurs for applications for authorisation, the Committee members expressed their interest by applying to the pool of rapporteurs and indicating absence of conflict of interest. The pool of Rapporteurs, as outlined in the confidential room document RAC/25/2013/06, had been agreed by the plenary without discussion. The Secretariat noted that there are three substances on the Annex XIV of the REACH Regulation for which none of the RAC members showed interest (acids generated from trioxide and their

oligomers, ammonium dichromate and sodium chromate) and requested members to consider volunteering again.

8. RAC Manual of Conclusion and Recommendations

The Chairman introduced the topic by recalling the history and current status of the Manual of Conclusions and Recommendations. He gave the floor to the Secretariat who proposed a way forward with the Manual. During the subsequent discussions workload issues, the transient character of a Manual and overlaps with technical guidance were raised. It also became clear that the RAC members, while expressing the need for consistent opinions, preferred to have an informal, non-public document as an *aide memoire* for the use of the membership only; this was particularly supported by the newer members.

After the Chairman had summarised key points of the discussions, he proposed that the Secretariat come up with a much simplified proposal which takes account of the preferences of the Committee.

9. AOB

a) Stockholm Convention decision on hexabromocyclododecane (HBCDD) – relevance for annex XIV

Upon a question from one RAC member on interactions of the REACH provisions for HBCDD and the process under the Stockholm Convention on Persistent Organic Pollutants (POPs)[6], the Commission observer explained that HBCDD was recommended by the Persistent Organic Pollutants Review Committee (POPRC 8) to be included in Annex A of the Convention, which implies that parties must take measures to eliminate the production and the use of a chemical. In parallel to this process, the substance was included to Annex XIV of the REACH Regulation for its PBT properties. The Commission considers using in this case the interim opt-out option of the Convention and await the outcome of the last submission window for applications for authorisation. In future, the Commission as well as Member States need to closely monitor both processes and ensure the consistency between them.

[6] Stockholm Convention on Persistent Organic Pollutants - an international environmental treaty, signed in 2001 and effective from May 2004, that aims to eliminate or restrict the production and use of persistent organic pollutants (POPs).

07 June 2013

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
RAC 25, 04-07 June 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/25/2013**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC 25 minutes.
4. Report from other ECHA bodies and activities	
4a. Report on RAC 24 action points, written procedures and other ECHA bodies **SECR** presented document RAC/25/2013/01, containing the reports from MB-29 (21-22 March), SEAC-18 (6-8 March), MSC-29 (24-25 April), BPC-1 and -2 (Biocidal Products Committee) (26-27 March and 29-30 May), Forum-14 (19-21 March) and the Forum Working Group meetings.	**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-25 meeting on CIRCABC.
5. Harmonised classification and labelling (CLH)	
5.1. Sensitization criteria following the 2nd ATP to the CLP Regulation **RAC** decisions on sensitisation and the interpretation of the skin sensitisation criteria (Cat 1 vs. Cat 1A/1B) following the 2nd ATP to the CLP Regulation has been provided to the Committee.	**SECR** to upload the presentation to the CIRCABC non-confidential website.
5.2a. Etridiazole (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**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 rapporteur.

	SECR to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.2b. Metosulam (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in Table 1 below.	**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.
5.2c. Organic acids	
5.2c. a) Octanoic acid RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. 5.2c. b) Nonanoic acid RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. 5.2c. c) Decanoic acid RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**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 rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.2d. Diisohexylphthalate (DIHP)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**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 rapporteur if necessary. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.2e. Imazalil (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**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 rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.2f. Tebuconazole (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in Table 1 below.	**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 rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.2g. Spirotetramat (ISO)	
RAC agreed on the classification and labelling for the hazard classes as indicated in bold in Table 2 below. Discussions on fertility, development and the aquatic hazards will be continued at RAC-26.	**SECR** to clarify open issues pertaining to fertility. **Rapporteurs** to revise the draft opinion following the clarification of open issues. **SECR** to circulate the revised draft opinion to RAC before RAC-26.
5.2h. Dimethenamid-P (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteurs** to revise the opinion in accordance with the discussions in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1i. Carvone (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification as indicated in Table 1 below.	**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.
5.2j. Tembotrione (ISO)	
RAC adopted by consensus, the opinion with a proposal to classify for Skin sensitisation, STOT RE and for toxicity to reproduction as indicated in Table 1 below.	**Rapporteur** to revise the ODD based on the RAC discussion. **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.
5.2k. Flonicamid (ISO)	
RAC adopted by consensus, the opinion with a proposal to classify for Acute Tox. 4 as indicated in Table 1 below.	**Rapporteur** to revise the ODD based on the RAC discussion. **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.

5.4 Appointment of RAC (co-)rapporteurs for CLH dossiers	
Call for expression of interest of (co-) rapporteur volunteerships for CLH dossiers listed in document **RAC/25/2013/02 (confidential room document)**.	**SECR** to launch the written procedure for the agreement of appointment of (co-rapporteurs).
5.5. General and procedural CLH issues	
5.5a. Opinion development process	
i. From adoption of the CLH opinion until publication of the ATP RAC took note of the presentation by the Commission on the further processes the CLH is undergoing after its adoption and until publication of the Adaptation to Technical Progress to the CLP Regulation	
ii. Update on PPP alignment RAC took note of the presentation by the ECHA Secretariat.	**SECR** to update the Committee about the alignment pilot project on a regular basis.
iii. The Biocidal Products Committee: set-up and relevant processes for RAC RAC took note of the presentation by the Chairman of the Biocidal Products Committee.	**SECR** to update the Committee about the upcoming workload in due course.
iv. Hazard classes for CLH opinion development RAC took note of the presentation by the ECHA Secretariat.	
6. Restrictions	
6.2 Restriction Annex XV dossiers	
6.2a. Lead in consumer articles – 1st version of RAC draft opinion	
RAC rapporteurs presented the first version of the RAC opinion.	**Rapporteurs** to take comments into account in the second version of the draft opinion (due by mid-August 2013). **Rapporteurs** in cooperation with the Secretariat to submit a response to comments for distribution to RAC members.
6.2b. 1-Methylpyrrolidin-2-one (NMP) - outcome of the conformity check	
RAC agreed that the dossier does not conform 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 for Chrysotile and agreed on the appointment of (co-	**Members** to volunteer to be included into the pool of (co-

)rapporteurs for Nonylphenol (room document ***RAC/25/2013/03 (confidential)***).	)rapporteurs for Chrysotile.
8. RAC Manual of Conclusions and Recommendations	
SECR presented RAC Manual of Conclusions and Recommendations ***(RAC/25/2013/07)***	**SECR** consider the comments and to review the document at a later stage.
7. Authorisation	
7.1 Capacity building	
SECR presented tasks of RAC in Application for Authorisation process. Within the frame of As/Cr dose-response curves project **HSE** (contractor) presented their methodology and the key cancer studies.	**SECR** upload the presentations in the non-confidential folder for RAC-25 documents on CIRCABC.
7.2 Recommendation of the review period in applications for authorisation	
RAC and SEAC discussed the recommendation for setting the review period. RAC and SEAC agreed on the overall approach for setting the review period.	**SECR** to table the revised document for discussion and agreement at September plenary meetings.
7.3 Revised working procedure for appointment of (co-)rapporteurs for authorisation applications	
RAC and SEAC discussed and agreed on the revised working procedure for appointment of (co-)rapporteurs for applications for authorisation.	**SECR** to upload the document on ECHA website.
7.4 Appointment of (co-) rapporteurs for authorisation applications) closed session	
RAC agreed on the pool of rapporteurs for the applications for authorisation	**SECR** to upload the document on confidential folder on CIRCABC.
9. AOB	
a) Stockholm Convention decision on HBCDD – relevance for Annex XIV	
RAC took note provided by the Commission on possible interactions between the Stockholm Convention on Persistent Organic Pollutants and the REACH Regulation	
10. Action points and main conclusions of RAC-25	
	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

Etridiazole (ISO)
Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
613-133-00-X	etridiazole (ISO); 5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole	219-991-8	2593-15-9	Carc. 2 Acute Tox. 4 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H317 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H317 H410		 M = 1 M = 1	

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
613-133-00-X	etridiazole (ISO); 5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole	219-991-8	2593-15-9	Carc. Cat. 3; R40 Xn; R22 R43 N; R50-53	Xn; N R: 22-40-43-50/53 S: (2-)24-36/37-46-60/61		

Metosulam (ISO)

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
616-214-00-8	metosulam (ISO); N-(2,6-dichloro-3-methylphenyl)-5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidine-2-sulfonamide	-	139528-85-1	Carc. 2 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H373 (eyes, kidneys) H400 H410	GHS08 GHS09 Wng	H351 H373 (eyes, kidneys) H410		M=1000 M=100	

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
616-214-00-8	metosulam (ISO); N-(2,6-dichloro-3-methylphenyl)-5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidine-2-sulfonamide	-	139528-85-1	Carc. Cat. 3; R40 Xn; R48/22 N; R50-53	Xn; N R: 40-48/22-50/53 S: (2-)36/37-46-60-61	N; R50-53: C ≥ 0,025 %: N; R51-53: 0,0025 % ≤ C < 0,025 %: R52-53: 0,00025 % ≤ C < 0,0025 %	

Organic acids

Octanoic acid

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
607-708-00-4	octanoic acid	204-677-5	124-07-2	Skin Corr. 1C Aquatic Chronic 3	H314 H412	GHS05 Dgr	H314 H412			

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
607-708-00-4	octanoic acid	204-677-5	124-07-2	C; R34 N; R51-53	C; N R: 34-51/53 S: (1/2-)26-36/37/39-45-61		

Nonanoic acid

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
607-197-00-8	nonanoic acid	203-931-2	112-05-0	Skin Irrit. 2 Eye Irrit. 2 Aquatic Chronic 3	H315 H319 H412	GHS07 Wng	H315 H319 H412			

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
607-197-00-8	nonanoic acid	203-931-2	112-05-0	Xi; R36/38 N; R51-53	Xi; N R: 36/38-51/53 S: (2-)46-61		

Decanoic acid

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
607-709-00-X	decanoic acid	206-376-4	334-48-5	Skin Irrit. 2 Eye Irrit. 2 Aquatic Chronic 3	H315 H319 H412	GHS07 Wng	H315 H319 H412			

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
607-709-00-X	decanoic acid	206-376-4	334-48-5	Xi; R36/38 N; R51-53	Xi; N R: 36/38-51/53 S: (2-)46-61		

Diisohexylphthalate (DIHP)

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
607-710-00-5	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
607-710-00-5	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	271-093-5	68515-50-4	Repr. Cat. 2; R60-61	T R: 60-61 S: 45-53		

Imazalil (ISO)

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
613-042-00-5	imazalil (ISO); 1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1*H*-imidazole	252-615-0	35554-44-0	Carc. 2 Acute Tox. 3 Acute Tox. 4 Eye Dam. 1 Aquatic Chronic 1	H351 H301 H332 H318 H410	GHS08 GHS06 GHS05 GHS09 Dgr	H351 H301 H332 H318 H410		M=10	

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
613-042-00-5	imazalil (ISO); 1-[2-(allyloxy)-2-(2,4-dichlorophenyl)ethyl]-1*H*-imidazole	252-615-0	35554-44-0	Carc. Cat. 3; R40 Xn; R20/22 Xi; R41 N; R51-53	Xn; N R: 20/22-40-41-51/53 S: (2-)36/37/39-46-61		

Tebuconazole (ISO)

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
603-197-00-7	tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol	403-640-2	107534-96-3	Repr. 2 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H361d*** H302 H400 H410	GHS08 GHS07 GHS09 Wng	H361d*** H302 H410		M=1 M= 10	

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
603-197-00-7	tebuconazole (ISO); 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol	403-640-2	107534-96-3	Repr. Cat. 3; R63 Xn; R22 N; R50-53	Xn; N R: 22-50/53-63 S: (2-)22-36/37-61	N; R50-53: C ≥ 25 % N; R51-53: 2.5 % ≤ C < 25 % R52-53: 0.25 % ≤ C < 2,5 %	

Dimethenamid-P (ISO)

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
616-215-00-3	dimethenamid-P (ISO); 2-chloro-N-(2,4-dimethyl-3-thienyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide	-	163515-14-8	Acute Tox. 4 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H317 H400 H410	GHS07 GHS09 Wng	H302 H317 H410		 M=10 M=10	

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
616-215-00-3	dimethenamid-P (ISO); 2-chloro-N-(2,4-dimethyl-3-thienyl)-N-[(2S)-1-methoxypropan-2-yl]acetamide	-	163515-14-8	Xn; R22 R43 N; R50-53	Xn; N R: 22-43-50/53 S: (2-)24-37-60-61	N; 50-53: C ≥ 2,5 %: N; 51-53: 0,25 % ≤ C < 2,5 % 52-53: 0,025 % ≤ C < 0,25 %	

Carvone (ISO)

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
606-148-00-8	carvone (ISO); 2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one [1] d-carvone; (5S)-2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one [2] l-carvone (5R)-2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one [3]	202-759-5 [1] 218-827-2 [2] 229-352-5 [3]	99-49-0 [1] 2244-16-8 [2] 6485-40-1 [3]	Skin Sens. 1	H317	GHS07 Wng	H317			

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
606-148-00-8	carvone (ISO); 2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one [1] d-carvone; (5S)-2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one [2] l-carvone (5R)-2-methyl-5-(prop-1-en-2-yl)cyclohex-2-en-1-one [3]	202-759-5 [1] 218-827-2 [2] 229-352-5 [3]	99-49-0 [1] 2244-16-8 [2] 6485-40-1 [3]	R43	Xi R: 43 S: (2-)46-24-37		

Tembotrione (ISO)

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
606-149-00-3	tembotrione (ISO); 2-{2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl}cyclohexane-1,3-dione	-	335104-84-2	Repr. 2 Skin Sens. 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H361d H317 H373 (eyes, kidneys, liver) H400 H410	GHS08 GHS07 GHS09 Wng	H361d H317 H373 (eyes, kidneys, liver) H410		M=100 M= 10	

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
606-149-00-3	tembotrione (ISO); 2-{2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl}cyclohexane-1,3-dione	-	335104-84-2	Repr. Cat. 3; R63 R43 Xn; R48/22 N; R50-53	Xn; N R: 43-48/22-50/53-63 S: (2-)36/37-46-60-61	N, R50-53: C ≥ 0,25 % N, R51-53: 0,025 % ≤ C < 0,25 % R52-53: 0,0025 % ≤ C < 0,025 %	

Flonicamid (ISO)

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
616-216-00-9	flonicamid (ISO); *N*-(cyanomethyl)-4-(trifluoromethyl)pyridine-3-carboxamide		158062-67-0	Acute Tox. 4	H302	GHS07 Wng	H302			

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
616-216-00-9	flonicamid (ISO); *N*-(cyanomethyl)-4-(trifluoromethyl)pyridine-3-carboxamide		158062-67-0	Xn; R22	Xn R: 22 S: (2-)46		

Table 2. Agreed new or revised hazard classes, category and hazard statement codes in Annex VI, CLP and DSD[7]

Spirotetramat (ISO)
Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
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	**Skin Sens. 1A** **Eye Irrit. 2** **STOT SE 3** Repr. 1B (or 2) Aquatic Acute 1 Aquatic Chronic 1	**H317** **H319** **H335** H360Fd (or H361fd) H400 H410	GHS08 GHS07 GHS09 Dgr (or Wng)	**H317** **H319** **H335** H360Fd (or H361fd) H410		 M = 1 M = 1	

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
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	**Xi; R36-37** **R43** Repr. Cat. 2 (or 3); R60 (or R62)-63) N; R50-53	T; N R: **36-37-43**-50/53-60(or 62)-63 S: to be decided when opinion is adopted	**R43: C ≥ 0,1 %** N; R50-53: C ≥ 25 % N; R51-53: 2,5 % ≤ C < 25% R52-53: 0,25 % ≤ C < 2.5 %	

[7] Hazard classes, category and hazard statement codes are written in **bold** if they were agreed by RAC during the meeting. Discussions on other hazard classes with yellow back ground are still on-going.

Part III. List of Attendees of the RAC-25 meeting (4-7 June 2013)

RAC members	**ECHA staff**
BARANSKI Boguslaw	ATLASON Palmi
BARRON Thomasina	BARMAZ Stefania
BJORGE Christine	BOUSTRAS Georg
BORGES Teresa	BOWMER Tim
CARVALHO João	BROECKAERT Fabrice
Di PROSPERO FANGHELLA Paola	CSAK Viktoria
DUNAUSKIENE Lina	De BRUIJN Jack
DUNGEY Stephen	DVORAKOVA Dana
GREIM Helmut	ERICSSON Gunilla
GRUIZ Katalin	HELLSTEN Kati
HAKKERT Betty	HONKANEN Jani
JENSEN Frank	KIISKI Johanna
KADIKIS Normunds	KIOKIAS Sotirios
KAPELARI Sonja	KLAUK Anja
KORATI Safia	KOKKOLA Leila
LEINONEN Riitta	KOSK-BIENKO Joanna
LUND Bert-Ove	LOGTMEIJER Christiaan
PARIS Pietro	LUDBORZS Arnis
PASQUIER Elodie	MAGGIORE Angelo
PINA Benjamin	MERKOURAKIS Spyridon
POLAKOVICOVA Helena	MOSSINK Jos
PRONK Marja	MYÖHÄNEN Kirsi
RUCKI Marian	NYGREN Jonas
RUPPRICH Norbert	ORISPÄÄ Katja
SCHULTE Agnes	Van der PLASSCHE
SMITH Andrew	RIVERO Debora
SOERENSEN Peter	RODRIGUEZ IGLESIAS Pilar
STOLZENBERG Hans-Christian	ROGGEMAN Maarten
TADEO José Luis	SADAM Diana
TSITSIMPIKOU Christina	SOSNOWSKI Piotr
Van der HAGEN Marianne	SPJUTH Linda
VIVIER Stéphanie	THUVANDER Ann
Invited expert	VAINIO Matti
FAIRHURST Steve (invited expert for capacity building authorisation)	Van HAELST Anniek

Dossier submitters		ÖBERG Tomas
BEEKMAN Martijn (NL dossier submitter for NMP)		WIEMANN Christine, BASF (an observer acting as an expert to an observer representing ECPA for dimethenamid-P)
VASS Anne Marie (Swedish dossier submitter for lead in consumer articles)		**Remote participants**
Advisers (to the RAC members)		**RAC members**
ALESSANDRELLI Laura (Di Prospero Fanghella)		BRANISTEANU Radu
KORHONEN Hanna (Leinonen)		
NÚÑEZ Laura (Tadeo) adviser for CLH Rapporteurs for tembotrione		**Dossier submitters**
EKOKOSKI Elina (Leinonen)		GOMEZ Jeannette (NL DS for etridiazole, tebuconazole)
PECZKOWSKA Beata (Baranski) adviser for CLH Rapporteurs for flonicamid and etridiazole		GUNNARSDOTTIR Sjöfn (NL DS for etridiazole and tebuconazole)
ROMOLI Debora (Paris) adviser for CLH Rapporteurs for tebuconazole and carvone		HERMANN Georgia (DE DS for imazalil, dimethenamid-P)
EFSA observer		MÜLLER Andre (NL DS for etridiazole, tebuconazole, carvone)
PARRA MORTE Juan		STARK Christiane (DE DS for imazalil, dimethenamid-P)
Commission observers		
LUVARA Giuseppina		**Commission observers:**
SCAZZOLA Roberto (DG ENTR)		BERTATO Valentina (ENTR) for restrictions
LEFEVRE Remi (DG ENV)		GIRAL-ROEBLING Anne (ENTR) for restrictions
GALLEGO Mateo		ROZWADOWSKI Jacek (ENTR) for restrictions
Stakeholder observers		**Advisers:**
ROWE Rocky (ECPA)		GOMEZ-CONTRERAS Jeannette (adviser to RAC member Marja Pronk)
POOLE Alan (ECETOC) (only 4.6.2013)		GUNNARSDOTTIR Sjöfn (adviser to RAC members Betty Hakkert and Marja Pronk)
ANNYS Erwin (CEFIC)		HERINGA Minne (adviser to RAC members Betty Hakkert and Marja Pronk)

DOLORES Romano (EEB)		McGARRY Helen (adviser to RAC member Andrew Smith)
MUNARI Tomaso (EuCheMS)		SMITH Helen (adviser to RAC member Andrew Smith)
VEROUGSTRAETE Violaine (Eurometaux)		STARKE Sue-Martina (adviser to RAC member Hans-Christian Stolzenberg)
Other observers		**Excuses**
VARNAI Veda, Croatian observer		BRANISTEANU Radu (RAC member)
HARTMANN Kirstin, Bayer CropScience (an observer acting as an expert to an observer representing ECPA for tebuconazole)		MULLOOLY Yvonne (RAC member)
MARTENS Mark, Jansen (an observer acting as an expert to an observer representing ECPA for imazalil)		SCHLUETER Urs (RAC member)
NOMURA Masano, ISK Japan (an observer acting as an expert to an observer representing ECPA for flonicamid)		STASKO Jolanta (RAC member)
PAYRAUDEAU Virgine, Bayer CropScience (an observer acting as an expert to an observer representing ECPA for metosulam)		MORRIS Alick (SCOEL)
RAO Shaila, Chemtura (an observer acting as an expert to an observer representing ECPA for etridiazole)		TAYLOR Katy (ECEAE)
RYMAN Jessica, ILZRO (an observer acting as an expert to an observer representing Eurometaux for lead in consumer articles)		BARRY Frank (OECD)
SEMINO-BENINEL Giovanna, Bayer CropScience (an observer acting as an expert to an observer representing ECPA for tembotrione)		
TEMEROWSKI Michael, Bayer CropScience (an observer acting as an expert to an observer representing ECPA for spirotetramat)		

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

SEAC Members
ALEXANDRE João
BENDL Jiri
BOUSTRAS Georgios
BRIGNON Jean-Marc
DALTON Marie
DANTINNE Catheline
FANKHAUSER Simone
FEYAERTS Jean-Pierre
FIORE-TARDIEU Karine
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
GRANDI Silvia
KIISKI Johanna
KNOFLACH Georg
LUTTIKHUIZEN Cees
RODRIGUEZ DE SANCHO Maria Jesus
SCHUCHTAR Endre
SIMON Franz Georg
SLEZAK Zbigniew
STOYANOVA-LAZAROVA Elina Velinova
THIELE Karen
THORS Åsa
VOIVONTAS Dimosthenis

SEAC Advisors, Invited Experts, Dossier Submitters (DS) & Observers
CASTELLI Stefano (Invited Expert, IT)
COGEN Simon (Advisor to J-P. Fayaerts)
D'AMICO Flaviano (Advisor to S. Grandi, IT)
GOLOVACIOVA Llona (Invited Expert, LT)
HENNIG Philipp (Advisor to K. Thiele)
KORHONEN Hanna (Advisor to J. Kiiski)
LANGTVET Espen (Observer, NO)
PUES Jonathan (Advisor to C. Dantinne, via Webex)
SLETTEN Thea Marcelia (Invited Expert, SE)
VERHOEVEN Julia (Advisor to C. Luttikhuizen)

SEAC Stakeholder Observers
HOLLAND MIKE (EAERE)
JANOSI Amaya (CEFIC)
MOUCHEBOEUF Jean (UEAPME)
MUSU Tony (ETUC)
WATERSCHOOT Hugo (EUROMETAUX)

Representatives of the European Commission
BENGYUZOV Manol (DG ENTR)
GALLEGO Mateo (DG ENV)

ECHA staff
JACQUEMIN Katline
ORISPÄÄ Katja
ÖBERG Tomas
SADAM Diana

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-25 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-25 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-25 meeting

04/06/2013
RAC/A/25/2013

Final Agenda
25th meeting of the Committee for Risk Assessment

4-7 June 2013
ECHA Conference Centre (Annankatu 18, Helsinki)
4 June: starts at 9:00
7 June: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

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

RAC/25/2013/01
For information

b) RAC work plan for all processes

For information

Item 5 – Harmonised classification and labelling (CLH)

5.1 Sensitisation criteria following the 2nd ATP to the CLP Regulation

For discussion and agreement

5.2 CLH dossiers

a) Etridiazole
b) Metosulam
c) Organic acids
    a. Octanoid acid,
    b. Nonanoic acid,
    c. Decanoic acid
d) Diisohexylphthalate (DIHP)
e) Imazalil
f) Tebuconazole
g) Spirotetramat
h) Dimethenamid-P
i) Carvone
j) Tembotrione
k) Flonicamid

For discussion/adoption

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

RAC/25/2013/02 (confidential room document)

For agreement

5.4 General and procedural CLH issues

RAC/25/2013/05

For information/discussion

Item 6 – Restrictions

6.1 General restriction issues

For information

6.2 Restriction Annex XV dossiers

a) Lead in consumer articles – 1st version of RAC draft opinion

For discussion

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

For agreement

6.3 Appointment of (co-)rapporteurs for restriction dossiers

RAC/25/2013/03(confidential)

For information/agreement

Item 7 – Authorisation

7.1 Capacity building

For information

7.2 Recommendation of the review period in applications for authorisation

RAC/25/2013/08

For discussion/agreement

7.3 Revised working procedure for appointment of (co-)rapporteurs for authorisation applications

RAC/25/2013/04

For discussion/agreement

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

RAC/25/2013/06 (confidential room document)

For agreement

Item 8 – RAC Manual of Conclusions and recommendations

RAC/25/2013/07

For information/agreement

Item 9 – AOB

a) Stockholm Convention decision on HBCDD - relevance for Annex XIV

Item 10 – Action points and main conclusions of RAC-24

Table with Conclusions and Action points from RAC-24

For adoption

ANNEX II (RAC-25)

Documents submitted to the members of the Committee for Risk Assessment for the RAC-25 meeting.

Number	Title
RAC/A/25/2013	Final Draft Agenda
RAC/25/2013/01	Report on RAC 24 action points, written procedures and other ECHA bodies
RAC/25/2013/02 (room document, confidential)	Appointment of RAC (co-)rapporteurs for CHL dossiers
RAC/25/2013/03 (confidential)	Appointment of (co-)rapporteurs for restriction dossiers
RAC/25/2013/04 (confidential)	Revised working procedure for appointment of (co)rapporteurs for authorisation applications
RAC/25/2013/05	Evaluation of hazard classes during the CLH process by the Committee for Risk Assessment
RAC/25/2013/06 (confidential)	Appointment of (co)rapporteurs for authorisation applications
RAC/25/2013/07	RAC Manual of Conclusions and Recommendations
RAC/25/2013/08	Recommendations of the review period in applications for authorisation
RAC/25/2013/09 (room document)	Annex 3 – Records of the targeted public consultation on the carcinogenicity and the reproductive toxicity of Etridiazole

o0o

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

Name of participant	**Potential conflict of interest in relation to**	**Reason**
RAC members		
Bert-Ove LUND	Lead in consumer articles	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Elodie PASQUIER	Metosulam Flonicamid	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Norbert RUPPRICH	Imazalil Dimethenamid- P	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Agnes SCHULTE	Imazalil Dimethenamid- P Phenolic benzotriazoles (UV-320 and UV-328)	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Hans-Christian STOLZENBERG	Imazalil Dimethenamid- P	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA

o0o