RAC/M/23/2012
Final
8 February 2013

Final

Minutes of the 23rd Meeting of the Committee for Risk Assessment (RAC-23)

(27-30 November 2012)

Part I Summary Record of the Proceedings

1 Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 23rd meeting of the Committee for Risk Assessment (RAC). He informed the meeting that two new RAC members, João Carvalho and Safia Korati, had been appointed by the Management Board on 28 September 2012 and asked them to briefly introduce themselves. The Chairman then informed the meeting that two RAC members, Alicja Andersson and Zhivka Halkova, had resigned in October 2012 and thanked them both on behalf of the Committee for their contribution and long service since the start of its activities. Apologies were received from three members, one of whom took part in substance-related discussions by remote access, as did several other participants.

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. He 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 draft agenda (RAC/A/23/2012) was adopted with some modification; under Agenda item 8, Any Other Business, a discussion was requested on several procedural aspects, amongst which whether ECHA could launch (written) request for editorial, changes in adopted opinions, under which circumstances new public consultations can be launched, a request for transparent procedures regarding the feedback from expert meetings to the plenary meeting and procedural aspects regarding written comments to the minutes of RAC meetings. 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 conflicts of interest to any of the specific agenda items. Eight members, two stakeholder observers, one Commission observer and the RAC Chairman declared potential conflicts of interest, each to specific agenda items. These members did not participate in voting under the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. The Chairman did not participate in the Agenda item on formaldehyde. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

4 Report from other ECHA bodies and activities

a) Report on RAC 22 action points, written procedures and other ECHA bodies

The Secretariat informed the Committee on administrative issues as set out in room document RAC/23/2012/01, which included an overview of the adoptions, consultations, and agreements undertaken by written procedure since the last RAC meeting as well as 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).

5 Harmonised classification and labelling (CLH)

5.1 CLH dossiers

a) 3-Iodo-2-propynylbutylcarbamate (IPBC)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that IPBC is used as a biocide and currently does not have an entry in Annex VI to the CLP Regulation. The deadline for adoption of the opinion is 25 January 2013. The Dossier Submitter (Denmark) proposed the following hazard classes: Acute Tox. 3, H331, Acute Tox. 4, H302, Eye Dam. 1, H318, Skin Sens. 1, H317, STOT SE3, H335, Aquatic acute 1, H400, M=10 (N; R50) and Aquatic chronic 1, H410, M=1. During the public consultation, third parties proposed the following additional hazard classes: Skin irritation, STOT-RE, Carcinogenicity and Reproductive toxicity.

At RAC 22, the following hazard classes were agreed: Acute Tox. 4, H302, Acute Tox 3, H331 and Eye Dam. 1, H318. RAC also agreed at that time not to classify for acute dermal toxicity or skin irritation and concluded that the supplementary labelling "Repeated exposure may cause skin dryness or cracking" EUH066 (R66) was not appropriate as it is only relevant for solvents with defatting properties. RAC also agreed that the substance should be classified for skin sensitisation and that the classification provisions of the 2nd ATP containing new subcategories for skin sensitisation should be taken into consideration.

The Chairman then invited the Rapporteurs to present the draft opinion.

Based on the positive result of the Guinea Pig Maximisation Test (GPMT; Vohr, 2001) the Rapporteurs recommended RAC to classify the substance for skin sensitisation in the category 1A. Some RAC members supported the Rapporteurs but others questioned whether the negative results of the other GPMT study (Larsen, 1993) and the Buehler test could be dismissed. It was stated that the GPMT study did not fulfil the requirements of OECD TG 406 and the Buehler test is not as sensitive as the GPMT study. The expert accompanying ECPA expressed an opinion that due to the results of the human patch tests, which should be leading over the animal data, IPBC should be classified in sub-category 1B.

RAC members requested the Rapporteurs to indicate the doses used for induction and challenge in the GPMT test by Larsen (1993) and this information was duly presented by the Rapporteurs. It was considered that there were valid arguments to support classification in either sub-categories 1A or1B. RAC therefore agreed to classify IPBC as Skin sens. 1 without any division into sub-categories.

RAC agreed with the Dossier Submitter's proposal not to classify the substance for carcinogenicity and mutagenicity.

The Rapporteurs recommended not to classify IPBC for reproductive toxicity. RAC members asked for a more detailed presentation of the key studies concerning developmental effects and maternal toxicity and following presentation of additional information by the Rapporteurs and by industry, RAC agreed on no classification for reproductive toxicity for IPBC.

RAC also decided not to classify the substance for STOT SE considering that the observed effects in larynx were more appropriate for STOT RE 1 than for STOT SE 3. Concerning the environmental classification of IPBC, the Rapporteurs proposed to classify it as Aquatic Acute 1 with an M factor 10 and Aquatic Chronic 1 with an M factor of 10. The Rapporteurs considered that the data from the soil study did not represent degradation in the aquatic

environment and could not therefore overrule the results from the ready biodegradation test. RAC discussed the different tests submitted in the report regarding degradation. The reported ready biodegradability test shows that the substance is not readily degraded, however, the concentration of the test substance (50 mg/l) is close to the inhibition concentration of microorganisms (EC20 = 57 mg/l). On the other hand, the aerobic soil degradation study shows a rapid degradation of IPBC, and the result of this test is in agreement with other studies such as the inherent biodegradation test which can be used only as additional information because it had some deficiencies. Taking into account all the reported information and the expert judgment RAC concluded that IPBC is rapidly degradable in the aquatic environment. Therefore, RAC agreed to classify IPBC as Aquatic Acute 1 with M factor 10 and Aquatic Chronic 1 with M factor 1.

RAC adopted the opinion on the harmonised classification of IPBC by consensus. The Secretariat will make an editorial check of the opinion documents in consultation with the Rapporteurs and forward the adopted opinion and its annexes to the Commission and publish it on the ECHA website.

b) Formaldehyde

The Acting Chairman for this agenda item, Pilar Rodríguez Iglesias, welcomed two experts accompanying the CEFIC and ECPA stakeholder observers.

She reported that the substance was being discussed at a RAC plenary meeting for the second time, and that the revised draft opinion had been circulated prior to the meeting. During the recent revision of the draft opinion, the Rapporteurs focused on the justification of a classification for carcinogenicity based on epidemiological data, proposing Carc. 1B and in addition Muta. 2. The Acting Chairman invited one RAC member acting as the representative of the Dossier Submitter to explain the data and the applied weight of evidence for the classification into Carc. 1A as proposed by France. Afterwards the Acting Chairman asked the Rapporteur to present the weight of evidence and the justification for their proposal of Carc. 1B based on the epidemiological data and the animal studies.

During the discussion some RAC members expressed the view that both Carc. 1A and 1B could be justified. However, most members were in favour of Carc. 1B, choosing to base the classification largely on the animal data rather than the extensive but difficult to interpret epidemiological studies. No RAC member supported Carc. 2, although the experts accompanying the CEFIC and ECPA stakeholder observers provided several arguments in favour.

Following the agreement of the carcinogenicity classification, the Acting Chairman invited the Committee to discuss the mutagenicity hazard. It was recognised that a classification would have to be assigned based on the wording of the criteria in the CLP Regulation, even though it had been concluded that the substance is not likely to reach the germ cells. RAC finally agreed to classify formaldehyde as Muta. 2 while one RAC member announced that he would consider taking a minority position in favour of not classifying formaldehyde for mutagenicity depending on the final wording of the opinion. The acting Chairman noted this and requested the Rapporteur to include an appropriate wording.

RAC adopted the opinion on Formaldehyde. It was agreed to circulate the opinion with the final revisions to RAC for approval before it is published on the ECHA website.

c) Methyl-2,5-dichlorobenzoate

The Chairman welcomed the expert accompanying the ECPA stakeholder observer. He reported that the substance is a plant protection product (PPP) being used as a growth regulator and as a fungicide for grafting grapevines. The deadline for adoption of the opinion is 13 February 2013.

The substance does not currently have an entry in Annex VI to the CLP Regulation for harmonised classification and labelling. Following the public consultation, the Dossier Submitter (Germany) proposed classification and labelling as Acute Tox. 4, H302 and Aquatic Chronic 2, H 411. In addition to the above, the Rapporteur initially proposed classification as STOT RE 2, H373 (nervous system). The revised draft opinion based on the preliminary discussions was circulated prior to this meeting.

The Chairman reported that this is the second discussion of this substance in the Committee and that RAC had agreed at its 22nd meeting to classify the substance as Acute Tox. 4, H302 and had also started to discuss effects on the nervous system. The Chairman reported that the revisions related to classification for effects on the nervous system, such as paralysis, ataxia, sedation and coma, seen in acute and repeated dose oral toxicity studies and that the proposed additional classification had now been revised by the Rapporteur to STOT SE 3, H336 (CLP) as this was considered more appropriate. Two comments in support of this revised proposal had been received from members.

The Rapporteur presented the revisions to the draft opinion, considering the severe but transient findings of paralysis and ataxia reported in two repeated dose oral studies as clear evidence of toxicity to the nervous system. Comparable effects, plus sedation and coma, are seen in acute toxicity studies, at slightly higher doses, also causing lethality in some animals. As the effects in the repeated dose studies are transient, lasting from 10 minutes to six hours after dosing, and do not worsen with repeated dosing, STOT SE 3 was considered appropriate. RAC agreed with the Rapporteur and did not consider that classification with STOT SE 3 and Acute Tox. 4 would be a double-classification as some effects (paralysis in particular) occur below-lethal dose levels.

The environmental classification with Aquatic Chronic 2, H411 (CLP) proposed by the Dossier Submitter following the public consultation was supported by the RAC. Additional calculated data as well as an analysis of structural analogues were considered to substantiate the need for classification.

RAC adopted the opinion on methyl-2,5-dichlorobenzoate by consensus.

d) Cycloxydim

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and then reported that cycloxydim is used as a plant protection product, for which there is no current entry in Annex VI to the CLP Regulation (CLP). The deadline for final adoption of the opinion is 13 February 2013.

The proposal was first discussed at RAC-22. The Dossier Submitter (Austria) proposed classification with regard to only one hazardous property, flammability according to the criteria of Directive 67/548/EEC (Dangerous Substances Directive; DSD), (i.e. as highly flammable with F; R11).

The Chairman informed RAC that the Rapporteurs considered that reproduction should be considered by RAC and had presented two options at RAC-22: one suggesting classification with Repr. 2, H361d (developmental toxicity), while the other option would be no classification as proposed by the Dossier Submitter. During the written RAC consultation that followed RAC-22, the responding RAC members supported the Rapporteurs' proposal to further discuss the new option for classification in Repr. 2. In order to provide additional input to the RAC discussion, the Secretariat launched a written expert consultation based on specific questions related to the developmental toxicity findings. Two comments were received.

The Chairman then invited the Rapporteurs to present the draft opinion who proposed in agreement with the Dossier Submitter to classify cycloxydim as highly flammable with F; R11 according to DSD, and not to classify the substance for flammability according to CLP. The difference in the classification may be due to the fact that the criteria in CLP and DSD

refer to two slightly different test methods for flammability. RAC agreed with the proposed classification of cycloxydim for flammability according to DSD criteria.

Concerning reproductive toxicity, the Rapporteurs concluded based on results of the prenatal and pre-peri-postnatal toxicity studies (both on Wistar rats) that cycloxydim did not cause severe disturbance of general health conditions of treated dams at doses which caused reduced pup weights, reduced survival and skeletal effects. It is not reasonable to assume that developmental effects are solely a secondary effect. Also, a specific maternally-mediated mechanism is not known. Persistence of a skeletal anomaly until day 21 p.p. cannot be considered to be a minor developmental change. Therefore, classification of cycloxydim as Repr. 2, H361d (CLP) is justified according to the Rapporteurs.

Industry informed that according to their knowledge it was not clear if the skeletal anomalies were seen in the adult animals, but there did not seem to be any difference in the survival rate after postnatal day 21.

RAC also noted that the skeletal anomaly may be regarded as a structural malformation which may lead to functional impairments. RAC agreed to classify cycloxydim for Repr. 2, H361d (CLP).

RAC agreed with the Dossier Submitter's proposal supported by the Rapporteurs to not classify cycloxydim for environmental hazard classes.

RAC adopted the opinion by consensus proposing a harmonised classification of Repr. 2; H361d (CLP) and; F; R11 and Repr. Cat. 3; R63, (-DSD). The Secretariat will make an editorial check of the opinion documents in consultation with the Rapporteurs and forward the adopted opinion and its annexes to the Commission and publish it on the ECHA website.

e) Tetrahydrofurfuryl alcohol (THFA)

The Chairman welcomed the expert accompanying the Cefic stakeholder observer. He noted that THFA is widely used as intermediate, as a solvent and a plasticiser and has a harmonised classification in Annex VI to the CLP Regulation (Eye Irrit. 2, H319) and the legal deadline for adoption of the opinion is 24 May 2013.

The proposal submitted by France recommends a classification of Repr. 2 (H361fd) according to the CLP Regulation. The Chairman noted that this was a second discussion of the dossier at a RAC plenary meeting and invited the Rapporteur to present the revised draft opinion.

The Rapporteur noted that the available studies indicate that THFA may have adverse effects on reproductive toxicity for both fertility and development. The conclusion for fertility was based on testicular toxicity and delayed parturition as well as effects on pregnancy outcome, bearing in mind that the latter could be a direct or an indirect effect. For development, the revised draft opinion indicated that the toxicological relevance of the decreased foetal weight was uncertain as were the filamentous tail findings. The Rapporteur noted that the resorptions, decreased number of live pups born, number of live pups on postnatal day (PND) 0 and 4 as well as delivery & live-birth index at some doses were not due to maternal toxicity, and thus proposed that Repr. 1B would be more appropriate than Repr. 2.

In the discussion that followed, RAC confirmed its support for the proposed classification of tetrahydrofurfuryl alcohol as Repr. 1B, H360Df according to the CLP criteria. The classification for toxicity to reproduction under the CLP Regulation was explained for the benefit of the expert accompanying the Cefic stakeholder observer, who asked for clarification.

The opinion on tetrahydrofurfuryl alcohol (THFA) was adopted by consensus.

f) Fyrolflex ((1-methylethylidene)di-4,1-phenylene tetraphenyldiphosphate)

The Chairman reported that this substance is used as a flame retardant additive in thermoplastic resins for the production of components used in electrical and electronic goods. The legal deadline for adoption of the opinion is 24 May 2013. The substance currently has a harmonised classification as Aquatic Chronic 4, H413 (the so-called 'safety net' classification according to CLP). The Dossier Submitter, the UK on behalf of industry had proposed the removal of the harmonised environmental classification for consideration by RAC based on new studies. They justified this by the absence of ecotoxicological effects in the available aquatic toxicity studies up to the level of water solubility as well as by a low level of bioaccumulation of the substance shown in the available BCF tests.

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

The Rapporteur reported that the substance was initially classified as R53 according to the criteria of the DSD based on its low water solubility, not being readily biodegradable and having a log K_{ow}>3. New information on bioaccumulation, chronic toxicity in fish and daphnia would, however, warrant the removal of this classification.

The results of the two available BCF studies were 6.8 to 62 L/kg w.w. and ≤159 L/kg w.w., respectively and as such are both clearly below the cut-off value for bioaccumulation of ≥500 according to CLP. With a view to analytical limits of detection as reason for the limit value of ≤159, also the ≥100 criterion according to DSD can be considered not met. Therefore bioaccumulation is unlikely. Furthermore, in the available aquatic toxicity studies no toxicity could be shown up to the levels of water solubility. One RAC member, while agreeing with the proposed removal of the environmental classification, requested to better reflect the uncertainty of the aquatic toxicity test results related to the low water solubility and measured test concentrations of the substance in the opinion. The opinion will be revised by the Rapporteur in order to reflect the uncertainty of the aquatic toxicity test results related to the low water solubility and measured test concentrations of the substance.

RAC adopted the opinion on (1-methylethylidene)di-4,1-phenylene tetraphenyldiphosphate by consensus.

g) PX-200 (Tetrakis (2,6-dimethylphenyl)-m-phenylenebiphosphate)

The Chairman reported that the substance is used as a fire-preventing agent in electronic circuit boards. The legal deadline for adoption of the opinion is 11 November 2013. He informed RAC that the substance has an existing harmonised classification as Aquatic Chronic 4, H413 and as Skin Sens. 1, H317 while the Dossier Submitter (UK) proposed to remove the aquatic chronic classification, justified by the absence of eco-toxicological effects in all available aquatic toxicity studies and a (mainly QSAR-based) re-consideration of the bioaccumulation potential of the substance.

The Chairman reported that the substance was being discussed at a RAC plenary meeting for the first time and invited the Rapporteur to present the evaluation of the available evidence for the potential lack of an aquatic hazard.

The Rapporteur reported that there would not be sufficient conclusive evidence for the absence of bioaccumulation potential, based on the available information on the partition coefficient (> 6.2 measured and 11.79 based on QSAR calculations considered too uncertain), and a non-valid experimental BCF value. In addition, due to the very poor solubility of PX-200 and the absence of any effects in the available aquatic toxicity tests the Rapporteur considered there was limited but none the less adequate justification for removing the 'safety net' classification.

One RAC member stressed the importance of the test solution preparation technique in relation to the differences found in the level of test substance concentration achieved in

the chronic aquatic toxicity studies which was found to be orders of magnitude lower than in the available acute aquatic toxicity studies.

RAC adopted by consensus the opinion on PX-200, agreeing to remove the environmental classification. The opinion will be revised by the Rapporteur in order to reflect the discussions at RAC-23, e.g. to better explain the uncertainties concerning exposure, the weaker read-across and the confirmed absence of vertebrate toxicity. The Secretariat will make an editorial check of the opinion documents in consultation with the Rapporteur and if needed will consult the Committee before the opinion is published on ECHA's website.

h) Fenpyrazamine

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that fenpyrazamine is a plant protection product used as a fungicide in the control of grey mould (*Botrytis*). The legal deadline for adoption of the opinion is 24 July 2013 and the substance currently has no harmonised classification. The Dossier Submitter (Austria) had proposed to classify the substance as Aquatic Chronic 2, H411 (CLP), N; R51-53 (DSD) and not to classify for any other end points.

The Chairman reported that this was the first discussion of the substance at a RAC plenary meeting and invited the Rapporteurs to present their proposal based on comments received during the public consultation on the dossier or sent by RAC members with regard to the first draft opinion document.

The Rapporteurs presented their agreement with the Dossier Submitter's proposal to classify for Aquatic Chronic 2 and asked RAC to consider the available information on carcinogenicity.

The Dossier Submitter proposed no classification for carcinogenicity. A numerical increase in the tumour incidence was seen in thyroid gland and liver. The carcinogenic effects in the thyroid gland were concluded by the Dossier Submitter to be due to UGT induction, a pathway that according to the CLP guidance cannot be directly extrapolated to humans and therefore is not considered a sufficient concern to justify classification. RAC agreed to this conclusion. The Dossier Submitter further claimed that a small increase in liver tumours was due to a phenobarbital like mode of action (MoA), and would thus not be relevant for humans. RAC, however, concluded that the small increase seen in liver tumours was not sufficient for classification in any case and thus an evaluation of the MoA was not required. A phenobarbital-like mode of action (MoA) is not listed in the CLP guidance as not relevant for humans and while sceptical of its relevance, RAC did not draw any final conclusions on this MoA.

RAC adopted the opinion on fenpyrazamine by consensus.

i) Etofenprox

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and reported that the substance is used as a biocide (wood preservative and insecticide). The legal deadline for adoption of the opinion is 24 July 2013. He informed the RAC that the substance does not yet have a harmonised classification and that the Dossier Submitter (Austria) proposes a harmonised classification as: STOT RE 2 (liver, kidneys), Reproductive toxicity - effects on or via lactation (Lact.), Aquatic Acute 1 with an M-factor of 100 and Aquatic Chronic 1 with an M-factor of 1000. This proposal had been supported during public consultation, except for STOT RE 2. The Rapporteur agreed with the proposal by the Dossier Submitter in relation to lactation and the aquatic classification, but not to the proposed classification for STOT RE 2 (repeated dose toxicity). An additional labelling under DSD with R33 due to cumulative effects was proposed during public consultation, and the Rapporteur agreed with this proposal.

The Chairman reported that the substance was being discussed in a RAC plenary meeting for the first time and invited the Rapporteur to present the draft opinion and the evidence available in the dossier.

The Rapporteur argued that classification with STOT RE 2 was not warranted as the effects seen were not severe enough and occurred above the relevant guidance values. RAC agreed with the Rapporteur. The Rapporteur further argued that classification for effects on or via lactation was warranted as effects were seen in offspring exposed *in utero* and during lactation, but not in offspring exposed only *in utero*. It was further argued that toxicokinetic studies have shown that the substance is actively secreted into milk and ingested by pups at a 20 times higher concentration compared to the dams (concentration of substance in pup stomach content compared to maternal plasma). RAC agreed that classification for effects on or via lactation was justified, not only under CLP (as proposed by the Dossier Submitter) but also under DSD. There was a discussion on whether additional labelling with R33 under DSD would be required, but several RAC members disagreed, and it was decided not to add this labelling. RAC agreed that the environmental classification proposed was justified based on the available data and argumentation provided in the draft opinion.

RAC adopted by consensus the opinion on etofenprox.

j) Muscalure

The Chairman reported thatcis-tricos-9-ene (Muscalure) is a biocide, recently included in Annex I of Directive 98/8/EC (Product Type 19: Repellents and attractants) and does not currently have an entry in Annex VI to the CLP Regulation. The deadline for adoption of the opinion is 24 July 2013. He informed that the Dossier Submitter (Austria) proposed to classify Muscalure as Skin Sens. 1B, H317, (Xi; R43 under DSD).

The Chairman then invited the Rapporteurs to present draft opinion.

The Rapporteurs agreed with the Dossier Submitter to classify the substance as Skin Sens. 1B, H317. The proposal was based on the Guinea pig Maximisation test, conducted in compliance with GLP requirements according to OECD 406. All animals had skin reaction with intradermal induction of a 5% cis-tricos-9-ene in a mixture in corn oil and Freund Adjuvant and epidermal induction (challenge) with undiluted cis-tricos-9-en.. At challenge 7 out of 20 animals (35%) scored positive, although the skin reaction was seen later than expected. RAC supported the classification proposal.

Some RAC members questioned why other hazard classes were not assessed. The Rapporteur responded that there were either no data available or no classification proposal. For biocides, the Rapporteurs reminded the meeting that some studies are not necessary provided a full justification is given. RAC requested the Rapporteurs to insert a statement in the opinion to make it clear which endpoints had not been assessed by the RAC.

The Rapporteurs also agreed with the Dossier Submitter's proposal not to classify cis-tricos-9-ene (Muscalure) for environmental hazards. The substance is readily biodegradable, rapidly degradable and does not show aquatic toxicity. One RAC member expressed the opinion that the degradation assessment and read-across on analogue substances were insufficiently described but overall he agreed with no classification for environmental hazards.

RAC adopted the opinion on cis-tricos-9-ene (Muscalure) by consensus as proposed by the Dossier Submitter. The Secretariat will make an editorial check of the opinion documents in consultation with the Rapporteurs and will forward the adopted opinion and its annexes to the Commission and publish them on the ECHA website.

k) Dimethyltin dichloride (DMTC) and

l) Dimethyltin bis(2-ethylhexylmercaptoacetate) (DMT EHMA); 2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecan-1-oate

The Chairman reported that both substances are used as heat stabilizers or their components in PVC and currently do not have an entry in Annex VI to the CLP Regulation. The deadline for adoption of the opinions is 31 March 2013. A classification proposal was submitted and discussed by the Technical Committee on Classification and Labelling (TC C&L) for health endpoints in October 2006. A further study (Ehman, 2007) was published on the developmental toxicity of dimethyltin dichloride (DMTC) since the TC C&L discussions and has been integrated into the CLH report. The hazard classes proposed by the Dossier Submitter (France) were:

- ***DMTC***: Repr. 2, H361d, Acute Tox.3, H301, Acute Tox. 3, H311, Acute Tox.2, H330, Skin Corr.1C, H314, STOT RE1, H372 (nervous system).

- ***DMT EHMA***: Repr. 2, H361d, Acute Tox. 4, H302, Skin Sens. 1A, H317, STOT RE 1, H372 (nervous system)

The Rapporteur clarified that for Reproductive toxicity and Specific Target Organ Toxicity, no data are available for DMT EHMA. Instead, a direct read-across from DMTC is used. This is justified as DMT EHMA is reported to be rapidly hydrolysed in the stomach to form DMTC. Some members questioned the pH at which the gastric hydrolysis studies had been carried out at as being too low but accepted that the substance would hydrolyse. For other endpoints than Reproductive toxicity and Specific Target Organ Toxicity, read-across was not applied.

An additional classification for EUH071 (corrosive for respiratory tract) was proposed for DMTC during the public consultation. One RAC member asked the Rapporteur for further clarification on this proposed classification and whether it was justified in the opinion. DMTC is corrosive to the skin and toxic via inhalation. According to the guidance it should be classified as EUH071.

With regard to both DMTC and DMT EHMA, the Rapporteur proposed to classify both substances as Repr. 2, H361d due to uncertainties in the tests results of the maternal toxicity and developmental neurotoxicity studies. He was asked by RAC to add further justification as to why the substances should be classified as Repr. 2 as opposed to no classification and to point out in regard to the new developmental toxicity study that there is a clear toxic effect. RAC also recommended that the Rapporteur add a sentence that the cleft palates are not clearly related to the maternal toxicity. RAC therefore agreed to the classification of both DMTC and DMT EHMA as Repr. 2.

RAC considered that with regard to specific target organ toxicity the effects seen that warrant classification are calculated to be at or near the guidance values for STOT RE 1 for DMT EHMA. RAC recommended also that the immune system should be added as a target organ instead of thymus, based on effects seen in other organs of the immune system. The Rapporteur agreed to those recommendations.

RAC adopted the opinions on the harmonised classification of dimethyltin dichloride and dimethyltin bis(2-ethylhexylmercaptoacetate)by consensus. The Secretariat will make an editorial check of the opinion documents in consultation with the Rapporteur and forward the adopted opinions and its annexes to the Commission and publish it on the ECHA website.

m) Styrene

The Chairman welcomed an expert accompanying the CEFIC stakeholder observer. He noted that styrene is a high volume monomer used in plastics and rubbers. The deadline for adoption of the opinions is 8 April 2013. He reported that the substance was being discussed at a RAC plenary meeting for the second time and while at RAC-21 a classification for STOT RE 1 (hearing organs; inhalation) had already been agreed,

a decision on classification for reproductive toxicity needed to be made. The Chairman informed RAC that during the last RAC consultation round, three comments had been received relating to developmental toxicity and to maternal effects; overall, these comments suggested either classification as Repr. 2, H361d or no classification.

The Chairman then invited the Rapporteur to present the evidence on reproductive toxicity. The ensuing discussion mainly focussed on the significance of the effects on body weight and the findings in the 2-generation reproduction toxicity study. The issues raised included the extent to which the findings pointed to a consistent pattern of toxicity and whether or not they reflected developmental toxicity, as opposed to post-natal toxicity. On the other hand, it was also considered that the findings represented toxicological effects, which were detectable after cessation of direct exposure, and that overall the weight of evidence favoured classification as Repr. 2.

RAC adopted the opinion on styrene by consensus. It was agreed to circulate the opinion with the final revisions to RAC for an editorial commenting round before the opinion is published on ECHA's website.

5.2 Requests under Article 77(3) (c) - CLH dossiers

a) Gallium arsenide (GaAs)

The Chairman welcomed the expert accompanying the Eurometaux stakeholder observer and noted that GaAs is a semiconductor used in microelectronics industry.

He noted that this was the fourth discussion at a RAC plenary meeting of the draft opinion on reproductive toxicity of gallium arsenide initiated by an Article 77(3)(c) request from the Executive Director of ECHA[1].

In its opinion[2] of 25 May 2010, RAC supported the Dossier Submitter's proposal for classification of GaAs as Repr. 1B (CLP) for effects on fertility based on clear evidence in repeated dose toxicity studies showing testicular toxicity in two species, supported by a potential for gallium to accumulate in rat testis following inhalation exposure.

During the public consultation held on the basis of the second Art. 77(3)(c) request[3] which concerned the carcinogenicity of GaAs and in the information subsequently submitted by Eurometaux in December 2011, one of the referenced reports (Tanaka et al, 2000) showed some effects of GaAs on other organs than the testes (such as the lung) in the intratracheal study using hamsters by Omura et al (1996a). This was one out of four key studies demonstrating testis toxicity of GaAs. Industry had presented a hypothesis on a potential mode of action and later on in the opinion development process industry drew RAC's attention to a peer-reviewed scientific publication on this issue.

The Rapporteurs were requested at RAC-22 to revise the draft opinion based on the previous RAC discussions and written comments provided by RAC, so that it reflected the

[1]By the mandate from 21 December 2011, revised 17 April 2012 RAC is requested, pursuant to Art. 77(3)(c) of REACH, to: *Further to the evaluation of the information on toxicity to reproduction submitted during public consultation on carcinogenicity to take into account also information submitted by Eurometaux in December 2011 and draw up an opinion on the appropriate classification and labelling for reproductive toxicity accordingly*.

[2]ECHA/RAC/CLH-0000000792-73-03/F

[3]Mandate from the Executive Director of ECHA dated18 February 2011by which RAC was requested, pursuant to Art. 77(3)(c) of REACH, to: *Review and evaluate any information arising in the public consultation in order to decide whether it is new and relevant and to draw up an opinion accordingly to assist the Commission to decide on the appropriate classification of gallium arsenide in relation to carcinogenicity.*

evidence and all members' comments in a balanced way. The revised draft opinion had been subject to a RAC consultation before the RAC-23 plenary meeting. The Rapporteurs presented the available data and referred also to the additional summary paper which they had provided in order to respond in detail to questions raised by RAC. Their proposal to classify gallium arsenide as Repr. 2 was subsequently discussed.

Several RAC members raised their concerns that the hypothesis presented in which testis toxicity is caused by lung toxicity causing hypoxia had not been demonstrated convincingly enough. The absence of observations typical of a hypoxic condition (in the 14 week NTP inhalation study in mice and rats) as well as clinical effects, challenges the evidence of severe hypoxia as such. It was noted that there were alternative mode(s) of action for the testis toxicity, which could not be dismissed.

It was mentioned that it had not been shown that As accumulates in testes[4], which however, some RAC members did not see as sufficient evidence to exclude a specific testis effect of GaAs, even if it would be the case.

A number of RAC members also clearly expressed their view that the effects on testes even if considered secondary, cannot be seen as non-specific. On the contrary, the relationship between the lung toxicity and the toxicity to reproduction can be seen as rather specific and as such this would warrant classification as Repr. 1B according to the CLP criteria.

It was also noted that the effects on respiratory system were already known and different modes of action were considered in 2010 when the previous RAC opinion had been formulated.

The Chairman thanked the Rapporteurs and RAC for the discussion which clearly showed that a more broad based opinion considering all available information and comprising all arguments is needed. It was agreed that the Secretariat would briefly summarize the evidence and the discussions so far in order to facilitate the RAC members and to allow the Rapporteurs to broaden the opinion. The Secretariat will also inform the Executive Director of the current status of the opinion development and request the extension of the mandate. The revised draft opinion will be subject to a RAC consultation and will be distributed to RAC for further discussion at RAC-24.

b) Epoxiconazole

The Chairman welcomed the expert accompanying the ECPA stakeholder observer. He noted that epoxiconazole is used as a fungicide and briefly reminded the Committee of the mandate pursuant to Art. 77(3)(c) of REACH from the Executive Director of ECHA which requested RAC to develop and adopt an opinion on toxicity to reproduction of epoxiconazole, taking into account the previous RAC opinions[5], the additional information report (AIR) recently been provided by industry and the outcome of the public consultation on the above report.

Epoxiconazole is already harmonised in Annex VI of the CLP Regulation with a classification of: Carc. 2, H351; Repr. 2, H361fd and Aquatic Chronic 2, H411.

The Chairman noted that this was the second discussion at a RAC plenary meeting of the draft opinion on reproductive toxicity of epoxiconazole in relation to the current Art. 77(3)(c) request and invited the Rapporteurs to present the revised opinion. The Rapporteurs then presented the opinion which had been redrafted in accordance with the comments raised during the previous RAC discussion and in the RAC consultation round. Two key adverse effects were discussed in the opinion: 1) post implantation losses and

[4] In the first RAC opinion from May 2010, the potential of Ga to accumulate in rat testis following inhalation exposure was recognised.

[5]RAC opinion No. CLH-O-0000000630-85-05/F of 17 March 2010
RAC opinion No. ECHA/RAC/A77-O-0000001412-86-02/F of 11 March 2011

resorptions and 2) malformations (cleft palates); while three main issues related to these effects are highlighted in the draft opinion: a) maternal toxicity, b) choice of the guinea pig as a test species and c) mode of action for the two types of effects. Based on the observed effects on development as mentioned above, classification as Repr. 1B (CLP) was proposed for developmental toxicity.

In the discussion, RAC members broadly supported the conclusions presented by the Rapporteurs in the revised opinion. It was repeated, that the high incidence of cleft palates in rats was already seen as sufficient evidence for classification in Category 1B during the RAC discussion under the previous Art. 77(3)(c) mandate on epoxiconazole. This malformation is rarely seen in rats. This result had been confirmed in one of the new rat studies (and shown to be independent of co-administration of oestradiol). Skeletal findings had been shown in the guinea pig. No clear mechanism for the cleft palates had been demonstrated and the possible relevance of this malformation (as also observed by other substances of the azole class) to humans was considered. The late resorptions/post-implantation losses as demonstrated in the rat, were reduced or diminished when rats were co-administered with oestradiol, and were not seen in guinea pigs. Data on post implantation losses had been shown also in a non-human primate (baboon) with another aromatase inhibitor, letrozole. RAC members considered that the guinea pig may not necessarily be a better model in relation to humans than the rat for this effect. It was recognised that rats, guinea pigs, non-human primates (based on baboon data on letrozole) and humans are sensitive to the general mode of action of aromatase inhibition and that physiological species differences may lead to various responses although through a common mechanism.

RAC adopted the opinion by consensus confirming the previous opinions on the harmonised classification of epoxiconazole as toxic to reproduction, category 1B, with regard to developmental toxicity (Repr. 1B; H360D).

Thus, taking into account also the existing harmonised classification in Annex VI for epoxiconazole for reproductive toxicity, the resulting harmonised classification for this hazard class will be category 1B with H360Df.

5.3 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 Chairman invited RAC to agree upon the volunteers for the upcoming CLH dossiers and receiving approval from the members, thanked the volunteers for their commitment.

5.4General and procedural CLH issues

a) State of play of CLH dossiers

The Chairman pointed out to the Committee that the Secretariat had produced a document entitled "State of play of CLH dossiers" RAC/23/2012/03 for their information which had been uploaded to CIRCA BC and which provides a detailed overview of the current status of CLH dossiers.

b) Opinion development process – cooperation between ECHA and EFSA

The Secretariat provided an update on the coordination of the ECHA CLH process with the approval process for new active substances in plant protection products, with a view to avoid conflicting opinions. It was reported that the RAC opinion on the CLH proposal for a

new active substances may have to be adopted with shorter time than 18 months, and that both ECHA and EFSA would have to refer mutually to the respective public consultations (PC) on their websites. Members were informed that a pilot case with the insecticide Sulfoxaflor had been agreed, which would involve the parallel launch of the respective PCs. Further alignment of the EFSA peer review and the ECHA CLH opinion development process will be explored in practice.

One RAC member asked whether a shorter timeline for the adoption of the RAC opinion would be feasible in view of the need to consider all hazard classes for an active substance. Another RAC member asked how to proceed in case of different information included in the DAR and in the CLH dossier which would appear probable where the Competent Authority for the preparation of the DAR might not be the same as that preparing the CLH dossier. A third RAC member asked whether there would already be similar considerations for active substances under the new Biocides Regulation. The Chairman explained that the alignment in the case of biocidal products active substances will be considered later on and that RAC would be kept updated on a regular basis on the alignment issues.

c) Opinion development process – selection of CLH endpoints for consideration by RAC

The Secretariat reported on a presentation made to CARACAL the previous day of a document regarding the type and number of hazard classes to be considered by RAC for active substances contained particularly in pesticidal and biocidal products. The Secretariat clarified that a final decision on this issue could only be made after the CARACAL members had provided their views on the ECHA document. RAC will be kept informed of developments.

6 Restriction

6.1 General restriction issues

a) Update on intended restriction dossiers

The Secretariat provided an update on up-coming restriction dossiers. As already informed in September 2012, there are currently two new substances in the Registry of Intentions:

- lead and lead compounds in articles intended for consumer use prepared by Sweden and

- 1-methyl-2-pyrrolidone (NMP) prepared by the Netherlands.

The lead dossier will be submitted to ECHA in January and the NMP dossier in April 2013.

The Chairman also informed the Committee that the Nonylphenol restriction dossier was resubmitted to ECHA on 26 November 2012. However, the processing of this dossier will start with the next (January 2013) submission window, which means that the conformity check process in the Committees will start in February and the agreement on the conformity would have to be reached at the March 2013 plenary meeting of RAC and SEAC.

In addition, RAC was informed that ECHA had received a request to prepare an Annex XV restriction dossier on cadmium and its compounds used in plastic materials that are not covered by the existing restriction entry 23 and to extend the existing restriction to the placing on the market of paints containing cadmium.

6.2 Restriction Annex XV dossiers

a) Chromium VI – fourth version of the draft opinion

The Chairman welcomed the Danish Dossier Submitter who participated via the Webex connection. The deadline for adoption of the opinion is 16 December 2012. He reminded the Committee that chromium (VI) can be formed during the chrome tanning process when chromium (III) is oxidised. Chromium (III) compounds are added in some tanning processes to improve durability by cross-linking collagen. The proposed restriction focuses on the risk to consumers (including workers as consumers) of skin sensitisation from direct or indirect skin contact with leather articles that contain chromium (VI). This includes articles for which there is relatively short, repetitive skin contact as well as longer term, repeated contact.

The Chairman informed the RAC that the restriction dossier on chromium (VI) was open for public consultation from 16 March to 16 September 2012. The RAC written commenting round on the 3rd version of the RAC opinion finished on 26 October and the Rapporteurs prepared the 4th version of the draft opinion for discussion at RAC 23. The 3rd rapporteurs` dialogue took place on 30 October, while the second Forum advice was uploaded to CIRCA BC on 15 November.

The Chairman then invited the Rapporteur to present the 4th version of the RAC opinion, who first referred to the wording proposed in the 4th version of the draft opinion and the main conclusions of the second Forum Advice (concerning limit value and enforceability aspects of the restriction proposal). He reported also on issues addressed in the draft opinion since RAC-22, including 'post-formation', coated articles and technological advances (test method). He summarised the main conclusions of the opinion concerning hazard, exposure and risk assessment which had been previously discussed at RAC-22. The Committee reiterated its agreement with the Rapporteurs' proposals on these aspects.

In the next part of the presentation, the Rapporteur focused on the calculation of the prevalence of chromium (VI) allergies in the EU using the CE-DUR method. This is intended to facilitate an assessment of the number of the existing and avoided cases in the future, which in turn can be used as part of the calculation of the benefits of the restriction. The Dossier Submitter originally based their calculation on a 10-year prevalence. However, the Rapporteurs modified this value with chromium-specific correction factors and multiplied it by a factor of 4.2 to reflect the expected lifetime of sufferers with the chromium (VI) allergy. The methodology of the calculation had been generally agreed at the last (RAC-22) meeting. The Rapporteur stressed that the calculation relies to an extent on expert judgment and presented the main uncertainties identified in the assumptions. The Rapporteurs asked if the Committee could agree to provide their sister Committee (SEAC) with a range, maximum, minimum or mean of prevalence values to work with, so reflecting the uncertainties.

Overall, the Committee concluded that these estimates represented the best interpretation of the available data that could be provided at this time. They were considered to be an improvement on those provided originally by the Dossier Submitter. The Committee noted that all of the assumptions used had been explained as clearly as possible by the Rapporteurs. One of the questions considered in this regard was whether such benefits estimates should only relate to the patients who give strong positive, unequivocal patch test scores. In relation to the factor of 4.2, RAC discussed how persistent chromium (VI) allergy actually is when there is no further exposure. The Rapporteurs informed the Committee that experts in dermatology whom they had consulted had informed them that once a person is sensitised to chromium (VI), they remain sensitized for life. This opinion was also supported by one of the observers based on unpublished data on the persistence of three metal allergies.

RAC members noted that both the Dossier Submitter's and RAC Rapporteurs' different calculations gave very similar results. The benefits of consultating clinical and epidemiological experts in similar cases in the future was also noted by RAC.

One of the RAC members taking into consideration the number of assumptions proposed to the Committee suggested to provide the opinion without any numbers concerning prevalence. The Rapporteur replied that in his opinion RAC had enough information to provide a range of values. The proposal to give the range of prevalence estimation was supported all members of the Committee provided that the key assumptions are communicated in the opinion.

RAC adopted the opinion by consensus. The Rapporteurs and the Secretariat were asked to include the range of prevalence estimates in the opinion. The Rapporteurs will ensure that the supportive documentation (BD and RCOM) is in line with the adopted RAC opinion. The Secretariat will forward the adopted opinion and its supportive documentation to SEAC and will publish the adopted opinion and its supportive documentation on the ECHA website and CIRCA IG.

b) Dichlorobenzene – second version of the draft opinion

The Chairman noted that ECHA had submitted this dossier and that the purpose is to restrict the use of 1,4-dichlorobenzene (DCB) in toilet blocks and air fresheners used in toilets or other domestic or public indoor areas, or offices. The deadline for adoption of the opinion is 19 March 2013.

The draft Forum advice was made available to RAC and SEAC on 5 October. Interested RAC members took the opportunity to assist the Rapporteurs via Webex on 26 October 2012. The public consultation on the restriction dossier on 1,4 DCB will close on 19 December 2012. The Chairman announced that the discussion should focus on the 2nd version of the RAC opinion and should conclude on open issues to be implemented in the 3rd version of the RAC opinion.

The RAC Rapporteurs then presented the second version of the draft opinion by outlining the basis for DNEL derivation, health effects and exposure assessment. The Rapporteurs proposed a lower assessment factor (AF) of 1 to be used to calculate DNELs compared to the factor of 5 used in the restriction proposal to express the severity of the observed effects. The Rapporteurs' view was supported by RAC, and the Rapporteurs were asked to confirm the risk calculations in the next version of the opinion.

For the health impact assessment, the Rapporteurs concluded that there was no definite link between the observed nasal lesions and lung function. In relation to the Elliott study which associates a decrease in lung function with blood concentrations of DCB, the view expressed by the Rapporteurs was that due to the uncertainties in the study the effects cannot be solely attributed to DCB but to a combination with other VOCs. This was also supported by RAC, and the Rapporteurs were asked to include further justification in the opinion on how the Elliott study was viewed. With regard to the alternatives to DCB, RAC felt that further justification was needed in the draft opinion to explain why camphor, is not considered a good alternative from a human health viewpoint.

The draft opinion supports the proposed restriction on consumer use, as risks are identified under reasonable worst case conditions and suitable alternatives exist. The RAC Rapporteurs recommended that the risks for professional users are acceptable under the exposure conditions identified in the risk modelling, consequently the restriction on professional use is not supported. Regarding alternatives, no suitable direct alternative was identified (as camphor is not considered appropriate due to its hazardous properties), which is effective where cleaning is infrequent and traffic use is high , other alternatives such as products which combine deodorising and cleaning properties are not as effective in masking odours in public toilets where use is high and cleaning is infrequent. Alternative

techniques (such as additional cleaning or retrofitting of the installations) are also considered as possible alternatives.

The RAC members supported the view taken by the Rapporteurs in the second draft opinion on the restriction of DCB for consumer use. The Rapporteurs were asked to finalise the drafting of the opinion, based on the discussion at RAC-23, which together with the revised BD, will be provided to RAC in due course for information.

6.3 Requests under Article 77(3)(c) - restriction dossiers

a) Non-classified phthalates (DINP and DIDP)

The Chairman welcomed the experts accompanying respectively the EuPC, Cefic and Eurometaux stakeholder observers.

He reminded RAC that this is an Article 77(3)(c) request for an opinion on a draft review report prepared by ECHA concerning DINP and DIDP and invited the Rapporteur to present the third version of the RAC opinion. The Rapporteur summarised the most critical points in particular related to the selection of the appropriate starting point for DNEL derivation, differences in absorption between adults and children, the migration rate, and the mouthing time.

The ECHA report used a LOAEL of 22 mg/kg/d for DNEL derivation for DIDP based on statistically significant increased incidences of spongiosis hepatis in the Cho et al (2008) study.

The Rapporteur questioned the results of the study due to the absence of spongiosis hepatis in the control group. There was some support for this conclusion, but members pointed to the fact that the historical control data referred to were from NTP studies and would thus have limited relevance for evaluating the Korean study by Cho et al. Moreover, members pointed out that a zero control incidence is well within the range of historical controls.

Concerns were also expressed regarding elevated incidences in focal necrosis. It was further noted that spongiosis hepatis is seen in association with peliosis hepatitis (characterized by blood-filled cavities), and that taken together the dose-response becomes more prominent. It was also indicated that spongiosis is not only seen in the Cho study with DIDP, but also in studies with DINP and with DEHP, and might therefore be phthalate related. One member explained that treatment-related lesions similar to spongiosis hepatic are described in human pathology (sisnusoidal dilations or sinusoidal ectasia), but that the terminology differs.

It was noted that other subchronic studies on DIDP are available, although with limitations. As was the case when the EU RAR was prepared, no long-term repeated dose toxicity studies were available; the authors of the EU RAR therefore performed a parallel risk characterisation on the basis of two NOAELs, from respectively a dog and a rat study. Industry clarified that one of the available 90-day rat studies was performed with a substance currently on the market and therefore considered the study more relevant than the second 90-day study that was used in the EU RAR. It was suggested that a weight of evidence approach be used, built on several available studies. Considering the uncertainties discussed, and bearing in mind the actual question in the mandate, i.e. whether, based on the available evidence presented in the draft review report, RAC is of the opinion that the selection of the NOAELs by ECHA is appropriate and sufficiently justified, it was concluded that RAC might not have to agree on one NOAEL but rather focus on the appropriateness of ECHA's approach.

Concerning DINP, the Rapporteur expressed support for the NOAEL of 15 mg/kg/d selected by ECHA in the draft review report, but at the same time voiced understanding for the dose-spacing issue. Several members expressed their support and pointed to the fact

that no new data is available to invalidate previous conclusions from the scientific committees. Industry noted ECHA's review report could be clearer in relation to the conclusions of the 'Pathology Working Group' (PWG) from 1999 that had re-assessed the slides of both studies on DINP and concluded on a NOAEL of 88 mg/kg/d. ECHA clarified that the report of the pathology working group was fully taken into account in the draft review report and undertook to further specify the PWG conclusion on the NOAEL in its final review report.

The Rapporteur questioned the assumption made in ECHA's draft review report that children would absorb more than adults (100% versus 50%). In his view the results of kinetics studies in human volunteers depend on the number of urinary metabolites measured, and if all metabolites would be measured absorption would be 100%. He was also of the opinion that the differences in absorption were covered by the Assessment Factor of 10 for intra-species differences. Members pointed out that the draft report was in line with the opinion of RAC on the restriction proposal by Denmark on four phthalates and noted that the draft report was also in line with the ECHA guidance. ECHA informed the Committee that the assumption in the RAC opinion on the four phthalates of 70% absorption of DEHP in adults was based on toxicokinetic studies in several species and that the studies in humans merely confirmed that the absorption in rats is similar to humans. For DINP and DIDP less data is available, and the conclusion of 50% absorption in adult rats and humans from the EU RAR was therefore maintained in the draft report.

Industry asked why ECHA had not taken into account the Kurata studies from 2012, which according to them indicated lower absorption of DEHP in young marmosets. A member remarked that in his view the study did not seem to provide such evidence, and that perhaps on the contrary the data might be supportive of the assumption that absorption is higher in young animals.

An ad-hoc meeting with 9 RAC members (including the Rapporteur) and 5 ECHA staff members further discussed the issues raised in plenary. The Rapporteur reported on the conclusions of the ad-hoc group in plenary. The group had agreed on a NOAEL of 15 mg/kg/d as the starting point for DNEL derivation of DINP, but with the reservation that there are indications that the value could be higher. Concerning the NOAEL for DIDP, no agreement was reached on the starting point to be used. It was agreed however to explore a weight of evidence approach using several studies. No agreement had been reached concerning the absorption assumptions. The ad-hoc group recommended a mouthing time of 2 hours per day to the RAC and supported the proposed value for migration of 45 $\mu g/cm^2/h$.

The Chairman informed that the Secretariat would request to extend the deadline of the mandate. The Rapporteur was requested to prepare a fourth version of the RAC opinion taking into account the comments received during RAC-23 and to submit it to the Secretariat by the end of December. Following further consultation with RAC, the Rapporteur will be asked to prepare a 5^{th} draft opinion for discussion and possible agreement via written procedure or at RAC-24.

6.4 Appointment of (co-)rapporteurs for restriction dossiers

The Secretariat asked RAC to agree on the appointment of (co-)rapporteurs for two upcoming restriction dossiers: 1-Methyl-2-pyrrolidone (NMP) (to be submitted by the Netherlands) and Lead and lead compounds in articles intended for consumer use (to be submitted by Sweden). RAC agreed to appoint the Rapporteurs recommended by the Chairman and listed in the room document RAC/23/2012/04.

7 Authorisation

7.1

a) Authorisation – capacity building DNEL setting for DEHP

The Secretariat provided an update on the newly established trial exercise "reference DNELs and dose response curves". It was agreed at the last RAC-22 plenary meeting to start this trial as an integral part of an efficient authorisation process.

The Chairman gave the floor to one of the RAC members involved with the trial exercise to present the derivation of the draft 'reference DNEL' for the substance DEHP, stressing that this was work in progress. DEHP is one of the phthalate substances that are on the authorisation list (Annex XIV to the REACH regulation). The draft reference DNEL for DEHP was prepared by the Secretariat in close cooperation with volunteer members (meeting document RAC/23/2012/05 rev 1) and were based on a) the EU RAR, and b) the adopted RAC opinion on the restriction proposal for placing on the market and use of certain articles containing four classified phthalates submitted by Denmark in 2011. The DNELs were then compared with those provided in the public section of REACH registration dossiers. The relatively small differences in observed DNEL values for DEHP can be accounted for in various ways, by the use of: separate endpoints and studies, different toxicokinetic assumptions and absorption factors leading to different assessment factors.

Members emphasised that the justification for the differences between ways of deriving DNELs must be described and assessed whenever RAC provides reference DNELs in the future. It was recognised that data from the EU RAR are most often considered to be the basis for such discussions. Some members were of the view that any divergence from the opinion expressed therein would be only acceptable when well justified or if new data would have emerged.

RAC expressed appreciation for the work provided by the RAC members involved, in cooperation with the Secretariat and emphasised that these discussions will increase RAC's readiness for the upcoming authorisation process. The RAC members expressed a wish to develop DNELs also for other relevant substance on the authorisation list and in order to be as efficient as possible; it was highlighted that such an exercise should focus on substances for which multiple AfAs are expected.

RAC expressed broad support for the trial and emphasised the benefits and the time saving potential. Members are invited to comment on the proposed DNEL derivation for DEHP. Based on comments received the document will be revised by the Secretariat and uploaded to the ECHA website to inform possible applicants. The Chairman repeated that the Secretariat is looking forward to members' further expressions of interest to participate in the work of DNEL derivation and establishing dose-response curves.

b) Participation of case-owners and stakeholder observers in opinion development process

The Secretariat presented the document RAC/23/2012/06 which had been endorsed by the ECHA Management Board and discussed in both RAC and SEAC on ECHA's approach to the participation of applicants, third parties and stakeholder observers in the process of Application for Authorisation under REACH

The Chairman thanked the Secretariat for informing the Committee about ECHA's approach in this respect.

7.2 Appointment of (co-)rapporteurs

The Secretariat collected names of volunteers for future applications for authorisations listed in a room document. RAC agreed to appoint the volunteers to the pool of authorisation rapporteurs. The Chairman pointed out that, additional members may volunteer for the pool of rapporteurship at any time by indicating their interest to the Secretariat.

8. AOB

Under this agenda item, the Committee briefly discussed a range of issues related to opinion development and agreement of opinions:

- The newly introduced practice at RAC-23 of agreeing on the action points in the case of CLP, REACH restrictions and Art. 77(3)c requests from the Executive Director, immediately following the Chairman's summing up on a given agenda item was felt by the members to be an improvement to the manner of reaching agreement on agenda items and the adoption of opinions. The Secretariat was encouraged by the Committee to continue this, including, in the case of CLP the presentation, an agreement of the relevant classification tables.

- It was noted that a recent written request from the Secretariat regarding editorial corrections to previous adopted RAC opinions on CLP classification to bring them into line with upcoming ATP publication would need further consideration. It was questioned whether once adopted opinions should or could be changed via a written procedure

- It was not clear to some members whether the launch of a second public consultation in the absence of new information could or should be considered. Some members asked the Secretariat for clarification to this point.

- Some members noted that in the previous RAC meeting(s) the outcome of expert meetings was not always reported back to the plenary meeting. In view of transparency and efficiency the Secretariat was requested to ensure adequate feedback.

- Should RAC members' comments during the drafting of the minutes be rejected on occasion by the Secretariat , then the Secretariat should provide clear reasons for doing so or at least in view of transparency show in the track changes version which comments were received. Some RAC members noted that some of their comments were not visible at all.

5 December 2012
FINAL

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
RAC 23, 27-30 November 2012
(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/23/2012**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC 24 minutes.
5. Harmonised classification and labelling (CLH)	
5.1 CLH dossiers	
5.1 a 3-Iodo-2-propynylbutylcarbamate (IPBC)	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in the table 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.
5.1 b Formaldehyde	
RAC adopted the opinion with a proposal for the harmonised classifications as indicated in the table below.	**Rapporteur** to revise the opinion in accordance with the discussions in RAC and to provide it to the SECR. **SECR** to launch an editorial commenting round once the revised opinion is received. **SECR** to introduce any editorial comments and forward the adopted opinion and its annexes to COM and to publish it on the ECHA website.
5.1 c Methyl-2,5-dichlorobenzoate	
RAC adopted by consensus, the opinion with a proposal for the harmonised classifications as indicated in the table 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.
5.1 d Cycloxydim	
RAC adopted by consensus, the opinion with a proposal for the harmonised classifications as indicated in the table 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.
5.1 e Tetrahydrofurfuryl alcohol (THFA)	
RAC adopted by consensus the opinion with a	**SECR** to make an editorial check of the

proposal for the harmonised classifications as indicated in the table below.	opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1 f Fyrolflex (1-methylethylidene)di-4,1-phenylene tetraphenyldiphosphate)	
RAC adopted by consensus the opinion with a proposal to remove the harmonised classification Aquatic Chronic 4 from Annex VI to CLP.	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1 g PX-200 (tetrakis(2,6-dimethylphenyl)-m-phenylenebiphosphate)	
RAC adopted by consensus the opinion with a proposal to remove the harmonised classification Aquatic Chronic 4 from Annex VI to CLP.	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1 h Fenpyrazamine	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in the table 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 publish it on the ECHA website.
5.1 i Etofenprox	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in the table 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.
5.1 j Muscalure (cis-tricos-9-ene)	
RAC adopted by consensus the opinion on the endpoints proposed by the Dossier Submitter and during public consultation for the harmonised classifications as indicated in the table below.	**Rapporteurs** to revise the draft opinion reflecting the view of RAC concerning the justification of the opinion on the environmental classification. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1 k Dimethyltin EHMA (dimethyltinbis(2-ethylhexyl-mercaptoacetate); 2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecan-1-oate**)**	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in the table 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.
5.1 l Dimethyltin dichloride	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in the table 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.
5.1 m Styrene	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in the table below.	**Rapporteur** to revise the opinion in accordance with the discussions in RAC and to provide it to the SECR. **SECR** to launch an editorial commenting round once the revised opinion is received. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.2 Requests under Article 77(3) (c) - CLH dossiers	
5.2 a Gallium arsenide	
RAC discussed the revised draft opinion on reproductive toxicity.	**SECR** to request an extension of the deadline for the mandate. **SECR** to briefly summarize the evidence and the discussions so far in order to facilitate the members and to allow the Rapporteurs to broaden the opinion. **Rapporteurs** to revise the draft opinion taking into account the evidence and the discussions so far. **SECR** to launch a RAC consultation with a view to further developing the draft opinion. **SECR** to distribute the revised draft opinion documents to RAC for discussion and possible agreement at RAC 24.
5.2 b Epoxiconazole	
RAC adopted by consensus the opinion confirming the previous opinions on the harmonised classification of epoxiconazole toxic to reproduction 1B; H360D.	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to launch an editorial commenting round once the revised opinion is received. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.3 Appointment of RAC (co-)rapporteurs for CLH dossiers	
Agreement (co-) rapporteurs for the substances listed in document **RAC/23/2012/02 CONFIDENTIAL**.	**SECR** to upload in RAC CIRCABC the updated document to reflect RAC appointments for CLH substances. **Members** to volunteer for CLH substances.

6. Restrictions	
6.2 Restriction Annex XV dossiers	
a) Chromium VI – 4th version of the draft opinion	
RAC Rapporteurs presented the fourth version of the draft opinion. RAC discussed the main changes made to the draft opinion of RAC. RAC adopted the opinion by consensus.	**Rapporteurs** and **SECR** to replace in the opinion the medium values with the range of prevalence estimation. **Rapporteurs** to ensure that the supportive documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supportive documentation to SEAC. **SECR** to publish the adopted opinion and its supportive documentation on the ECHA website and CIRCA IG.
b)Dichlorobenzene – 2nd version of the draft opinion	
RAC Rapporteurs presented the second version of the draft opinion.	**Rapporteurs** to prepare the third version of the draft opinion in accordance with the discussion in RAC and to provide it to SECR. **Rapporteurs** together with **SECR** to update the BD to be in line with the revised version of the draft opinion. **SECR** to distribute the revised draft opinion and BD to RAC for information.
6.3 Requests under Article 77(3)(c) - restriction dossiers	
a) Non-classified phthalates (DINP and DIDP)	
RAC Rapporteur presented the third version of the draft opinion and responded to RAC members' comments. RAC discussed the main changes made to the draft opinion of RAC.	**SECR** request to extend the deadline of the mandate. **Rapporteur** to take the comments received during RAC discussion into account when preparing the fourth version of the RAC opinion and to submit it to **SECR** by **the end of December**. **SECR** to launch RAC consultations. **Rapporteur** to revise the draft opinion following the comments received and to provide it to SECR. **SECR** to distribute the revised draft opinion documents to RAC for discussion and possible agreement via written procedure or at RAC 24.
6.4 Appointment of (co-)rapporteurs for restriction dossiers	
RAC agreed on the appointment of (co-) rapporteurs for the substances NMP (1-mehthyl-2-pyrrolidone), lead and lead compounds in articles (room document **RAC/23/2012/04 CONFIDENTIAL**).	**SECR** to upload in RAC CIRCABC the updated document to reflect RAC appointments for restriction dossiers.

7. Authorisation	
7.1 a) Capacity building DNEL setting for DEHP	
RAC discussed the setting of the DNEL for DEHP. **RAC/23/2012/05 rev 1 (*room document*)** RAC approved the methodology and considered this a useful way forward for setting DNELs in authorisation.	**SECR** to launch a commenting round on the DEHP DNEL proposal. **Members** to volunteer for future tasks.
7.2 Appointment of RAC (co-)rapporteurs for Authorisations	
Agreement (co-) rapporteurs for the substances listed in document **RAC/23/2012/07 rev 1 CONFIDENTIAL**.	**SECR** to upload in RAC CIRCABC the updated document to reflect RAC appointments for the pool of authorisation (co-)rapporteurs. **Members** to volunteer for authorisation dossiers.

Item 9 – Action points and main conclusions of RAC 23	
	SECR to upload the adopted action points to CIRCABC.

Proposed new or revised classification in Annex VI, CLP and DSD, adopted by RAC

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)		
	3-iodoprop-2-yn-1-yl butylcarbamate	259-627-5	55406-53-6	Acute Tox 3 Acute Tox 4 Eye Dam. 1 Skin Sens.1 STOT RE1 Aquatic Acute 1 Aquatic Chronic 1	H331 H302 H318 H317 H372 (larynx) H400 H410	GHS05 GHS06 GHS08 GHS09 Dgr	H331 H302 H318 H317 H372 (larynx) H410		 M =10 (acute) M =1 (chronic)	

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
	3-iodoprop-2-yn-1-yl butylcarbamate	259-627-5	55406-53-6	T; R23-R48/23 Xn; R22 Xi; R41 R43 N; R50	T; N R: 22-23-41-43-48/23-50 S: to be completed for the opinion	N; R50: C ≥ 2.5 %	

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)		
	formaldehyde	200-001-8	50-00-0	Carc. 1B Muta. 2 Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* Skin Corr. 1B Skin Sens. 1	H350 H341 H331 H311 H301 H314 H317	GHS06 GHS08 GHS05 Dgr	H350 H341 H331 H311 H301 H314 H317		* Skin Corr. 1B; H314: C ≥25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Eye Irrit. 2; H319: 5 % ≤ C < 25 % STOT SE 3; H335: C ≥ 5 % Skin Sens. 1; H317: C ≥ 0,2 %	B, D

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
	formaldehyde	200-001-8	50-00-0	Carc. Cat. 2; R45 Muta. Cat. 3; R68 T; R23/24/25 C; R34 R43	T; C R: 23/24/25-34-43-45-68 S: to be completed for the opinion	T; R23/24/25: C ≥25 % Xn; R20/21/22: 5 % ≤ C < 25 % C; R34: C ≥25 % Xi;	B, D

						R36/37/38: 5 % ≤ C < 25 % R43: C ≥ 0,2 %	

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)		
	methyl 2,5-dichlorobenzoate	220-815-7	2905-69-3	Acute Tox. 4 STOT SE 3 Aquatic Chronic 2	H302 H336 H411	GHS07 GHS09 Wng	H302 H336 H411			

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
	methyl 2,5-dichlorobenzoate	220-815-7	2905-69-3	Xn; R22 N; R51-53	Xn; N R: 22-51/53 S: to be completed for the opinion		

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)		
	cycloxydim (ISO); 2-[(1E)-N-ethoxybutanimidoyl]-3-hydroxy-5-(tetrahydro-2H-thiopyran-3-yl)cyclohex-2-en-1-one	405-230-9	101205-02-1	Repr. 2	H361d	GHS08 Wng	H361d			

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
	cycloxydim (ISO); 2-[(1E)-N-ethoxybutanimidoyl]-3-hydroxy-5-(tetrahydro-2H-thiopyran-3-yl)cyclohex-2-en-1-one	405-230-9	101205-02-1	F; R11 Repr. Cat. 3; R63	F; Xn R: 11-63 S: to be completed for the opinion		

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)		
603-061-00-7	tetrahydrofurfuryl alcohol; tetrahydrofuran-2-ylmethanol	202-625-6	97-99-4	Repr. 1B Eye Irrit. 2	H360Df H319	GHS08 GHS07 Dgr	H360Df H319			

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
603-061-00-7	tetrahydrofurfuryl alcohol; tetrahydrofuran-2-ylmethanol	202-625-6	97-99-4	Repr. Cat. 2; R61 Repr. Cat. 3; R62 Xi; R36	T R: 61-36-62 S: to be completed for the opinion	Xi; R36: C ≥ 10%	

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 state-ment Code(s)	Suppl. Hazard statement Code(s)		
015-192-00-1	tetrakis(2,6-dimethylphenyl)-*m*-phenylenebiphosphate	432-770-2	139189-30-3	Skin Sens. 1	H317	GHS07	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
015-192-00-1	tetrakis(2,6-dimethylphenyl)-*m*-phenylenebiphosphate	432-770-2	139189-30-3	R43	Xi R: 43 S: to be completed for the opinion		

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)		
	fenpyrazamine	-	473798-59-3	Aquatic Chronic 2	H411	GHS09	H411			

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
	fenpyrazamine	-	473798-59-3	N; R51-53	N R: 51/53 S: to be completed for the opinion		

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)		
	etofenprox (ISO); 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether	407-980-2	80844-07-1	Lact. Aquatic Acute 1 Aquatic Chronic 1	H362 H400 H410	GHS09 Wng	H362 H410		 M =100 (acute) M =1000 (chronic)	

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
	etofenprox (ISO); 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzyl ether	407-980-2	80844-07-1	R64 N; R50-53	N R: 50/53-64 S: to be completed for the opinion	N; R50-53: C ≥ 0.25% N; R51-53: 0.025% ≤ C < 0.25% R52-53: 0.0025 % ≤ C < 0.025%	

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)		
	cis-tricos-9-ene; (9Z)-tricos-9-ene	248-505-7	27519-02-4	Skin Sens. 1B	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
	cis-tricos-9-ene; (9Z)-tricos-9-ene	248-505-7	27519-02-4	R43	Xi R: 43 S: to be completed for the opinion		

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)		
-	dimethyltinbis(2-ethylhexyl-mercaptoacetate); 2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecan-1-oate	260-829-0	57583-35-4	Repr. 2 Acute Tox. 4 Skin Sens. 1A STOT RE 1	H361d H302 H317 H372(Nervous system, immune system)	GHS07 GHS08 Dgr	H361d H302 H317 H372(Nervous system, immune system)			

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
-	dimethyltinbis(2-ethylhexyl-mercaptoacetate); 2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecan-1-oate	260-829-0	57583-35-4	Repr. Cat. 3; R63 T; 48/25 Xn; R22 R43	T R: 22-43-48/25-63 S: to be completed for the opinion		

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)		
-	dimethyltin dichloride; dichloro(dimethyl) stannane	212-039-2	753-73-1	Repr. 2 Acute Tox. 3 Acute Tox. 3 Acute Tox. 2 Skin Corr. 1 STOT RE 1	H361d H301 H311 H330 H314 H372 (Nervous system, immune system)	GHS05 GHS06 GHS08 Dgr	H361d H301 H311 H330 H314 H372 (Nervous system, immune system)	EUH071		

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
-	dimethyltin dichloride; dichloro(dimethyl) stannane	212-039-2	753-73-1	Repr. Cat. 3; R63 T+; R26 T; R24/25-48/25 C; R34	T; C R: 24/25-26-34-48/25-63 S: to be completed for the opinion		

Proposed 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)		
601-026-00-0	styrene	202-851-5	100-42-5	Flam. Liq. 3 Repr. 2 Acute Tox. 4* Eye Irrit. 2 Skin Irrit. 2 STOT RE 1	H226 H361d H332 H319 H315 H372 (hearing organs)	GHS02 GHS07 GHS08 Dgr	H226 H361d H332 H319 H315 H372 (hearing organs)		*	D

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
601-026-00-0	styrene	202-851-5	100-42-5	R10 Repr. Cat. 3; R63 T; R48/20 Xn; R20 Xi; R36/38	T R: 10-20-36/38-63 S: to be completed for the opinion	Xn; R20: C ≥12.5% Xi; R36/38: C ≥12.5%	D

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Part III. List of Attendees of the RAC-23 meeting (27-30 November 2012)

RAC members
BARANSKI Boguslaw
BARRON Thomasina
BJORGE Christine
BORGES Teresa
CARVALHO João
DI PROSPERO FANGHELLA Paola
DUNAUSKIENE Lina
DUNGEY Stephen
GREIM Helmut (28-30 November 2012)
GRUIZ Katalin
HAKKERT Betty
JENSEN Frank
KADIKIS Normunds
KAPELARI Sonja
KORATI Safia
LEINONEN Riitta
LUND Bert-Ove
MULLOOLY Yvonne
PARIS Pietro
PASQUIER Elodie
PICHARD Annick
PINA Benjamin
POLAKOVICOVA Helena
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SCHULTE Agnes
SMITH Andrew
SOERENSEN Peter
SPETSERIS Nikolaos
STASKO Jolanta
STOLZENBERG Hans-Christian
TADEO José Luis
Van der HAGEN Marianne

ECHA staff
ATLASON Palmi
BARMAZ Stefania
BOWMER Tim
BROECKAERT Fabrice
DVORAKOVA Dana
ERICSSON Gunilla
FUHRMANN Anna
HELLSTEN Kati
HONKANEN Jani
HUUSKONEN Hannele
KARJALAINEN Ari
KIOKIAS Sotirios
KIVELÄ Kalle
KLAUK Anja
KOKKOLA Leila
LUSCHÜTZKY Evita
MAGGIORE Angelo
MATTHES Jochen
MERKOURAKIS Spyridon
NYGREN Jonas
ORISPÄÄ Katja
PELTOLA Jukka
RIVERO Debora
RODRIGUEZ IGLESIAS Pilar
ROGGEMAN Maarten
SADAM Diana
SOSNOWSKI Piotr
SPJUTH Linda
VAINIO Matti
Van HAELST Anniek

Advisers (to the RAC members)		**Other observers**
CATONE Tiziana (de Prospero Fanghella) adviser for CLH Rapporteur muscalure		VARNAI Veda (Croatian observer)
GUSTAFSON Anne-Lee (Lund)		BRIDGES James (an observer acting as an expert (University of Surrey) to an observer representing EuPC non-classified phthalates)
KORHONEN Hanna (Leinonen)		DEKANT Wolfgang (an observer acting as an expert (University of Würzburg) to an observer representing Eurometaux non-classified phthalates)
MAHIOUT Selma (Leinonen)		FRANKE Kristian (an observer acting as an expert (Staehler Int GmbH) to an observer representing ECPAMDCB)
Mc ELVENNY Damien (Schulte)adviser for CLH Rapporteur formaldehyde		GELBKE Heinz-Peter (an observer acting as an expert (GMX) to an observer representing Cefic for formaldehyde and styrene) and(an observer acting as an expert (GMX) to an observer representing Eurometaux GaAs)
Mc GARRY Helen (Smith)adviser for CLH Rapporteur THFA		KEMENY Monika (an observer acting as an expert (BASF) to an observer representing ECPA cycloxydim)
Mc MICKAN Sinead (Mullooly)		MORFELD Peter (an observer acting as an expert (Evonik Services) to an observer representing ECPA_formaldehyde)
NUNES Laura (Tadeo)adviser for CLH Rapporteur cycloxydim, IPBC and muscalure		NEALE Mike (an observer acting as an expert (Lkc) to an observer representing ECPA etofenprox)
PECZKOWSKA Beata (Baranski) adviser for CLH Rapporteur formaldehyde		PICCIRILLO Vincent J (an observer acting as an expert (VJP Consulting) to an observer representing Cefic THFA)
SKAUG Vidar (van der Hagen)		SARGINSON Nigel (an observer acting as an invited expert (ExxonMobil) to an observer representing CEFIC non-classified phthalates
ULDUKIENE Vilma (Dunauskiene)adviser for CLH Rapporteur for TFHA		STINCHCOMBE Stefan (an observer acting as an expert (BASF) to an observer representing ECPA epoxiconazole)
		WARREN Simon (an observer acting as an expert (Sumitomo) to an observer representing ECPA fenpyrazamine)
		WERNER Michael (an observer acting as an expert (ICC) to an observer representing ECPAIPBC)

Commission observers		**Remote participants**
ROZWADOWSKI Jacek (DG ENTR)		BRANISTEANU Radu (RAC member)
SCAZZOLA Roberto (DG ENTR)		DALTON Marie (SEAC co-Rapporteur for DCB)
LEFEVRE Remi (DG ENV)		FOCK Lars (adviser to Jensen and Dossier Submitter for chromium VI)
		GEORGIOU Stavros (SEAC Rapporteur for DCB)
Stakeholder observers		GUNNARSDOTTIR Sjöfn (RAC advisor for Marja Pronk)
ROWE Rocky (ECPA)		GIRAL Anne (COM observer for non-classifiedphthalates)
MEISTERS Marie-Louise (ECETOC)		SCHLUETER Urs (RAC member and co-Rapporteur for Chromium VI)
JANOSI Amaya (CEFIC)		SCHUCHTAR Endre (SEAC Rapporteur for chromium VI)
SOBALLA Volker (Business Europe)		
TILLIEUX Geoffrey (EuPC)		**Excuses**
VEROUGSTRAETE Violaine (Eurometaux)		BRANISTEANU Radu (RAC member)
		LOSERT Anne-Marie (RAC member)
		SCHLUETER Urs (RAC member)
		TSITSIMPIKOU Christina (RAC member)
		GOURMELON Anne (OECD)
		MUNARI Tomaso EuCheMS)
		TAYLOR Katy (ECEAE)
		Absent
		TROISI Gera (RAC member)

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-23 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-23 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-23 meeting

27 November 2012
RAC/A/23/2012

Final Agenda
23rd meeting of the Committee for Risk Assessment

27-30 November 2012
ECHA Conference Centre (Annankatu 18, Helsinki)
27 November: starts at 9:00
30 November: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/23/2012
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 22 action points, written procedures and other ECHA bodies

RAC/23/2012/01
For information

Item 5 – Harmonised classification and labelling (CLH)

5.1 CLH dossiers

a) 3-Iodo-2-propynylbutylcarbamate (IPBC)
b) Formaldehyde
c) Methyl-2,5-dichlorobenzoate
d) Cycloxydim
e) Tetrahydrofurfuryl alcohol (THFA)
f) Fyrolflex

g) PX-200
h) Fenpyrazamine
i) Etofenprox
j) Muscalure
k) Dimethyltin EHMA
l) Dimethyltin dichloride
m) Styrene

For discussion/adoption

5.2 Requests under Article 77(3) (c) - CLH dossiers

a) Gallium arsenide
b) Epoxiconazole

For discussion/adoption

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

RAC/23/2012/02
For agreement

5.4 General and procedural CLH issues

a) State of play of CLH dossiers

RAC/23/2012/03
For information

b) Opinion development process

Item 6 – Restrictions

6.1 General restriction issues

a) Update on intended restriction dossiers

For information

6.2 Restriction Annex XV dossiers

a) Chromium VI – 4th version of the draft opinion

For adoption

b) Dichlorobenzene – 2nd version of the draft opinion

For discussion

6.3 Requests under Article 77(3)(c) - restriction dossiers

a) Non-classified phthalates (DINP and DIDP)

For discussion

6.4 Appointment of (co-)rapporteurs for restriction dossiers

RAC/23/2012/04

For agreement

Item 7 – Authorisation

7.1

a) Authorisation – capacity building DNEL setting for DEHP

RAC/23/2012/05

For discussion

b)Participation of case-owners and stakeholder observers in opinion development process

RAC/23/2012/06

For information

7.2 Appointment of (co-)rapporteurs

RAC/23/2012/07

For agreement

Item 8 – AOB

Item 9 – Action points and main conclusions of RAC-23

Table with Conclusions and Action points from RAC-23

For adoption

ANNEX II (RAC-23)

Documents submitted to the members of the Committee for Risk Assessment for the RAC-23 meeting.

Number	**Title**
RAC/A/23/2012	Final Draft Agenda
RAC/23/2012/01	Report from other bodies and activities
RAC/23/2012/02 (confidential)	Appointment of RAC (co-) rapporteurs for CLH dossiers
RAC/23/2012/03 (confidential)	State of play of CLH dossiers
RAC/23/2012/04 (confidential)	Appointment of RAC (co-) rapporteurs for restriction dossiers
RAC/23/2012/05 rev.1	Authorisation – capacity DNEL setting for DEHP
RAC/23/2012/06	Participation of case-owners and stakeholder observers in authorisation opinion development process
RAC/23/2012/07 (confidential)	Appointment of RAC (co-) rapporteurs for authorisation dossiers
RAC/23/2012/08 Room document	Note concerning mouthing time assumptions in ECHA´s draft report on DINP and DIDP
RAC/23/2012/09 Room document	Biomonitoring data

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ANNEX III (RAC-23)

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		
Stephen DUNGEY	Fyrolflex PX-200	His institution was involved in providing some information
Helmut GREIM	Epoxiconazole	He attended a workshop sponsored by BASF where epoxiconazole was discussed.
Frank JENSEN	Chromium VI Styrene IPBC	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Bert-Ove LUND	Epoxiconazole	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Elodie PASQUIER	Gallium Arsenide Formaldehyde THFA Dimethyltin EHMA Dimethyltin dichloride	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Annick PICHARD	Formaldehyde Gallium Arsenide	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Hans-Christian STOLZENBERG	IPBC	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Peter Hammer SØRENSEN	Chromium (VI) Styrene IPBC	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Stakeholders	**Potential conflict of interest in relation to**	**Reason**
ECETOC Marie-Louise MEISTERS	Formaldehyde	She is an employee at DuPont
Business Europe Volker SOBALLA	Non-classified phthalates (DINP and DIDP)	He is an employee at Evonik Services

COM	**Potential conflict of interest in relation to**	**Reason**
Roberto SCAZZOLA	Formaldehyde	He worked in the team who prepared the dossier
RAC Chairman	**Potential conflict of interest in relation to**	**Reason**
Tim BOWMER	Formaldehyde	Recent experience with formaldehyde

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