RAC/M/28/2014
Final
29 May 2014

Minutes of the 28th Meeting of the Committee for Risk Assessment (RAC-28) 4 – 7 March 2014 and 11 – 14 March 2014

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 28th meeting of the Committee for Risk Assessment (RAC). Apologies were received from six members (4-7 March) and seven (11–14 March). He noted that there were 34 members registered for the first (REACH) week and 33 members registered for the second (CLH) week, as against an average of 36 to 37 members attending normal meetings. He expressed his thanks to the members for their solidarity and willingness to deal with the increased workload. The Chairman welcomed four new RAC members, who introduced themselves. The participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed once no longer needed. The Chairman noted that the minutes would be published on the ECHA website and would include a full list of participants as given in Part III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the two week meeting, noting that adjustments could be made if necessary at the start of the CLH week (11 March).

The Final Draft Agenda (RAC/A/28/2014) was adopted with this one addition. The agenda and the list of all meeting documents, including conclusions and action points are attached to these minutes as Annexes I and II, respectively.

3. Declarations of conflicts of interests to the Agenda

The Chairman informed the Committee in relation to the ongoing discussion regarding the practice of members declaring a potential conflict of interest when the dossier is submitted by a Member State Competent Authority or executing agency by whom the member is employed and when this member has not been personally involved in the preparation or evaluation of the dossier. He noted that the issue had been referred to the ECHA Conflicts of Interest Advisory Committee (CoIAC) whose report to the Executive Director of ECHA was expected imminently. Pending this outcome and further discussion in the ECHA Management Board, the current practice will be maintained. He repeated that members in the aforementioned position were asked not to vote (an infrequent event in a consensus body such as RAC) but were not limited in any way in their participation either in RAC consultations or in the debate in Committee and as in the past could intervene freely.

The Chairman then requested all participants to declare any potential conflicts of interest to any of the agenda items. Fifteen members and two advisers declared potential conflicts of interest, or had this declared for them by the Chairman, each to specific agenda items. In the event of a vote, these meeting participants were requested to refrain from voting on the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

One RAC member expressed her disagreement with the Chairman declaring a potential conflict of interest for a member. According to the member, the reason for not declaring a potential conflict of interest in relation to specific dossiers prepared by Member State Competent Authority by whom she was employed was that she had not been personally involved in any stage of the preparation of those dossiers. The member further pointed out that excluding a member from opinion making based on a potential CoI on a specific agenda point would in the view of the member seriously impact the consistency of the Committee decisions.

The Chairman reiterated that the practise since the start of the RAC and SEAC had been that members with concurrent employment at a CA submitting a dossier to the Committees were required to declare a potential conflict of interest on that specific case and that in the interests of fairness and consistency, this applied to all members evenly. The RAC will be informed of the recommendations of CoIAC and if available, any decision of ECHA at RAC 29 in June 2014.

4. Report from other ECHA bodies and activities

a) Report on RAC-27 action points, written procedures and other ECHA bodies

The Chairman informed the Committee that all action points of RAC-27 had been completed, or were on-going; noting that the publication of some adopted opinions had been delayed but that these would be finalised and uploaded to the ECHA website as soon as possible. The summary of all consultations, calls for expression of interest in (co-)rapporteurship and written procedures is available in a meeting document on CIRCABC (see Annex IV). He also informed the Committee that the final minutes of RAC-27 had been adopted via written procedure and were uploaded to CIRCABC and on the ECHA website on 28 February, and thanked those members who had provided comments on the draft.

b) RAC work plan for all processes

The Chairman presented the updated RAC work-plan for 2014, covering the three processes of restriction, authorisation and harmonised classification and labelling of substances. He informed the meeting that the ongoing analysis of the workload for the Committees for 2014 indicated a rise from 40 opinions in 2013 to more than 70 in 2014 (more than 50 CLH, six restrictions and 12 authorisations). The Chairman noted that the RAC-31 meeting scheduled for the last week of November 2014 will also be a two week meeting, as indicated on the Committee web page.

5. Update of stakeholder participation in the work of RAC (closed session)

The Secretariat presented the annual report on the participation of stakeholder organisations (STOs) in the work of RAC for the period January 2013 – December 2013. This included an overview of the attendance records of current STOs, as well as information on ECHA accredited stakeholder organisations who have expressed an interest in the work of RAC since the last update of the STO list.

The RAC accepted the Secretariat's proposal on the revision of the list of stakeholder organisations regarded as observers to RAC.

The RAC agreed to:

- Send a reminder to three STOs who have not attended the last four plenary meetings. Should these organisations not attend the following plenary, they would be deleted from the list of RAC STOs.
- Accept two new STOs representing general interests; to be included in Part I of the list of RAC STOs.
- Accept six new STOs representing sectoral interests; to be included in Part II of the list of RAC STOs.

The Secretariat will update the list of RAC STOs, which will be published on ECHA’s website.

The Secretariat reminded members that the participation of STOs in the work of RAC is governed by the Committee's Rules of Procedure[1], as well as the ECHA Code of Conduct for observers from stakeholder organisations at ECHA meetings[2], while more specific information on the ECHA's approach to the participation of applicants, third parties and stakeholder observers in the application for authorisation process is described in a separate note[3].

The discussion continued on stakeholder relations in general and members expressed positive views on the role of the stakeholders over the previous year.

Several members requested that the Code of Conduct be clearly explained to the new stakeholders before granting them access to the Committee, noting the need for members to be able to carry out their duties for RAC without disturbance. The Secretariat agreed to take action on this point and responded that should members personally receive any contacts from stakeholders with regard to their function as RAC members, they should notify this immediately to ECHA.

6. Harmonised classification and labelling (CLH)

6.1 CLH dossiers

a-c) Boric acid, Disodium octaborate tetrahydrate (DOT) and Disodium octaborate anhydrate (DOA)

The Chairman welcomed an expert accompanying the Cefic stakeholder observer. He reported that borates have a long regulatory history, boric acid already being classified as Repr. 1B (H360FD) with an SCL of 5.5% in Annex I to the CLP Regulation, but that DOT and DOA do not yet have a harmonised classification. The Chairman pointed out that Poland had submitted a CLH dossier for boric acid, proposing a revision of the current classification to Repr. 2 for developmental effects only (H361d), and that the Netherlands had submitted CLH proposals for DOT and DOA aiming at a classification into Repr. 1B (H360FD) for both substances and proposing no classification for DOT for other hazard classes than reproductive toxicity. DOT is used as an active substance in biocidal products.

The RAC confirmed the Dossier Submitter's (DS) proposals not to classify DOT for any of the health hazards presented with the exception of toxicity to reproduction. Similarly, no classification was agreed as appropriate for the aquatic environment. One RAC member suggested the Rapporteur to reflect the application of the classification strategy for metals when evaluating the aquatic hazard in the opinion for DOT, because this was not elaborated in the draft opinion. RAC agreed to this approach.

The reproductive toxicity of the three borates was then discussed by RAC on the basis of the evidence presented in the CLH dossiers and the material provided by the European Borates Association (EBA).

In the view of the Rapporteurs, the animal data on its own justified classification as Repr. 1B for both fertility and development. The DS of the dossier for boric acid and EBA had further submitted data from epidemiological studies (both occupational and non-occupational exposure) which in their view showed that boric acid does not cause effects on fertility (arguing to remove the F from H360FD) and is only suspected to induce developmental toxicity in humans

[1] http://echa.europa.eu/documents/10162/13579/rac_rops_en.pdf
[2] https://echa.europa.eu/documents/10162/13559/conduct_code_stakeholder_observers_en.pdf
[3] https://echa.europa.eu/documents/10162/13555/stakeholder_participation_in_afa_en.pdf

(arguing for Repro 2, H361d). This was further argued by the Industry expert, who pointed out that the available human studies had a high statistical power, comparable to the animal studies, and should therefore be taken into account. The RAC in taking these studies into account, however, argued that since the doses were still significantly lower when compared to the animal studies, this did not affect the conclusion on classification. The adviser to one of the RAC members pointed out that the epidemiological studies were interesting for risk assessment but not for classification; further stating that the epidemiological studies from China were not completely negative and that some effects were seen. Taking the ECHA guidance into account it was concluded that the negative human data provided did not contradict the animal data.

Data on a possible protective role of zinc against the fertility and developmental effects of boron compounds was also discussed, as proposed in the CLH dossier and by the EBA during the public consultation. The overall view of the RAC was that the zinc studies would be more relevant in a risk assessment context, but had relatively little bearing on hazard classification. The RAC also noted that the results of these new studies tended to confirm the existing animal database.

Another argument, proposed by the DS in the boric acid dossier and by EBA, was that humans are likely to be less susceptible to the reproductive effects of borates, due to a mechanism of action involving Histone deacetylase/Hox genes, which would in their opinion show that the effects seen in animals are a high-dose phenomenon, and as such not relevant for humans which are only exposed to lower doses. RAC however concluded that if the proposed mechanism would only lead to effects at high doses it is not likely to be the relevant mechanism since effects in animals are not only seen at high doses.

It was also argued by the Industry expert that boron is an essential mineral in humans and that homeostatic control would likely protect humans from any adverse effects. RAC responded that there are several other essential minerals that are toxic at higher doses and hence concluded that this could not be used as an argument for dismissing the relevance of the reproductive toxicity effects in humans.

In conclusion, after weighting all the evidence, the RAC finally agreed to classify boric acid, DOT and DOA as Repr. 1B for effects on fertility and developmental toxicity (H360FD).

As to the setting of concentration limits, the Chairman noted that proposals for DOT and DOA were provided (DOT: 4.5%; proposal for DOA: 3.7%) by the DS (Netherlands) while no SCL was proposed for the reproductive toxicity hazard class for boric acid by the respective DS (Poland). The Rapporteur pointed out that the SCL that is currently assigned for boric acid in Annex VI had been derived on the basis of an older method which has in the meantime been replaced by the method contained in the ECHA Guidance, using ED_{10} values. The Rapporteur explained that for reasons of consistency with current borate entries (i.a. boric acid) in Annex VI, the SCLs proposed for DOT and DOA were also derived with the older method. However, the members felt that the new, revised guidance should be respected for any new entries in Annex VI. It was agreed to assign the generic concentration limit (0.3%) applicable to Repr. 1B instead for DOT and DOA.

For boric acid which has an entry in Annex VI, the RAC agreed to include a statement in the opinion that the current SCL listed for boric acid in Annex VI was derived with an outdated method but to retain the current SCL for the purpose of this opinion as the DS had made no proposal to change the existing SCL.

For the sake of maintaining consistency for the SCLs listed for boron compounds on Annex VI, the preparation of a CLH dossier proposing the update of the SCLs

using the new method for all boron compounds with a harmonised classification was recommended by several members.

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

d) Bupirimate (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that the pesticide active substance bupirimate (ISO) was being tabled for a first plenary discussion. Bupirimate (ISO) currently has no harmonised classification in Annex VI to CLP. The Dossier Submitter (NL), proposed classification as: Carc. 2, Skin Sens. 1B; Aquatic Chronic 1 (M=1) and the legal deadline for adoption of the RAC opinion would be 1 January 2015.

The Chairman invited the Rapporteur to present the opinion. During the subsequent discussion, the RAC members agreed to the Dossier Submitter's proposal not to classify for acute toxicity for any route of exposure, for specific target organ toxicity after single exposure or for skin and eye irritation. RAC agreed to classify for skin sensitisation 1B after weighing up the (weakly) positive results of a Guinea Pig Maximisation Test (GPMT) and the negative results of an LLNA (Local Lymph Node Assay). The GPMT for bupirimate was considered positive since the response observed in test animals was attributed at least in part to the skin sensitisation property of bupirimate, in the presence of some skin irritation.

RAC agreed to classify bupirimate as Aquatic Chronic 1 with an M-factor of 1, on the basis of a NOEC value of 0.10 mg/l resulting from a fish test and the lack of rapid degradability of the substance (not readily degradable, not degradable in a water-sediments simulation and hydrolytically stable).

Consideration of the DS proposal on carcinogenicity and any remaining hazard classes will be completed at RAC 29.

e) Direct blue FC 57087

The Chairman reported that the dossier submitter (Germany) proposed to remove the current Annex VI classification of the substance as follows: Acute Tox. 4; H332, Acute Tox. 4; H312, Acute Tox. 4; H302 (all minimum classifications) and STOT SE 2; H371. The original classifications of Direct Blue FC 57087 under DSD were Xn, R20/21/22 and Xn, R68/20/21/22 and were based on a methanol content in the substance of ≥ 3% at the time of registration. The current classification according to the CLP regulation was obtained by translating from the DSD classification. Due to changes in the production technology, currently the methanol content in Direct Blue FC 57087 is < 3% (specifications 0% to 1.5%; mean < 0.5%, with recent measurements indicating that the content is much lower). During a RAC consultation, the Rapporteur and several members supported the DS conclusion for no classification.

The Rapporteur informed the RAC that the results of acute toxicity tests of Direct Blue FC 57087 (via the oral route and dermal route) show LD_{50}: > 2000 mg/kg bw. There were no data concerning inhalation acute toxicity. He concluded that the classifications for acute toxicity or for STOT SE 2, H371 are not warranted.

RAC adopted by consensus the opinion to remove the current harmonised classification and labelling. Following an editorial check, the opinion will be published on ECHA's website. The Chairman thanked the Rapporteurs for their presentation of the arguments and the Committee for their participation.

f) Flumioxazin (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer, noting that the pesticide active substance flumioxazin (ISO) was being tabled for a first plenary discussion and that the legal deadline for adoption of the RAC opinion would be 5th March 2015. He explained that the substance was also under peer-review in EFSA and that their conclusions needed to be finalised soon, noting that if RAC could adopt the opinion already at this meeting, this would facilitate EFSA.

The Chairman reported that the CLH proposal reviews the current entry in Annex VI to CLP where it is listed as Repr. 1B, Aquatic Acute 1 (M_{acute} = 1000) and Aquatic Chronic 1. The dossier submitter (CZ) proposed to declassify the substance for reproductive toxicity and to assign in addition an M-factor =1000 to the chronic aquatic classification. The Chairman noted that at RAC-28, the discussion would focus on both hazard classes that have been proposed for review.

The Rapporteur then summarised the large volume of reproductive toxicity data in her presentation. During the subsequent discussion RAC members considered whether the current classification should stand or could be modified to Repr. 2, the ECPA expert providing valuable input. No support was expressed for the proposal by the DS to declassify the substance for reproductive toxicity. In particular, as there was limited anemia in the dams, and it was not clear if there was anemia in the pups. It was questioned whether the observed anaemia normally leads to reproductive effects. Likewise it was questioned what the relevance of effects observed in rats would be to humans, taking into account the heterogeneity of erythroblast populations.

RAC agreed to request from the Dossier Submitter clarifying information on the link between the possible induction of anaemia in the rat embryo and the proposed mechanism, especially at the low dose which was developmentally toxic/teratogenic in the rat. The Chairman suggested to the Committee to continue the opinion development by means of a written consultation in RAC, taking into account the information requested from the DS, and to finalise the discussion and adopt the opinion in the June meeting (RAC-29).

After presentation of the evaluation of the aquatic hazard class, the RAC agreed to follow the DS' proposal also to assign a chronic M-factor of 1000 to the Aquatic Chronic 1 classification.

The Chairman thanked the Rapporteurs for their presentation of the arguments, the Committee for their participation in the discussion.

g) Bisphenol A

The Chairman welcomed an expert accompanying the Cefic stakeholder observer. He reported that Bisphenol A (BPA) is a monomer mainly used in the production of polycarbonate plastics and epoxy resins. In 2002, BPA had been classified as Repr. cat. 3 according to the DSD. Currently, the classification of BPA is harmonised in Annex VI of the CLP Regulation as Skin Sens. 1; H317, Eye Dam. 1; H318, STOT SE 3; H335 and Repr. 2; H361f following a direct translation from DSD.

Since the TC C&L classification, new studies on BPA have been published as well as new criteria in the CLP Regulation and its guidance. The French dossier submitter proposed to strengthen the harmonised classification and labelling for sexual function and fertility to Repr. 1B; H360F of Bisphenol A. The CLH report

was based on the studies considered as key studies in a report on the health effects of BPA by ANSES, 2011 irrespective of their publication date, on the new data on fertility published since 2002 (bibliographical search stopped 31/12/2012) and on the key studies from the previous TC C&L discussions.

The Rapporteurs presented the available information, compared it with the CLP criteria and supported the CLH proposal as proposed by the dossier submitter. In the following discussion, RAC concluded that there were adverse effects on reproductive capacity (functional fertility as reflected e.g. by reduced litter size and/or number of litters per pair) following oral exposure to BPA in a multi-generation guideline study in mice (NTP, 1985) in the mid- and high-dose groups and in a multi-generation study in rats (Tyl et al., 2002) in the high-dose group. Also other adverse effects on fertility and sexual function, such as decreases in reproductive organ weights, proportion of motile sperm and/or epididymal sperm concentration were observed in three of the two- or multi-generation guideline studies (NTP, 1985; Tyl et al., 2002 and 2008) but not in the two-generation study on rats (Ema et al., 2001), testing only low BPA doses.

It was argued by the Cefic industry expert that the actual doses in the NTP, 1985 multi-generation dietary study in mice were higher than reported in the CLH report. According to him the more accurate doses were around 500, 900 and 1900 mg/kg bw/day in the low, mid and high dose groups, respectively, when estimating the doses on the basis of food consumption and body weight. The rapporteur clarified that some guidelines for test methods specified a limit dose of 1000 mg/kg bw/day for the oral route of exposure but effects above that dose could still be relevant for classification. It was noted, however, that the litter size was reduced also at the middle dose that was in any case below 1000 mg/kg bw/day. RAC concluded that as the adverse effects on sexual function and fertility at the mid and/or high-doses were not co-occurring with marked systemic toxicity in any of the two- or multi-generation guideline studies, they were relevant for classification in accordance with the CLP criteria and the CLP guidance. RAC concluded that the adverse effects observed in these studies were not considered to be secondary non-specific consequences of other toxic effects.

Several non-guideline studies in rodents were also considered as relevant by RAC. The doses in the supplementary studies were normally lower than the mid and/or high dose levels investigated in the guideline studies (apart from the two-generation study on rats testing only low BPA doses). Whereas the oral non-guideline studies were mostly negative with regards to reproductive capacity, most of the subcutaneous studies reported effects on female reproductive capacity in a dose- and time-dependent manner. Also other toxic effects related to sexual function and fertility (such as ovarian toxicity) were observed in some of the supplementary oral studies and in several of the supplementary subcutaneous studies. RAC concluded that the impaired female reproductive capacity and other effects related to it observed in the supplementary studies supported the findings in the guideline studies. In addition, although the non-guideline studies in males had some limitations, an impaired sperm production accompanied with lower testosterone levels was observed in several of the studies

The Cefic industry expert pointed out that it was important to consider the quality of the studies and take into consideration also the negative studies in the total weight of evidence evaluation. RAC agreed with the Rapporteurs, that the four guideline studies were regarded as key studies and should be given most weight. With regard to the selection of the database, the rapporteurs clarified that RAC always assesses the information that is submitted in the CLH report by the dossier submitter plus the studies that are brought up by parties concerned during the public consultation. RAC noted that three of four guideline studies were available already during the discussions in the TC C&L, but the chemicals

legislation had changed after 2002, including new classification and labelling criteria and related guidance, providing clear provisions and advice on how to interpret systemic toxicity in relation to adverse effects on sexual function and fertility. According to CLP, the adverse effects on sexual function and fertility included also many other effects than functional fertility, such as alterations in reproductive organs and gamete production, that should be taken into consideration in a weight of evidence assessment.

Also the human evidence was discussed by RAC but was not considered robust enough to justify classification of Bisphenol A as Repr. 1A. It had been reported in many studies that the endocrine active form of BPA, the unconjugated BPA, has been detected in human serum, cord blood and in placenta, but the rapporteurs were also aware that the credibility of these measurements had been questioned due to the analytical techniques applied and potential contamination of the samples. The adviser of the Rapporteurs pointed out that there were also studies in non-human primates where unconjugated BPA had been measured in serum following oral exposure. She also noted that oral exposure levels in humans were very low in the studies measuring the blood levels of unconjugated and total BPA, and if the doses would have been higher it would be likely that unconjugated BPA would have been measured with the current analytical methods. Overall, RAC concluded that the findings observed in animal studies were considered relevant to humans.

RAC concluded that comparison of the evidence with the CLP criteria justified the proposed classification. The Committee adopted by consensus the opinion to harmonise the classification and labelling of BPA as Repr. 1B; H360F. The Chairman thanked the Rapporteurs for their clear presentation of the arguments and the Committee for their participation in the discussions.

h) Anticoagulant rodenticides:

The Chairman welcomed an expert accompanying the ECPA stakeholder observer.

He reported that the eight substances belonged to a group of anticoagulant rodenticides, i.e. those with an anti-vitamin K mode of action (AVKs) and were used mainly as the active substances in biocidal products for pest control of rats, mice and other rodents. Some of the substances already had a harmonised classification, however, only Warfarin is classified for toxicity to reproduction in category 1A (human teratogen).

The legal deadline for the adoption of the opinions is 4 September 2014.

The Chairman reported that the dossiers (submitted by eight different dossier submitters - Ireland, Italy, the Netherlands, Sweden, Norway, Denmark, Spain, Finland) were being discussed at a RAC plenary meeting for the third time and that as agreed at previous meetings the Committee would proceed on a substance by substance basis in comparison with the human data available for Warfarin, relying on a weight-of–evidence approach as required by CLP.

He also reminded the meeting that at RAC 27, first draft opinions on Brodifacoum and Flocoumafen were discussed. The Committee had agreed upon a harmonised classification for toxicity to reproduction for Brodifacoum of Repr. 1A; H360D.

At RAC 27, The Committee also agreed on acute toxicity for all routes of exposure (Acute Tox. 1) and specific target organ toxicity after repeated exposure (STOT RE 1, all routes) with the blood as the target organ for Flocoumafen.

Prior to the RAC 28 meeting first draft opinions (revised drafts in case of Brodifacoum and Flocoumafen) were subject to a RAC consultation.

Environmental classification for all eight AVKs was presented by the Rapporteurs and the Committee agreed upon the proposals. The details of the environmental classification are specified in the attached C&L table in Part II of these minutes.

By way of introduction, an overview of the dose-response relationship for developmental toxicity of Warfarin in humans was given by the Rapporteur.

The Chairman then invited the Rapporteurs to present the proposals for developmental toxicity in the following order: 1) mode of action (MoA), 2) human data, 3) animal data, 4) toxicokinetics and placental transfer, 5) summary of evidence and 6) weight of evidence.

In a general discussion on weight of evidence which preceded the substance-specific debate, RAC members re-confirmed the assumption that all AVKs acted in a similar mode of action (MoA) by inhibiting vitamin K epoxide reductase (VKOR) located in the liver and the bones. However, as stated already at the RAC 27 discussion by some RAC members, the common MoA on its own was not seen as sufficient for classification.

The general discussion further touched upon the data sets for each substance, its reliability and comparability. In response to one RAC member, it was confirmed that case reports exist for other substances e.g. acenocoumarol and phenprocoumon used as therapeutic drugs which were summarised in van Driel et al, 2002 and referred to in some draft opinions. One RAC member mentioned an in vitro study on 4 AVKs which showed the effect of inhibition of VKOR in the human liver.

Some RAC members repeated their comments about the potential limits of a standard OECD 414 study to pick up foetal haemorrhages and especially skeletal malformations (bone effects) raised already in relation to the discussion on Brodifacoum during RAC 27. In reaction to these comments the expert accompanying the ECPA stakeholder observer stressed that industry accepted no deficiency of the standard OECD 414 study design in this respect.

After a general discussion based on the first part of the presentations (incl. summary and weight of evidence) the Committee was presented with comparison with the criteria for each substance. The substance-specific discussion and the conclusion of the Committee is summarised below for each substance.

The DS in their specific CLH reports suggested that also specific concentration limits (SCLs) for repeated dose toxicity and for developmental toxicity should be set.

The Committee briefly discussed setting of SCLs at RAC 26, RAC 27 and at RAC 28 agreed upon the following approach.

For setting SCLs for STOT RE the most sensitive studies were chosen and all data were re-calculated using Habers law where appropriate in accordance with the guidance. The proposed SCL's are given in the C&L table in Part II of these minutes. The ECPA expert pointed out that rodenticides as products have been heavily regulated in the past and as a result, the concentrations of AVKs in the products were very low.

It was noted that for developmental toxicity a suitable data set is only available for warfarin. However, as the other AVK rodenticides are equally or more toxic than warfarin, it was not considered appropriate to apply the generic concentration limit for these substances (0.3%), but rather to base the SCLs on that proposed for warfarin. Thus, RAC was of the opinion that the SCL for warfarin could be used as a surrogate SCL for the other AVK rodenticides, resulting in a uniform SCL of 0.003% for all 8 AVK rodenticides classified for developmental toxicity by RAC. In the discussion, the expert accompanying the ECPA stakeholder observer questioned whether it was appropriate to set SCLs for

developmental toxicity of other AVK rodenticides in this way, recalling Article 10 of the CLP Regulation which required '*adequate and reliable scientific information showing that the hazard of a substance is evident when the substance is present at a level below the generic concentration limits*' set in Annex 1 of CLP. RAC, however, considered that the SCLs were justified.

1. Warfarin (ISO)

Warfarin already has a harmonised classification in Annex VI of the CLP Regulation as a known human reproductive toxicant (Repr. 1A), as STOT RE 1 (minimum classification without specification of exposure route) and as for environmental hazard as Aquatic Chronic 3.

RAC agreed to the DS proposal to classify the substance for acute toxicity as fatal for all routes of exposure (Acute Tox. 1; H330, Acute Tox. 1; H310, Acute Tox. 2; H300) and confirmed the existing classification as STOT RE 1; H372 with the blood as the target organ, removing the **).

RAC agreed to the proposal by the DS to classify the substance as toxic to aquatic life with long-lasting effects (Aquatic Chronic 2; H411).

The opinion was adopted by consensus.

2. Flocoumafen (ISO)

Flocoumafen already has a harmonised classification in Annex VI to the CLP Regulation as fatal if swallowed, if inhaled and if in contact with skin (minimum classification for the oral and inhalation routes), as causing damage to organs after prolonged or repeated exposure (STOT RE 1) and as very toxic to aquatic life with long lasting effects (Aquatic acute 1 and Aquatic chronic 1).

At RAC 27, the Committee agreed with the DS proposal for harmonised classification and labelling for acute toxicity (Acute Tox. 1 for all routes of exposure) and confirmed the classification for specific target organ toxicity after repeated exposure (STOT RE 1 with the blood as the target organ).

At RAC 28, the Committee focused on developmental toxicity of Flocoumafen, building upon the discussion at the previous meetings, the revised draft opinion and the presentation of the Rapporteur. A presumption that the MoA (inhibition of vitamin K epoxide reductase, VKOR) of Flocoumafen and Warfarin were similar was confirmed, however, no substance-specific human data were available. It was also noted that there was a difference in toxicokinetics between Warfarin and Flocoumafen, the latter having a lower concentration in plasma and blood, and probably causing higher maternal toxicity than Warfarin.

The assessment of Flocoumafen included consideration of the weight of evidence from the total database for the AVKs. This resulted in a conclusion that Flocoumafen has the capacity to adversely affect the human in utero development and RAC agreed on classification as Repr. 1B; H360D. RAC also agreed to the DS proposal to add an M-factor of 10 to both the acute and the chronic aquatic classification.

The opinion was adopted by consensus.

3. Difethialone (ISO)

The classification and labelling of the substance has so far not been harmonised at EU level.

Based on the weight-of-evidence discussion on developmental toxicity of AVKs and with respect to the substance-specific data set for Difethialone, the Committee agreed to classify the substance as Repr. 1B; H360D.

RAC agreed to the DS proposal for other hazard classes and proposed to classify the substance for acute toxicity in category 1 for all routes of exposure. RAC also agreed to the conclusion of the DS that based on the results of three rabbit studies, the classification for eye corrosion or irritation was not warranted, but an additional labelling with the supplemental hazard statement EUH070 'toxic by eye contact' should be added. Based on the results of the guinea pig test, classification for skin sensitisation was not warranted. Based on the result of a 90-day rat study, RAC supported the DS proposal to classify the substance for specific target organ toxicity after repeated exposure (STOT RE 1) with the blood as the target organ.

RAC agreed to the DS proposal to classify the substance as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) both with an M-factor of 100.

The opinion was adopted by consensus.

4. Coumatetralyl (ISO)

Coumatetralyl already has a harmonised classification in Annex VI to the CLP Regulation as fatal if swallowed (Acute Tox. 2, minimum classification), fatal if in contact with skin (Acute Tox. 1), as causing damage to organs after prolonged or repeated exposure (STOT RE 1) and as harmful to aquatic life with long lasting effects (Aquatic chronic 3).

Based on the weight-of-evidence discussion on developmental toxicity of AVKs and with respect to the substance-specific data set for Coumatetralyl, the Committee agreed to classify the substance as Repr. 1B; H360D.

RAC agreed to classify the substance for acute toxicity in category 2 for oral and dermal routes of exposure and in category 3 for inhalation

Based on the results of three oral repeated dose toxicity studies the Committee agreed with the DS proposal that the classification for specific target organ toxicity after repeated exposure with the blood as the target organ is warranted and thus confirmed the current entry.

RAC agreed to the DS proposal to upgrade the aquatic chronic classification, and as such, to classify the substance as very toxic to aquatic life with long-lasting effects (Aquatic Chronic 1; H410) with an M-factor of 10.

The opinion was adopted by consensus.

5. Brodifacoum (ISO)

Brodifacoum already has a harmonised classification in Annex VI to the CLP Regulation as fatal if swallowed (Acute Tox. 2, minimum classification), fatal if in contact with skin (Acute Tox. 1), as causing damage to organs after prolonged or repeated exposure (STOT RE 1) and as very toxic to aquatic life with long lasting effects (Aquatic acute 1 and Aquatic chronic 1).

At RAC 27, the Committee agreed upon harmonised C&L for developmental toxicity (Repr. 1A, H360D) justified by a similar MoA as for Warfarin and other therapeutic coumarins which are teratogenic in the human, by two human cases where the offspring were more severely affected than the mothers even when treated with vitamin K, by case study in a dog and by uncertainties in relation to the reliability of the experimental animal data in predicting effects in humans.

At RAC 28, the Committee agreed upon classification in category 1 for acute toxicity for all routes of exposure. The Committee confirmed the classification for specific target organ toxicity after repeated exposure (STOT RE 1) with the addition of blood as the target organ. As to skin sensitisation the Committee expressed doubts on reliability of the (poorly reported) study whose results showed higher sensitivity in a Buehler test compare to GPMT and LLNA tests, the

latter which is in general more reliable and shows higher sensitivity. The Committee concluded that no classification would be appropriate in this case.

As to environmental hazard classes, RAC agreed to the DS proposal to add an M-factor of 10 to both the acute and the chronic aquatic classification.

The opinion was adopted by consensus.

6. Difenacoum (ISO)

Difenacoum already has a harmonised classification in Annex VI to the CLP Regulation as fatal if swallowed (Acute Tox. 2, minimum classification), as causing damage to organs after prolonged or repeated exposure (STOT RE 1) and as very toxic to aquatic life with long lasting effects (Aquatic acute 1 and Aquatic chronic 1).

Based on the weight-of-evidence discussion on developmental toxicity of AVKs and with respect to the substance-specific data set for Difenacoum, the Committee agreed to classify the substance as Repr. 1B; H360D.

Based on the results of studies (rats and mice) the Committee proposed to classify Difenacoum for acute toxicity in category 1 for all routes of exposure. The classification for repeated dose toxicity (STOT RE) was confirmed, with the addition of blood as the target organ.

RAC agreed to the DS proposal to add an M-factor of 10 to both the acute and the chronic aquatic classification.

The opinion was adopted by consensus.

7. Bromadiolone (ISO)

The classification and labelling of the substance has so far not been harmonised at EU level.

Based on the weight-of-evidence discussion on developmental toxicity of AVKs and with respect to the substance-specific data set for Bromadiolone, the Committee agreed to classify the substance as Repr. 1B; H360D.

RAC agreed to classify the substance for acute toxicity in category 1 for all routes of exposure. Based on the data (90-day oral study in dogs, 28-day oral study in rats and 90-day oral study in rabbits) the Committee agreed to classify Bromadiolone for repeated dose toxicity (STOT RE 1) with the blood as the target organ.

RAC also agreed to the DS proposal to classify the substance as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1 and Aquatic Chronic 1, M=1 in both cases).

The opinion was adopted by consensus.

8. Chlorophacinone (ISO)

Chlorophacinone already has a harmonised classification in Annex VI to the CLP Regulation as fatal if swallowed (Acute Tox 2, minimum classification), fatal in contact with skin (Acute Tox. 1) and toxic if inhaled (Acute Tox. 3, minimum classification), as causing damage to organs after prolonged or repeated exposure (STOT RE 1) and as very toxic to aquatic life with long lasting effects (Aquatic acute 1 and Aquatic chronic 1).

Based on the weight-of-evidence discussion on developmental toxicity of AVKs and with respect to the substance-specific data set for Chlorophacinone, the Committee agreed to classify the substance as Repr. 1B; H360D.

The Committee agreed to modify the existing acute toxicity classification and to classify Chlorophacinone in category 1 for all routes of exposure. Based on two

studies (90-day oral toxicity study in rats and 21-day dermal toxicity study in rabbits) classification for repeated toxicity in category 1 with the blood as the target organ was confirmed by RAC.

RAC agreed to the DS proposal to add an M-factor of 1 to both the acute and the chronic aquatic classification.

The opinion was adopted by consensus.

In conclusion, the Chairman thanked the team of four Rapporteurs for their consistent and well-structured presentation of the arguments and the Committee for their active participation in the discussion on the AVK rodenticides, also noting with thanks the contribution of the industry expert in the discussions.

i) Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC)

The Chairman reported that the substance is a synthetic fragrance and that it is used in manufacture of various consumer products such as household cleaners, air fresheners, detergents including surface cleaners and personal care products; currently it had no entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of the opinion was 1 January 2015.

The DS (Sweden) proposed to classify HICC as Skin Sens. 1A; H317 GHS07, Warning; with a specific concentration limit (SCL=0.01%). HICC was identified as a cause of skin allergy in late 90's and more than 1500 cases were published in scientific literature since 1999.

In the Rapporteurs' presentation it was concluded that with over 40 diagnostic patch test studies, Repeated Open Application Tests and case reports with relatively high and substantial incidence of reactions in a defined population in relation to relatively low exposure, the substance fulfilled criteria for skin sensitisation, subcategory 1A. This conclusion was supported by the Committee.

RAC agreed with the Rapporteur that the human data did not provide adequate and reliable scientific justification for the DS proposal for setting a specific concentration limit. The generic concentration limit of ≥ 0,1% therefore applies. In accordance with the CLP Regulation, the supplemental hazard information statement code EUH208 would apply automatically to mixtures containing HICC at concentrations ≥ 0,01 %.

The Committee adopted the opinion on hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) by consensus. The Chairman thanked the Rapporteurs for their presentation of the arguments and the Committee for their participation in the discussion.

j) PHMB

The Chairman noted that the dossier submitter (France) proposed to add Acute Tox 2 – H330 (CLP) to the existing PHMB classification. A public consultation was held between 6 June and 22 July 2013, with two Member States supporting the proposed classification and one expressing a neutral position. The first draft of the opinion was subject to RAC comments in the period before the RAC-28 meeting. Two RAC members commented, both supporting the proposed classification.

The Chairman invited the Rapporteur to present the opinion. RAC adopted by consensus the opinion supporting the DS's proposal. The Chairman thanked the Rapporteur for her clear presentation of the arguments and the Committee for

their participation in the discussions. Following an editorial check, the opinion will be published on ECHA's website.

k) Chlorobenzene

The Chairman reported that the dossier submitter (Poland) proposed to classify Chlorobenzene as Skin. Irrit. 2 (H315) and to remove the minimum classification (*) from Acute Tox. 4 (H332).

The first draft of the opinion was subject to RAC comments in the period before the RAC-28 meeting (20/01-2014 – 14/02/2014). Based on the comments from Members the Rapporteur revised the draft opinion document. The Chairman invited the Rapporteur to present the opinion.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for her clear presentation of the arguments and the Committee for their participation in the discussions.

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

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

6.3 General and procedural CLH issues

a) Opinion development process

The Chairman informed the Committee that pursuant to the CLP Regulation, the classification according to the Dangerous Substances Directive (67/548/EEC, DSD) would be phased out for (substances in) mixtures by 1 June 2015. Consequently, the DSD classification should no longer be part of CLH opinions and of RAC discussions and the Rapporteurs are no longer expected to provide DSD classifications in the draft opinions.

The Secretariat informed the Committee about changes in the accordance check phase of the opinion development process, namely the start of the 18-month legal deadline for the development of the opinion which starts at the submission date of the dossier (supposing that one is in accordance). This may potentially mean shortening of a commenting period during the accordance check for the Rapporteurs.

With regard to the status of the new CLH report format, ECHA is currently considering the comments from the PEG consultation and those raised by RAC. Particular attention is given to section 13 and study summaries. The aim is to reach a balance between information needs and the workload of all involved. ECHA reiterated its offer to support the Dossier Submitters in this phase of the dossier preparation.

One RAC member repeated that while understanding the motivation behind the proposed request for study summaries in section 13 of the report, serious concerns remain as to the excessive burden this might cause to all involved.

In this context, the sector-specific observer from ECPA pointed out the difficulties that often occur in cooperation between manufacturers and sector representatives as regards provision of the data / study summaries.

7. Restriction

7.1 General restriction issues

a) Update on intended restriction dossiers

The Committee was provided with an update on intended restriction dossiers and informed that the Registry of Intentions currently includes the following notifications:

- **N,N-dimethylformamide; dimethyl formamide** (to be submitted by Italy in January 2015). The dossier submitter has announced that the dossier will cover placing on the market of articles containing DMF in concentration exceeding the level specified in the restriction. The restriction proposal will cover PROCs (Process Categories) and professional uses (i.e. mixtures of DMF as strippers, paints, etc), where a risk scenario is identified.
- **Methanol** (to be submitted by Poland in August 2014). The objective of the restriction is to avoid acute poisoning due to ingestion of methanol or mixtures containing high concentrations of methanol (such as windshield washer fluids or mixtures of technical alcohol (ethanol) with methanol). Such mixtures are now available for consumers. The proposed restriction will cover placing on the market of methanol and mixtures containing methanol in concentration equal, or greater than 3.0% by weight. Industrial uses as well as manufacturing of methanol or methanol-based mixtures are not included in the scope of the proposed restriction.
- **Bis(pentabromophenyl) ether (DecaBDE)** (to be submitted by ECHA on request of the Commission in August 2014), about which the Committee had been informed earlier.

Furthermore, the Secretariat informed that the intention for the dossier on **Cadmium and its compounds in plastics**, which was supposed to be submitted by ECHA on request of the Commission, had been withdrawn because of lack of information and uncertainties. ECHA will report their findings in an Annex XV report and will discuss the issue at the next CARACAL meeting.

b) Revision of the restriction process

At RAC-27, the Committee was informed about the measures proposed to be taken in order to improve the efficiency of the restriction process. The Secretariat provided an update on the results of the questionnaire carried out in December 2013 among RAC and SEAC members, MSCAs and accredited stakeholder observers of the two Committees, as well as on the work of the Restrictions Efficiency Task Force carried out so far (including their initial recommendations).

The Secretariat then presented to the Committee the revised opinion development procedure for the restriction process. RAC agreed to the revised procedure with small modifications (meeting document RAC/28/2014/05_rev.1). The Chair informed that the new procedure will be applied starting from the restriction dossiers that had passed the conformity check within this plenary meeting.

7.2 Restriction Annex XV dossiers

a) Opinion development

1) Nonylphenol – 2nd version of the draft opinion

The Chairman welcomed the dossier submitter representatives (Sweden) and the SEAC Rapporteurs, who followed the discussion remotely via WebEx. He reminded the Committee that the restriction dossier on Nonylphenol (NP) and Nonylphenol ethoxylate (NPE) had been submitted to ECHA in August 2013 and that the 2nd version of the RAC draft opinion and the related documents had been provided to the Committee on 18 February 2014.

The Rapporteurs presented the 2nd version of the RAC draft opinion. Already at RAC-27, the Rapporteurs had suggested using for further evaluation of the restriction proposal a common freshwater and seawater PNEC with the value of 0.4 µg/L. The Rapporteurs considered it adequate to derive a common PNEC, based on all relevant and reliable data from marine and freshwater species. RAC confirmed their agreement with the Rapporteurs' approach.

In relation to the Endocrine Disrupting (ED) effects of NP, the Rapporteurs noted that in the RAC draft opinion, they had not supported the dossier submitter's approaches to apply extra AF of 10 for ED properties when deriving a PNEC and to assume no threshold for adverse ED effects. Instead, the Rapporteurs proposed to conclude that while being well aware of NP's ED properties, RAC noted a reduced margin of safety for indicative ED effect concentrations, whereas all known adverse effects (both clearly ED related and others) are fully considered by the PNEC of 0.4 µg/L. Some members were of the view that a better explanation as to why the AF proposed by the dossier submitter had not been considered and supported applying extra AF of 10. The Chairman, however, highlighted that in the absence of any guidance at present, applying an arbitrary extra AF could appear insufficiently justified by specific information and suggested that the Committee should continue to focus on the available evidence. It was agreed that as a first step the Rapporteurs will review the explanation given in the draft opinion for not using an AF of 10 (unsupported by Guidance in any case), then check the relevant studies to describe better the ED effects that have already been taken into account in the PNEC. The wording of this part of the opinion is to be revised in the 3rd version of the RAC draft opinion.

In relation to the exposure, the Rapporteurs informed the Committee that they had received more detailed monitoring data from the UK and Lithuania within the ongoing public consultation. Based on the new data and the information used in the dossier, the Rapporteurs had concluded that at least a small proportion of freshwaters in several EU MSs are at risk due to NP exposure. Co-release of other NPEO degradation products will add to the risk, but this cannot be adequately quantified on the basis of the available data. Exposure seems ubiquitous, and domestic sources are important. The Rapporteurs had therefore concluded in their 2nd version of the draft opinion that action is needed on an EU-wide basis. They noted that southern Europe appears to have more sites at risk than the north.

With regard to the NPEO presence in textiles, the Rapporteurs informed the Committee that the Background Document (BD) had been updated with the data from one additional study. Data has been presented as a range and the preferred value (53 mg/kg) is the average of the geometric and arithmetic means. The Rapporteurs clarified that they had been provided with statistical advice that the geometric mean or median is preferable given the skew – the selected value might therefore still be rather high. Based on the data, around 20% of some textile article types may contain NPEO above 100 mg/kg (sometimes above 1,000

or even 10,000 mg/kg) and NPEO concentration is lower than 10 mg/kg in around 50% of the samples.

For NPEO releases from textiles, the Rapporteurs emphasised that these are based on the same textile import figures as before and take into account a new textile content figure. They added that EU-produced textiles are assumed to make around 10% contribution and have therefore been neglected.

The Rapporteurs further explained that textile washing appears to contribute up to about 30% to current NP emissions, though the figures are uncertain. The future scenario is difficult to predict, but taking the assumptions in the BD, there will be a slightly greater risk reduction capacity by 2021. The Rapporteurs concluded that the restriction is an adequate risk reduction option, but will possibly still leave some sites at risk from sources not covered by the proposed restriction.

With regard to the RMOs analysed in the dossier, the Rapporteurs noted that a lower limit (20 or 50 mg/kg rather than 100 mg/kg) with the same transitional period would only make a small difference to the risk reduction potential. A shorter transitional period would bring the desired result more quickly, but this had not been evaluated in the BD and would need further consideration by SEAC.

Finally, the Rapporteurs presented the revised wording of the restriction proposal, which takes into account the advice given by the Forum. Furthermore, NP is suggested to be excluded from the scope.

It was agreed that the Rapporteurs will prepare the 3rd version of the RAC draft opinion by the end of March, taking into account the discussion held at RAC-28. The Secretariat will open a written commenting round on this version.

2) 1-Methylpyrrolidin-2-one (NMP) – 2nd version of the draft opinion

The Chairman welcomed the dossier submitter representative (NL) and the SEAC Rapporteurs, who followed the discussion remotely via WebEx. He reminded the Committee that the restriction dossier on 1-Methyl-2-pyrrolidone (NMP) had been submitted to ECHA in August 2013 and that the 2nd version of the RAC draft opinion and the related documents had been provided to the Committee on 18 February 2014.

The Rapporteur presented the 2nd version of the RAC draft opinion. He recalled that at the last RAC meeting, many RAC members were sympathetic towards the recommendation of the dossier submitter to apply an assessment factor of 10 for pregnant workers. However, deviating from the guidance without a scientific basis for it could be considered as outside the mandate of RAC. The Rapporteurs had therefore re-calculated the DNEL for pregnant workers based on an assessment factor of 5 for intraspecies differences, resulting in an inhalation DNEL of 10 mg/m³ rather than the proposed DNEL for pregnant workers of 5 mg/m³, and dermal DNEL of 4.8 mg/kg/day. The Rapporteurs had proposed in their 2nd version of the RAC draft opinion that the DNELs calculated for pregnant workers should be used for all workers. RAC agreed with the proposed approach and the DNEL values. The Rapporteurs recalculated the RCRs for the uses presented in the dossier using new DNELs and concluded that, as the values exceeded 1 for most uses, the risk for (pregnant) workers is not sufficiently controlled, and that further risk management measures are needed. RAC agreed with this conclusion.

The Rapporteur then presented the range of RMOs described in the dossier and explained that in the draft opinion, they had proposed a modified option 3 as the most appropriate EU wide measure. The proposed modification is that in addition to the mandatory inhalation DNEL proposed by the dossier submitter the general

requirement to protect against dermal exposure would be substituted with a requirement to use a mandatory dermal DNEL in the CSR. The reasons for supporting this option were that the updating of the CSRs would ensure that risk management measures are introduced/recommended for all uses and that dermal exposure (in contrast to the original proposal) would be properly assessed in relation to a dermal DNEL. This option would not require other enforcement approaches than those currently being in place for enforcing REACH provisions in different MSs, and that monitorability can be ensured by following how the exposure scenarios are adhered to. However, the Rapporteurs acknowledged that this restriction would not apply to manufacturers/importers registering less than 10 tonnes/year, as they are not required to produce a CSR (and subsequent downstream uses may not be covered by the restriction). This was seen as a limitation of this option by some of the members. It was clarified by the Secretariat that while currently there are 13 registrations for 1-10 tonnes that would not be covered by the restriction option proposed by the Rapporteurs, there are also 10 registrations for 10-100t and 7 for more than 1000t, so on the basis of the tonnage information from the dossier, it could be calculated that the fraction not covered is approximately 2% of the total volume. Several RAC members supported the modified option 3 as the most appropriate EU wide measure. Several other members, however, were of the view that none of the risk management measures described in the dossier are suitable to address the risk (option 0).

It was agreed that the Rapporteurs will prepare the 3rd version of the RAC draft opinion by the end of March, presenting more detailed analysis of the RMOs. The Secretariat will open a written commenting round on this version, in which RAC members would be expected to express their view regarding which option they would support.

The Chairman thanked the Rapporteurs for their presentation and the Committee for the progress made.

b) Conformity check

1) Isopropylidenediphenol (bisphenol A) - outcome of conformity check

The Chairman welcomed the dossier submitter representatives (France) and the SEAC Rapporteur, who followed the discussion remotely via WebEx. The Chairman reminded the Committee that the dossier on bisphenol A was submitted by France to ECHA on 17 January 2014. The conformity check process was launched in RAC and SEAC on 13 February and the Committees were expected to reach a conclusion on conformity by 14 March 2014 at the latest.

The representative of the DS provided an introductory presentation on the proposal to restrict BPA in thermal paper. BPA is used as a developer in the thermal reactive coating of the paper.

Subsequently the (co-)rapporteurs recommended that the dossier would be considered not in conformity. The (co-) rapporteurs explained that although the methodology of study selection is clarified, it cannot be ascertained from the report how the methodology was applied in practise. Concrete information on the rating of studies and how the key studies were selected would be needed to allow an independent assessment. As an example, several studies that were the basis for the TDI derived by EFSA were not discussed. The (co-) rapporteurs explained further that the Annex XV report does not include biomonitoring data in the

exposure assessment for consumers. Lastly, the (co-) rapporteurs presented their recommendations to the DS that would be relevant for the opinion development. Several members voiced support to the rapporteurs' conclusion, whereas others questioned it. The Chairman concluded that a majority of the Committee supported the rapporteurs' conclusion for non-conformity. One member expressed a dissenting view.

2) Cadmium and its compounds in artist paints - outcome of conformity check

The Chairman welcomed the dossier submitter representative (Sweden). The Chairman provided a brief background to the restriction proposal, which was submitted to ECHA by Sweden on 17 January 2014. On 13 February also the draft conformity check report was opened for RAC consultation.

The Chairman then asked the representative of the dossier submitter (Sweden) to present the main elements of the proposed restriction to the Committee. The proposed restriction concerns placing on the market and use of cadmium and its compounds in artists' paints, TARIC code [3213] and pigments TARIC code [3212] intended for the manufacture of artists' paints. The current restriction in REACH Annex XVII, Entry 23 restricts the use of cadmium and its compounds in paints covered by TARIC codes [3208] and [3209]. EFSA has expressed concern that the margin between the average weekly intake of cadmium from food by the general population and the health-based guidance values is too small and therefore recommends that exposure to cadmium at population level should be reduced.

In this restriction proposal the dossier submitter chose a quantitative risk assessment using two different endpoints, i.e. bone fractures and postmenopausal breast cancer. Exposure to cadmium is via food, due to the fact that the cadmium compounds used in artists' paints will eventually dissolve in the soil and hence there is a potential uptake through crops.

The Rapporteur then presented the outcome of the conformity check and recommended that the dossier should be considered in conformity.

The Commission representative noted that the scope of the Swedish proposal is not clear and should be clarified. Furthermore, she also pointed out that the restriction dossier is based on only one study (Gustafsson 2013) and that another risk management option could have been considered by the dossier submitter, namely the Sewage Sludge Directive 86/278/EEC. The Commission representative also requested RAC to assess the Gustafsson study as a first priority. The Rapporteurs agreed on the importance of the Gustafsson study and assured that it would be assessed as a first priority, pointing out that this was also addressed in the recommendations.

One of the members pointed out that the best way to reduce the risk would be to restrict the cadmium in sludge; therefore it would be better to control cadmium in the fertiliser. The rapporteurs responded by saying that the current Swedish proposal is what needs to be evaluated, but the effectiveness of the proposal would be evaluated and reflected in the RAC (and SEAC) opinions.

The Chairman concluded that RAC agreed that the cadmium in artist paints dossier conforms to the requirements of Annex XV. The Rapporteurs, together with the Secretariat, would finalise the recommendations based on the discussions held. The Chairman then informed the participants that following the conclusion of SEAC on conformity, the Secretariat would communicate the result and the recommendations to the dossier submitter.

The Chairman thanked the Rapporteurs for their presentation of the arguments and the Committee for their participation in the discussions.

3) Chrysotile - outcome of conformity check

The Chairman welcomed the dossier submitter representative (ECHA) and the SEAC Rapporteur, who followed the discussion remotely via WebEx. The Chairman introduced this proposal for an amendment to an existing restriction.

In January 2013, the European Commission requested ECHA to prepare an Annex XV restriction report with a view of prohibiting the placing on the market and use of diaphragms containing chrysotile, noting that special attention should be placed on assessing risks to human health and environment, on the availability of alternatives, and on the socio-economic impacts. ECHA duly submitted a report proposing to amend the existing restriction (Entry 6 paragraph 1 of REACH Annex XVII which covers six types of asbestos fibres). The restriction report proposes a modification to the existing entry such that the existing derogation is modified and extended for the two named companies until 2025, and that those companies need to annually report their use of and risks related to the use of chrysotile.

The RAC Rapporteur then presented the outcome of the RAC conformity check and recommended that the dossier should be considered in conformity. Furthermore, she outlined the recommendations for the dossier submitter.

After a short discussion, the Chairman concluded that the RAC agreed that the Chrysotile dossier conforms to the requirements of Annex XV and the Chairman then informed the participants that following the conclusion of SEAC on conformity, the Secretariat would communicate the results of the conformity check and recommendations to the dossier submitter.

The Chairman thanked the Rapporteurs for their presentation of the arguments and the Committee for their participation in the discussions.

4) Ammonium salts - outcome of conformity

The Chairman welcomed the dossier submitter representative (France) and the SEAC Rapporteur, who followed the discussion remotely via WebEx. He informed the participants that the restriction dossier on inorganic ammonium salts had been submitted by France on 15 January 2014 under Article 129 of REACH (safeguard clause) and was the first dossier of that kind to be processed by RAC and SEAC. This dossier followed a national measure adopted in France in June 2013 due to the fact that France had justifiable grounds for believing that urgent action was essential to protect the public from exposure to ammonia released from ammonium salts used as additives in cellulose wadding based insulation materials in buildings. The Commission authorised the French provisional measure in October 2013 and based on Article 129(3), France was required to prepare an Annex XV restriction dossier within three months of the date of the entry into force of the implementing Commission decision. The conformity check process in RAC and SEAC was launched on 13 February and the Rapporteurs' final draft conformity check outcome was made available to the Committee on 28 February 2014.

The representative of the dossier submitter provided an introductory presentation of the proposal. Substances in the scope of the submitted Annex XV proposal are inorganic ammonium salts that are used in cellulose wadding insulation for their flame retardant properties. These salts can lead to emissions of ammonia, which can act as an irritant gas for mucous membranes and respiratory tract. The conditions of the restriction are the following: inorganic ammonium salts may be used only if emission of ammonia is below 0.3 ppm, a threshold based on the

DNEL for the general population (long-term, inhalation route) and with respect to specific testing parameters.

The RAC Rapporteurs then presented the outcome of the RAC conformity check and recommended that the dossier should be considered not in conformity. They explained that the weakest element of the proposal is that the presented data on hazard identification, exposure values (emissions) and risk characterisation included in the dossier is not sufficient. Because of weaknesses in Part B of the dossier, it is also not possible to assess the risk reduction capacity of the proposed restriction.

The representative of the Commission presented to the Committee a letter which had been distributed to RAC and SEAC prior to RAC-28. In the view of the Commission, the Rapporteurs had gone too far and had started to evaluate information in the conformity check stage. According to the Commission, missing information should not be the reason to consider the dossier not in conformity, as more information could be obtained through the public consultation and in the opinion development process.

One RAC member supported the Commission and emphasised that in his view, RAC should conclude that this dossier was in conformity.

Many other members, however, supported the Rapporteurs. In their view, the dossier submitter had not presented the information available to them in a sufficiently convincing way in the proposal (in particular, concrete evidence of the links between the ammonia emissions from the construction sites and the reported clinical cases). The Committee was aware that under Art 129 of REACH, the DS had very limited time to prepare this dossier. This decision on non-conformity in their view should therefore be seen as providing the dossier submitter with an opportunity to substantially improve their proposal - in order to ensure that the Committees will have a good basis for their further evaluation during the opinion making process.

The Chairman concluded that RAC agreed (by simple majority) that the dossier on inorganic ammonium salts is not in conformity. One member expressed a dissenting view.

7.3 Appointment of (co-) Rapporteurs for restriction dossiers

The Secretariat presented the recommendation of the Chairman for the pools of (co-) rapporteurs for the restriction dossiers **methanol** (to be submitted by Poland), and **N,N-dimethylformamide; dimethyl formamide** (to be submitted by Italy) as outlined in the meeting document RAC/28/2014/07 RESTRICTED. RAC took note on the pools for co-rapporteurs as proposed in the recommendation.

The Chairman strongly encouraged interested members to volunteer to be included in the pool of (co-)rapporteurs for these dossiers.

8. Authorisation

Before the Committee's discussion on the applications for authorisation (AfA) the Secretariat provided a presentation indicating common issues which might be relevant for all the applications. The Secretariat indicated following areas:

1) scope of uses,

2) deviation from reference DNELs agreed by RAC,
3) risk characterisation ratios (RCR) close to the value of one,
4) possible drawbacks in the AfA submitted by manufacturers or importers for downstream users,
5) treatment of new data/information,
6) reflections on combined exposures/effects for different substances,
7) level of scrutiny,
8) general reflections.

1) Scope of uses

The issue of applicants proposing the inclusion of a very broad scope of their uses was discussed. The Committee noted that it is up to the applicant to set the scope of the use applied for. However, applicants should be aware of the consequences, e.g. the Committees could deliver a positive opinion on certain exposure scenarios within the broad use as defined by the applicant, but could also deliver a negative opinion for the whole broad use. The Secretariat confirmed that neither ECHA nor the Committees are in a legal position to reject broad scope uses at the conformity check stage.

The Committee also discussed the cases, when the applicant applies for uses clearly exempted from the scope of the authorisation process (e.g. consumer use of a medicine containing Annex XIV substances). ECHA suggested that the Pre-submission Information Sessions with the potential applicant and/or technical checks would be appropriate means for examining the validity of applications for exempted uses. During these, ECHA could recommend to the applicant to remove the exempted use. Nevertheless should the applicant decide to submit the application for authorisation for a use that is clearly exempted, the Committee might state that the application is out of the scope of authorisation. For the uses not clearly exempted from the scope of the authorisation because of overlap with other Regulations in the EU, ECHA would not be in a position to reject such applications until further clarifications are provided (e.g. by the Commission). In such a case the Committee shall deliver its opinion in the usual way.

2) Where Deviation from reference DNELs agreed by RAC

Where an applicant deviates in their application from the reference DNEL values agreed by RAC, the Committee considered that RAC should evaluate the applicant's risk assessment based on RAC DNELs, but should take the applicant's argumentation for deviating from this into account. Unless robust and valid justification is provided by the applicant, RAC would not deviate from its reference DNEL.

3) Risk characterisation ratios (RCR) close to value of one

When RCR values are close to one, the Committee can evaluate and then recommend the applicant to recalculate their RCRs. If after this, the RCRs are still close to 1 or just below 1, RAC could use expert judgement and/or suggest to recommend additional conditions and /or monitoring arrangements. RCRs close to 1 could also be one criterion for recommending a short review period.

Conversely, if the Committee concludes that the RCRs are above 1, then the risks are not adequately controlled. In such cases the application will then be evaluated as to whether risk has been minimised and will then follow the socio-economic analysis route. The Committee nevertheless still shall evaluate the residual risks to enable SEAC to weigh them against benefits.

4) Possible drawbacks in the AfA submitted by manufacturers or importers for downstream users

Concerning the differences of the applications for authorisation submitted by manufacturers or importers, and those by submitted by downstream users, secretariat made a few general observations: firstly, the REACH Regulation is designed with a top-down approach for both registration and authorisation processes; secondly, the burden of registration falls on manufacturers and importers, who should cover their whole supply chains unless downstream users' reports are submitted. The Secretariat also mentioned the difficulties for manufacturers and importers to obtain information on uses and exposure levels that are representative of all workplaces down their supply chains.

5) Treatment of new data/information

The Secretariat noted that from practical experience, manufacturers and importers tend to submit broad scope, generic applications which may be difficult to relate to representative workplace conditions in their applications for authorisation, while downstream users produce more specific and straightforward applications for a single or limited number of specific workplaces. They also highlighted that biomonitoring and exposure measurements data from downstream users are not always available to manufacturers and importers so to a certain extent generalisation cannot be avoided by the manufacturers and the importers.

The Committee noted that modelling could be used either as the main source of exposure estimation or to complement and confirm measured data.

Regarding the submission of new data or new information, the Committee distinguished two clear cases. The first case is when new data is submitted at the request of RAC. New data may be delivered by the applicant at different points in time during the process e.g. as written responses or via interactive discussions during the trialogue to the additional questions asked by RAC to get clarifications on essential elements of the risk assessment. The applicant may however come back with some elements out of the original scope of the questions. The Committee and the secretariat also noted that there are difficulties in distinguishing between clarifications on one hand and new data/information on the other.

The second case is when new data is submitted but not at the request of RAC. The Secretariat explained that in principle applicants are not allowed to submit spontaneous updates of their application during the opinion-making phase. In practice, rapporteurs may be informed about new developments or new data, which cannot be ignored, e.g. new exposure reports, changes in the status of the applicant etc. ECHA suggested and the Committee agreed to take a pragmatic approach for the moment on a case-by-case basis. Hence, the Committee should consider whether the information is critical for the concrete application for authorisation. It is also important to consider at what point in time new information is submitted, e.g. during the trialogue or in between the following plenaries. It is also important whether new information might have an impact to the proposed review period.

The Secretariat noted that the applicant can also bring new information in their comments on the final draft opinion agreed by the Committee, if they consider it necessary to do so.

6) Reflections on combined exposures/effects for different substances

During the discussion on combined exposures/effects for different substances, the Committee noted that the REACH Regulation as a whole is substance-specific. The evaluation within the Committee will therefore be carried out on a substance-use-applicant basis. The Committee previously agreed on the common approach, which inter alia requests that the evaluation of applications should be done for each application independently, and that RAC and SEAC provide opinions on the applications for authorisation based on their own merits. The Secretariat pointed out that in practice annex XIV entries may contain a group of substances in a single entry, e.g. HBCDDs and acids generated from chromium trioxide and their oligomers. The Committee examined two possible scenarios. The first, when two different but similar substances grouped in one application for the same use are evaluated. After a short exchange of views RAC agreed that it should give an opinion for each combination of substance and use in the application for authorisation. However, RAC can evaluate combined exposures, and if combined RCRs are above one, the Committee could recommend further conditions.

Another scenario concerns two separate but similar substances being submitted in two different applications. The Committee agreed that the evaluation should be done for each application independently. RAC should give an opinion per substance. RAC also agreed that the Committee should not evaluate combined exposures/effects across individual applications submitted, e.g. by different applicants, at different moments in time, for uses that are not identical.

7) Level of scrutiny

Regarding the level of scrutiny, the Committee agreed that it should not redo the applicant's assessments. RAC would focus on essential/critical points, e.g. when RCRs are around a value of one. RAC acknowledged difficulties being faced in practice with regard to finding acceptable boundaries between clarifications and improvement of the original quality of the application.

8) General reflections

RAC concluded in general that experience gained through the evaluation of the first applications for authorisation should be carefully documented in the minutes and ultimately in Committee procedures for future reference.

8.1 Authorisation application

a) Authorisation applications on Phthalates – 1st outline/version of the draft opinions (applications submitted within the August 2013 submission window)

The Chairman announced that the discussion on the first version of the draft opinions would take place in an observed session, i.e. with Stakeholder Observers present. However, in the unlikely event that confidential business information needed to be discussed, he would close the session as a precaution. He reminded the participants, including Stakeholder Observers of the need to keep the discussions on the applications confidential.

RAC was to discuss and where indicated agree on the draft (or outline) versions of the draft opinions of the seven applications for authorisation for a total of 16 uses of DEHP and DBP.

Please note that sequence in the minutes may differ to that in which dossiers were handled and agreed in Committee, as several of the dossiers are related to each other.

1. Two uses of DEHP submitted by ARKEMA FRANCE (DEHP 2a):
    i. Formulation of DEHP in compounds, dry-blends and Plastisol formulations
    ii. Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles

The (co)rapporteurs gave a brief overview of the applications by ARKEMA FRANCE, Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna (DEHP 2b) and DEZA a.s. (DEHP 2c) and described the developments since submission, in particular the outcome of the public consultation, the responses from the applicants to rapporteurs' information requests, as well as the outcome of the trialogue meetings. They clarified that the CSR is the same for all 3 applicants' uses 1 and 2.

The Rapporteurs continued by highlighting several shortcomings in the exposure assessment for workers. Amongst others it was remarked that only literature data was provided by the applicants, and that considering the broad scope of the applications, the number of samples and workers as well as the coverage of processes and industry sectors, was considered to be very limited.

The Rapporteurs explained the differences in the DNEL setting made by the applicants and the reference DNEL derived by RAC in April 2013. They considered that the general population's RCR is lower than 1, based on RAC's reference DNEL and the exposure values presented by the applicant. However, the workers' RCR are higher than 1 when using RAC's reference DNEL and exposure assumptions that differ from those used by the applicants.

The Rapporteurs presented the uncertainties in the DNEL setting and the exposure estimates. The influence of the uncertainties is towards a higher DNEL. On the other hand, the overall tendency of uncertainties for exposure assessment is more likely in the direction of higher exposure levels at the workplace. The influence of combined uncertainties on the RCR cannot be assessed as their magnitude is unknown.

The Committee discussed the applicants' justifications for deviating from the RAC reference DNEL, but concluded that the arguments were insufficient.

Following a detailed discussion, members considered that the exposure data for workers were not representative, and therefore supported the proposal of the Rapporteurs to use higher end exposure estimates (90^{th} percentiles and maximum values if 90^{th} were not available) in the opinion. It was pointed out that the consequence of this preliminary conclusion could be that adequate control might not have been demonstrated by the applicant and thus that the socio-economic route would need to be followed for these applications.

The possibility for including risk management measures as a condition in the authorisation was explored. Several members were of the view that considering the broad scope and the uncertainties surrounding the current exposure levels in unknown workplaces, it could be very difficult to propose meaningful risk management measures.

2. Two uses of DEHP submitted by Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna (DEHP 2b):
    i. Formulation of DEHP in compounds, dry-blends and Plastisol formulations
    ii. Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles

Due to the similarities of the dossiers, the uses i and ii for this application were discussed together with the application from ARKEMA FRANCE (DEHP2a, see minutes above).

3. Three uses of DEHP submitted by DEZA a.s. (DEHP 2c):
    i. Formulation of DEHP in compounds, dry-blends and Plastisol formulations
    ii. Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles
    iii. Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements.

Due to the similarities of the dossiers, the uses i and ii for this application were discussed together with the application from ARKEMA FRANCE (DEHP2a, see minutes above). The discussion on the use iii was postponed to RAC-29 for the reasons given below.

The Chairman informed the Committee that following the outcome of the trialogue meeting held for DEZA's uses of DEHP and DBP in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements (use 3 in DEHP2c and DBP2; see below), this use would not be further discussed at RAC 28. He clarified that the procedural aspects with regard to the admissibility of very extensive and crucial new information, not contained in the application but presented at the trialogue were being considered by the Secretariat.

4. Three uses of DBP and DEHP submitted by Roxel (UK Rocket Motors) Ltd (DEHP 3):
    i. Industrial use of DEHP in manufacture of solid propellants and motor charges for rockets and tactical missiles
    ii. Industrial use of DBP in manufacture of solid propellants and motor charges for rockets and tactical missiles
    iii. Industrial use of DBP within a specialty paint in manufacture of motors for rockets and tactical missiles

The Chairman welcomed the RAC Rapporteurs, the SEAC Rapporteur, who was following the discussion via WebEx, and the Authorisation Team.

The Rapporteurs then presented briefly the application, informed about the outcome of the rapporteur's dialogue, and trialogue and written consultations with the applicant. The Rapporteurs presented the conclusions of the first versions of the draft opinions of the application for authorisation for 3 uses.

Use 1 (DEHP) and 2 (DBP)

The Rapporteurs' referred to RAC's earlier opinion that both substances are threshold substances. In the Rapporteurs' opinion the applicant demonstrated adequate control of use of both substances on the basis of the RAC reference DNELs. In both uses 1 and 2 the combined RCRs (inhalation and dermal) are well below the reference value 1 (Use1, DEHP, RCR combined: ≈ 0.123; Use 2, DBP, RCR combined: ≈ 0.647). The substances are used in a mixture and the combined RCR for both substances remains below 1.

One RAC member asked for clarification why the applicant has deviated from the standard parameters in the modelling tools. The rapporteur clarified that due to

the risk of explosion and the use of very toxic substances the applicant applies extremely strict production procedures including efficient Local Exhaust Ventilation and Personal Protective Equipment standards and this justifies the deviation from the standard parameters. Another member was interested if the applicant has any monitoring data concerning the workers exposure to DEHP and DBP. It was clarified during the trialogue that the substances are used in very small quantity and at a very low concentration. Therefore, according to the applicant, it is not required to measure the potential for inhalation. The applicant did have measurement data of other substances used during the production process and the RCRs for those substances were below 1. The applicant assumed that also for DEHP and DBP, the RCR is below limit.

A RAC member inquired whether there could be combined exposure for workers due to activities of all three uses. The applicant provided information in writing that uses 1 and 2 do not occur in the same production hall as use 3 and the activities associated with these uses are not performed by the same group of workers. Therefore, combined exposure for workers across all uses is not assessed. The RAC member recommended that this is included in the justification.

The RAC agreed with the conclusion that for both substances in Use 1 and 2 the applicant demonstrated adequate control and that the risk assessment of alternatives is not applicable. A conclusion for adequate control was also made for the combined exposure of workers to use 1 and use 2. The RAC adopted its draft opinions for use 1 and 2, recommending granting of the authorisation.

Use 3 (DBP)

The Rapporteurs proposed to the RAC the conclusion that the applicant had demonstrated adequate control in use 3. The combined RCR (inhalation and dermal) is below 1 using the RAC reference DNELs (Use3, DBP, RCR combined: ≈ 0.924).

One RAC member noted that tier 2 modelling tools were used to calculate the exposure assessment, taking away some conservatism in the risk assessment. This is important to consider when the RCRs are close to 1. Additionally, the RCR for inhalation is very close to the RCR for dermal exposure which is unusual. In his opinion, the results should be verified and measurement data should be taken into account. Even if measurement data is not available for DBP, the applicant should be asked to present results based on an analogous substance used in the process for which monitoring data is available. Other members expressed opinions that the approach taken by the applicant in this use is not so conservative; therefore, the final conclusion should be carefully verified.

The authorization team summarised information provided by the applicant about their operational conditions: the painting is done in a building designed for this activity with a special LEV system, the applicant ensures use of proper PPE by workers. It was also clarified that the modelling tools used by the applicant (second tier tool Riskofderm and other) have been designed for high volume substances used in industrial applications, while in this case the volume of the substance is 40 kg/year.

The RAC asked the Rapporteurs and the ECHA Secretariat to request the applicant for measurement data (for other substances used in the process), a better illustrated explanation of the process, the volume of the substance used at one time and the frequency of the activity.

The Rapporteurs will prepare the second version of the draft opinion which will be subject for RAC consultations and discussion at the next plenary meeting.

The Chairman thanked the Rapporteurs for their work and the Committee for their participation in the discussion.

5. One use of DBP submitted by Sasol-Huntsman GmbH & Co. KG (DBP 1):
    i. Use as an absorption solvent in a closed system in the manufacture of Maleic Anhydride

The Chairman welcomed the RAC Rapporteurs, the SEAC Rapporteur, who was following the discussion via WebEx, and the Authorisation Team.

The Rapporteurs then informed about the outcome of the rapporteurs dialogue and the written consultations with the applicant, and presented the first version of the draft opinion of the application for authorisation for use of DBP as an absorption solvent in a closed system in the manufacture of maleic anhydride.

The Rapporteurs noted earlier conclusions that DBP is a threshold substance. They informed RAC that although the exposure assessment for environment is not relevant as DBP is listed on Annex XIV for its reprotoxic properties according to the applicant there is no emission to the environment. The human exposure via the environment was assessed and is shown to be negligible as the RCR for man via environment for combined oral and inhalation routes is less than 0.01.

Regarding the workplace inhalation exposure assessment, the Rapporteurs informed the RAC that the applicant used modelling tools to derive the exposure concentrations for the inhalation and dermal routes. The rapporteurs concluded that the modelling assumptions sufficiently reflect the operating conditions and that the conditions of use are well controlled. This includes also maintenance activities. During the single shift the combined exposure for the activities WCS1 and WCS2 are respectively 0.006mg/m³ (Combined inhalation exposure) and 0.015 mg/kg bw/day (Combined dermal exposure).

The Rapporteurs noted that the applicant had used the RAC reference DNEL values for reproductive toxicity and that this gave a combined RCR value of 0.13, which is around 10 times lower than the reference RCR of 1.

The Rapporteurs explained that biomonitoring data provided by the applicant supported the conclusion on adequate control and that the combined RCR for all routes is below 1 (including workers doing maintenance work). For evaluation purposes, the Rapporteurs calculated the RCR for dermal and inhalation exposure using biomonitoring data. The latter was higher than the modelled RCR for this route. However, this could be partially attributed to the conservative assumption that the whole burden is via the inhalation route. Being aware of this, the RAC took these RCRs as supportive of adequate control. The RAC agreed with the Rapporteurs proposal to include these conclusions in the Annex of the draft justification of the opinion. One RAC member suggested the Secretariat to include an explanation to the methodology used in the calculation of the RCRs using biomonitoring data.

The RAC discussed the need for the risk assessment of alternatives. It focused on the two commercially proven DIBE (diisobutyl hexahydrophthalate) based technology and water and xylene based technology. The RAC concluded that due to the lack of sufficient information it was not possible to assess whether the alternatives would lead to an overall reduction of risk. These conclusions were reflected in the draft opinion during plenary.

The Rapporteurs did not recommend specific conditions or monitoring arrangements over and above the RMMs and OCs that have already been included in the application. The COM representatives recommended that a standard text is included in the opinion in these circumstances. The RAC agreed with the Rapporteurs recommendations and proposed an editorial change to the draft

standard text included in the Annex to the justification. The RAC saw no reason to make any recommendation for a shorter review period.

The RAC agreed that the adequate control had been demonstrated by the applicant. Therefore, RAC agreed the text of the draft opinion on the application for authorisation, recommending granting of the authorisation.

The Chairman thanked the Rapporteurs for their work and the Committee for their participation in the discussion.

6. Three uses of DBP submitted by DEZA a.s. (DBP 2):

i. Use as an absorption solvent in a closed system in the manufacture of Maleic Anhydride

The Chairman invited the RAC Rapporteurs to present the case and the draft opinion. Due to the similarity with the application for use of DBP submitted by Sasol-Huntsman the rapporteur presented only the difference between both applications. While the exposure scenarios and the risk assessment are the same, there is some difference in the analysis of alternatives due to the different role of this applicant in the supply chain.

The RAC agreed that the same conclusions as in the application by Sasol-Huntsman should apply. The substance is a threshold substance and the adequate control had been demonstrated by the Applicant. The RAC agreed with the text of the draft opinion on the application for authorisation, recommending granting of the authorisation. The Secretariat was tasked to make similar changes to the draft opinion as those agreed for the Sasol-Huntsman opinion.

The Chairman thanked the Rapporteurs for their work and the Committee for their participation in the discussion.

ii. Use in propellants

The Chairman invited the RAC Rapporteurs to present the case. The Rapporteurs informed RAC about the activities concerning this use since the last RAC plenary.

During the work on the draft opinion the rapporteurs prepared several questions to the applicant concerning exposure assessment. They asked for clarifications concerning effectiveness rate of PPE and LEV for all Worker Contributing Scenarios, form of DBP (liquid or solid), detailed description of tasks/activities under relevant scenarios, the actual time of workers' exposure during shift of 8 hours and monitoring data. Written answers to the questions were provided by the applicant in additional documents submitted before the trialogue and during the trialogue. Nonetheless, a few issues were still remaining, e.g., PPE, combined exposure, and description of all PROCs. The RAC agreed with the Rapporteurs opinion that the currently available information is not sufficient to conclude on the risk and supported the Rapporteur's proposal to ask the applicant for further clarifications.

iii. Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

The discussion on the use iii) was postponed for the RAC-29 plenary meeting, for the same reasons outlined for Use 3 in DEHP2c.

7. Two uses of DEHP submitted by VINYLOOP FERRARA S.p.A., Stena Recycling AB and Plastic Planet srl:
    i. Formulation of recycled soft PVC containing DEHP in compounds and dry blends
    ii. Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles

The Rapporteur presented her preliminary views on the application for authorisation, pointing to the large number of documents in the application being claimed as confidential. After a brief exchange of views the Chairman decided to continue with the application in observed session, noting the Confidentiality Advisor's advice to the Chairman prior to the meeting to this effect.

The Rapporteur briefed the Committee about the content of the application for authorisation. DEHP content in recycled PVC was stated to contain one to 20 per cent of DEHP with an average value of below ten per cent. The Rapporteur also reminded the Committee that DEHP is considered as a threshold substance for which RAC agreed the reference DNEL values. Hence the application needs to demonstrate adequate control of the risks associated with the uses of the substance. However, the rapporteur also noted that DEHP has been linked to endocrine disruption as well, which could affect the setting of a threshold. Since DEHP is placed on Annex XV for it reproduction toxicity (57c), endocrine disruption (57f) is outside the scope of the present authorisation.

The applicants applied for the authorisation of the substance for two following uses: formulation of recycled soft PVC containing DEHP in compounds and dry-blends (use 1) and industrial use of recycled soft PVC containing DEHP in polymer processing by calendaring, extrusion, compression and injection moulding to produce PVC articles (use 2). The Rapporteur informed that use 2 also covers service life of the articles used by professionals, i.e. handling of PVC articles (industrial flooring, stall mats) and professional and industrial workers wearing PVC work clothes, footwear, rainwear, and service life for consumers, i.e. exposure from consumers to articles, gym, door, car mats, footwear, outdoor seats, handles.

During the discussion on the application for authorisation, the Rapporteur explained that at the trialogue the applicant provided analytical data in support of the claim about the content of DEHP in the recyclate, which is typically less than 10%. The applicant could also demonstrate that the content of other phthalates in the recyclate was below 0.1%, and thus is out of the scope of the authorisation process (Article 56.6 b of the REACH Regulation). The Rapporteur evaluated information as adequate, and she suggested that for approval of the application this information is added as a condition for approval. Some RAC members asked questions about concentration used in modelling. The rapporteur responded that 20% was used as a basis for modelling by the applicants. RAC did not discuss the rapporteur's question regarding the status of the recyclate as a "substance" or as a waste, considering it to be an issue of policy.

The Rapporteur also presented DNEL values used by the applicants for different exposed groups, i.e. workers (inhalation, dermal), consumers (inhalation, dermal, oral) and the general population via the environment (oral). Almost in all cases the applicants used higher DNEL values than the reference DNELs agreed by RAC. The Rapporteur also noted differences in intra-species assessment factors (3 *vs.* 5) and oral absorption rates used by the applicants and RAC. The Rapporteur concluded that there was no reason to deviate from the reference DNELs agreed by RAC. The conclusion received general support from the Committee members.

For both uses five biomonitoring studies of which two were conducted in the EU, and air monitoring studies on industrial workers are available.

- Processes involved under use 1 and use 2 are covered by 3 monitoring studies (NL, F, US) and supported by two additional biomonitoring studies (Taiwan) form which the highest geometric mean of the NL study (1983) was used in risk assessment by the applicants.
- Transfer of big bags by the industrial workers for both uses is calculated using the Advanced REACH Tool for modelling.
- Professional users exposure assessment resulting from use 2 is calculated using modelling data.
- Consumer exposure assessment resulting from use 2 is based on biomonitoring data used from the DEMOCOPHES project (LIFE 09ENV/BE/000410).

A preliminary assessment, using RAC reference DNEL values and exposure estimates derived by the applicants, shows RCRs around one and above one for industrial workers involved in use 1 and use 2. In the evaluation the rapporteur noted that the biomonitoring data were limited in view of the broad scope of the application.

Therefore the Rapporteur asked the following questions to the Committee:

1) Are the exposure data provided (i.e. biomonitoring) sufficiently representative for risk assessment?

2) Are high-end exposed workers (e.g. involved in dry-blending calendering or extrusion) sufficiently protected by the 90^{th} percentile?

3) How to deal with maximum air concentrations in relation to window of critical effect?

In their responses RAC members noted the importance of biomonitoring data from the workers at the production site. One member asked to take a closer look at already implemented risk management measures at the site, since they may be more stringent than in the studies. It was noted by the rapporteur that the applicants themselves do not perform the activities for which authorisation is being applied for, but rather they are carried out by downstream users. Data are lacking on the risk management measures applied by the actual downstream users. From the general presentation members could not judge whether the risks are adequately controlled, they also questioned the representativeness of the samples taken during the available biomonitoring studies for the site in question.

Proposed alternatives were the following:

1) Waste segregation by separating DEHP containing waste from DEHP-free waste;

2) DEHP elimination from the incoming post-consumer flexible PVC waste streams;

3) Replacement of post-consumer PVC waste by post-industrial PVC waste.

All the proposed alternatives were described by the applicants as being technically or economically unfeasible.

The Rapporteur will work on the first version of the RAC Draft Opinion. In the beginning of April the Secretariat will launch the RAC consultation on the first version of the RAC Draft Opinion.

The Chairman thanked the Rapporteurs for their work and the Committee for their participation in the discussion.

b) Authorisation application - outcome of conformity check

The Rapporteurs briefly presented the following applications for authorisation received by ECHA:

1) Application for authorisation submitted by Boliden Kokkola Oy on the following use of diarsenic trioxide:

> Use of diarsenic trioxide in the purification of metal impurities from the leaching solution in the zinc electro-winning process

2) Application for authorisation submitted by Nordenhamer Zinkhütte GmbH on the following use of diarsenic trioxide:

> Industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electrowinning process

3) Application for authorisation submitted by Linxens France on the following uses of diarsenic trioxide:

> Use 1: Formulation of diarsenic trioxide into a mixture
>
> Use 2: Industrial use of diarsenic trioxide as processing aid in gold electroplating

4) Application for authorisation submitted by DCC Maastricht B.V. OR C.I. on the following uses of Pigment Yellow 34 and C.I. Pigment Red 104:

> Use 1: Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use
>
> Use 2: Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)
>
> Use 3: Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc) or as road marking
>
> Use 4: Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use
>
> Use 5: Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use
>
> Use 6: Professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hotmelt road marking

The RAC agreed with the Rapporteurs that all above listed applications for authorisation are in conformity. The Secretariat will upload the Conformity Reports to the non-confidential part of CIRCABC and will send them to the applicants.

The teams of Rapporteurs also reported on some issues which could be relevant to the evaluation of the applications. They will formulate their questions to the applicants for further clarification. The Chairman thanked the Rapporteurs for their presentations and the Committee for their participation in the discussions.

8.2 Capacity building

a) ECHA project on carcinogenicity dose-response analysis of Trichloroethylene

The ECHA Secretariat presented the outcome of the project and a draft note concerning the publication of carcinogenicity dose-response relationships for trichloroethylene.

The RAC members discussed that a dose response relationship based on linear extrapolation would overestimate the excess risk in the low exposure range. Therefore a sub linear approach might be more appropriate, if adequate supporting evidence to describe the sub linear dose response is available.

Moreover, the members recommended adding information to the note to the effect that it is a RAC recommendation but that the applicant can deviate from this proposal provided they can justify it properly.

The RAC requested the contractor to modify the draft report within two weeks' time of the plenary meeting. The Secretariat will launch a written procedure for agreement on the draft note.

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

RAC agreed on the renewed pool of rapporteurs for AfA process. The Chairman of the RAC informed the members about appointment of co-rapporteurs for AfA on the uses of hexabromocyclododecane (HBCDD).

9. AOB

Update on Guidance activities

The Chairman informed the Committee that an update on Guidance activities was made available to the members via CIRCABC.

In closing the meeting, the Chairman thanked all the participants and the Secretariat for their patience and dedication during the two week meeting, noting the volume of work that had been agreed and adopted and the progress made.

Part III. List of Attendees of the RAC-28 meeting

4-7 March 2014 (A) and
11-14 March 2014 (B)

RAC members	ECHA staff
BARANSKI Bogusław (A+B)	BERGES Markus (A)
BARRON Thomasina (B)	BLAINEY Mark (A)
BIRO Anna (A+B)	BOWMER Tim, Chairman (A+B)
BJORGE Christine (A+B)	BROECKAERT Fabrice (B)
CARVALHO João (A+B)	DVORAKOVA Dana (A+B)
CZERCZAK Slawomir (A+B)	ERICSSON Gunilla (B)
Di PROSPERO FANGHELLA Paola (A+B)	HELLSTEN Kati (B)
DUNAUSKIENĖ Lina (A+B)	HONKANEN Jani (B)
DUNGEY Stephen (A)	JOVER BUSTILLO Vanessa (A+B)
GRUIZ Katalin (A+B)	KANELLOPOULOU Athanasia (A+B)
GUSTAFSON Anne-Lee (A+B)	KARJALAINEN Ari (B)
HAKKERT Betty (A (4-5 March)+B (11-13 March)	KIOKIAS Sotirios (A)
ILIE Mihaela (B)	KIVELÄ Kalle (A)
JENSEN Frank (A)	KLAUK Anja (B)
KADIĶIS Normunds (A+B)	KOKKOLA Leila (A+B)
KAPELARI Sonja (A+B)	KOSK-BIENKO Joanna (A)
KORATI Safia (A+B)	KOULOUMPOS Vasileios (A)
LEINONEN Riitta (A+B)	LAPENNA Silvia (B)
LUND Bert-Ove (A+B)	LOGTMEIJER Christiaan (A)
MENARD Anja (A+B)	LUDBORŽS Arnis (A+B)
MULLOOLY Yvonne (A)	LUSCHÜTZKY Evita (B)
PARIS Pietro (A+B)	MAGGIORE Angelo (B)
PASQUIER Elodie (B)	MARQUEZ-CAMACHO Mercedes (A)
PRONK Marja (A+B)	MOSSINK Jos (B)
RUCKI Marian (B)	MOTTET Denis (A)
RUPPRICH Norbert (A+B)	NICOT Thierry (A)
SCHLÜTER Urs (A)	NYGREN Jonas (B)
SCHULTE Agnes (A+B)	ORISPÄÄ Katja (A)
SMITH Andrew (A+B)	PELTOLA Jukka (A)
SOGORB Miguel (A+B)	RIVERO Debora (A+B)

SOERENSEN Peter (A (4-5 March)+B)	RODRÍGUEZ IGLESIAS Pilar (A+B)
SPETSERIS Nikolaos (A)	ROGGEMAN Maarten (A)
STOLZENBERG Hans-Christian (A+B)	SADAM Diana (A)
TADEO José Luis (A+B)	SOSNOWSKI Piotr (A+B)
TSITSIMPIKOU Christina (A)	SPJUTH Linda (B)
UZOMECKAS Zilvinas (A+B)	STOYANOVA Evgenia (A)
Van der HAGEN Marianne (A+B)	VAINIO Matti (A)
VARNAI Veda Marija (A+B)	VAN HAELST Anniek (A+B)
VIVIER Stephanie (B)	**Remote participants**
Invited experts	**RAC members:**
LARSEN Poul Bo (A)	BRANISTEANU Radu (A)
GIOVALLE Estelle (A)	DUNGEY Steve (B)
Advisers to the RAC members	HAKKERT Betty (A: 6-7.3)+(B:14.3.)
FLORIDI Elena (adviser to Pietro Paris) (A)	JENSEN Frank (B)
LINDEMAN Birgitte (adviser to Christine Bjoerge, and CLH adviser for Bishpenol A) (B)	LOSERT Annemarie (A+B)
MANTOVANI Alberto (adviser to Paola di Prospero and CLH adviser for borates) (B)	PASQUIER Elodie (A)
MURRAY Brendan (adviser to Thomasina Barron) (B)	VIVIER Stephanie (A)
NEUMANN Michael (adviser to Hans-Christian Stolzenberg) (A+B)	**SEAC members (AfA and restriction):**
NIEMELÄ Helena (adviser to Riitta Leinonen) (A)	BOUSTRAS George (A)
PAPPONEN Hinni (adviser to Riitta Leinonen) (A)	BRIGNON Jean-Marc (A)
PECZKOWSKA Beata (adviser to Boguslaw Baranski and CLH adviser for direct blue FC) (B)	DANTINNE Catheline (A)
PRUTNER Wiebke (adviser to Norbert Rupprich and CLH adviser for bupirimat) (B)	FIORE Karine (A)
RISSANEN Eeva (adviser to Riitta Leinonen) (B)	FOCK Lars (A)
ROMOLI Debora (adviser to Pietro Paris, and CLH adviser for flumioxazin) (B)	FRANKHAUSER Simone (A)
ROTHER Dag (adviser to Agnes Schulte and Urs Schlüter) (A)	FURLAN Janez (A)
Ter BURG Wouter (adviser to Betty Hakkert and Marja Pronk) (A)	GEORGIOU Stavros (A)
VILNISKE Lina (adviser to Lina Dunauskiene) (A)	LUTTIKHUIZEN Cees (A)
EU Commission observers	PALOTAI Zoltan (A)
LEFEVRE Remi (A)	THORS Åsa (A)

LUVARA Giuseppina (A)	
MORRIS Alick DG EMPL, SCOEL (A)	**Advisers:**
PIRSELOVA Katarina (A)	HERINGE Minne (adviser to Betty Hakkert) (A)
SCAZZOLA Roberto (B)	STARKE Martina (adviser to Hans-Christian Stolzenberg) (A+B)
Stakeholders observers	Ter BURG Wouter (adviser to Betty Hakkert) (A: 7 March)
ANNYS Erwin, CEFIC (A+B)	**FR dossier submitters:**
BARRY Frank, ETUC (A+B)	BARTHELEMY-BERNERON Johanna (bisphenol) (A)
ROMANO Dolores, EEB (A)	CAVALIERI Luisa (ammonium salts) (A)
ROWE Rocky, ECPA (B)	SADOINE Margaux (ammonium salts) (A)
SANTOS Tatiana, EEB (B)	TERENDIJ Carline (ammonium salts) (A)
VEROUGSTRAETE Violaine, Eurometaux (A+B)	**NL dossier submitter:**
Industry experts	BEEKMAN Martijn (NMP) (A+B)
BALL Wayne (Eurometaux, borates) (B)	GOMEZ Jeannette (bupirimate) (B)
BEYER Dieter (Cefic, BPA CLH) (B)	MÜLLER Andre (AVK) (B)
KAWAMURA Satoshi (ECPA, flumioxazin) (B)	TIESJEMA Gitte (AVK) (B)
STRUPP Christian (ECPA, bupirimate) (B)	**SE dossier submitters:**
WARREN Simon (ECPA, AVK) (B)	CARLSSON Mattias (cadmium) (A)
WILMER Jan/Dow Deutschland Inc (Cefic, AfA) (A)	CEDERBERG Inger (cadmium) (A)
Excuses	HENRIKSSON Jörgen (nonylphenol) (A)
BARRON Thomasina (A)	IVARSSON Jenny (nonylphenol, cadmium) (A)
BRANISTEANU Radu (A+B)	LESTANDER Dag (nonylphenol) (A)
DUNGEY Steve (B)	PARKMAN Helena (cadmium) (A)
ILIE Mihaela (A)	VIDARSSON Jenny (cadmium) (A)
JENSEN Frank (B)	WARHOLM Margareta (cadmium) (A)
LOSERT Annemarie (maternity) (A+B)	**NO dossier submitters:**
PASQUIER Elodie (A)	DUALE Nur (AVK) (B)
RUCKI Marian (A)	GAUSTAD Astrid (AVK) (B)
STASKO Jolanta (maternity) (A)	HOFER Tim (AVK) (B)
VIVIER Stephanie (A)	**ES dosser dossier submitters:**
MULLOOLY Yvonne (B)	CABALLERO Martinez (AVK) (B)
MUNARI Tomaso (EuCheMS) (A+B)	**FI dossier submitters:**
ROHDE Arlean (Concawe) (A+B)	EKOKOSKI Elina (AVK) (B)
SCHLUETER Urs (B)	**IT dossier submitters:**
SPETSERIS Nikolaos (B)	RUBBIANI Maristella (AVK) (B)
STASKO Jolanta (B)	**CZ dossier submitters:**
TSITSIMPIKOU Christina (B)	SKACEL Petr (flumioxazin) (B)

		Commission observers:
		BERTATO Valentina (ENTR) (A)
		BORRAS Anna (ENTR) (A)
		FERNANDES-de BARROS Mariana (ENTR) (A)
		GARCIA-JOHN Enrique (ENTR) (A)
		LINDENTHAL Robert (ENTR) (A+B)
		PIRSELOVA Katarina (ENV) (A)
		ROZWADOWSKI Jacek (A)
		STRECK Georg (A)
		EFSA :
		PARRA MORTE Juan (B)

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-28 meeting

ANNEX II List of documents submitted to the members of the Committee for Risk Assessment for the RAC-28 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-28 meeting

ANNEX IV Administrative issues and information items

4 March 2014
RAC/A/28/2014

Final Agenda
28th meeting of the Committee for Risk Assessment

4-7 March 2014 and
11–14 March 2014

ECHA Conference Centre (Annankatu 18, Helsinki)

4 March: starts at 9:00
7 March: ends at 13:00

11 March: starts at 9:00
14 March: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/28/2014
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 27 action points, written procedures and other ECHA bodies

RAC/28/2014/01
RAC/28/2014/02 (room document)
For information

b) RAC workplan for all processes

For information

Item 5 – Update on stakeholder participation in the work of RAC (closed session)

RAC/28/2014/03 RESTRICTED
For discussion and agreement

Item 6 – Harmonised classification and labelling (CLH)

6.1 CLH dossiers

a) Disodiumoctaborate anhydrate
b) Disodiumoctaborate tetrahydrate
c) Boric acid
d) Bupirimate (ISO) (ENV & HH up to Skin Sens)
e) Direct blue FC 57087
f) Flumioxazin (ISO)
g) Bisphenol A
h) Anticoagulant rodenticides:
    a. Warfarin (ISO)
    b. Flocoumafen (ISO)
    c. Difethialone (ISO)
    d. Coumatetralyl (ISO)
    e. Brodifacoum (ISO)
    f. Difenacoum (ISO)
    g. Bromadiolone (ISO)
    h. Chlorophacinone (ISO)
i) HICC
j) PHMB
k) Chlorobenzene

For discussion/adoption

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

RAC/28/2014/04 (restricted room document)
For agreement

6.3 General and procedural CLH issues

a) Opinion development process

For information

Item 7 – Restrictions

7.1 General restriction issues

a) Update on intended restriction dossiers

For information

b) Revision of the restriction process

RAC/28/2014/05
For discussion and agreement

7.2 Restriction Annex XV dossiers

a) Opinion development

1) Nonyl phenol – 2nd version of the draft opinion

For discussion

2) 1-Methylpyrrolidin-2-one (NMP) – 2nd version of the draft opinion

For discussion

b) Conformity check

1) Isopropylidenediphenol (bisphenol A) - outcome of conformity check

For agreement

2) Cadmium and its compounds in artist paints - outcome of conformity check

For agreement

3) Chrysotile - outcome of conformity check

For agreement

4) Ammonium salts- outcome of conformity

For agreement

7.3 Appointment of (co-)rapporteurs for restriction dossiers

RAC/28/2014/06 (restricted room document)
For information

Item 8 – Authorisation

8.1 Authorisation applications

b) Authorisation application on phthalates – 1st outline/version of the draft opinions (applications submitted within the August 2013 submission window)

8. Two uses of DEHP submitted by *ARKEMA FRANCE* (DEHP 2a):

   iii. Formulation of DEHP in compounds, dry-blends and Plastisol formulations
   iv. Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles

   For discussion

9. Two uses of DEHP submitted by *Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna* (DEHP2b):

   iii. Formulation of DEHP in compounds, dry-blends and Plastisol formulations
   iv. Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles

   For discussion

10. Three uses of DEHP submitted by *DEZA a.s.* (DEHP 2c):

    iv. Formulation of DEHP in compounds, dry-blends and Plastisol formulations
    v. Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles
    vi. Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

    For discussion

11. Three uses of DBP and DEHP submitted by *Roxel (UK Rocket Motors) Ltd* (DEHP 3):

    iv. Industrial use of DBP in manufacture of solid propellants and motor charges for rockets and tactical missiles
    v. Industrial use of DEHP in manufacture of solid propellants and motor charges for rockets and tactical missiles
    vi. Industrial use of DBP within a specialty paint in manufacture of motors for rockets and tactical missiles

    For discussion/agreement

12. The use of DBP submitted by *Sasol-Huntsman GmbH & Co. KG* (DBP 1):
    ii. Use as an absorption solvent in a closed system in the manufacture of Maleic Anhydride

    For discussion/agreement

13. Three uses of DBP submitted by *DEZA a.s.* (DBP 2):
    i. Use as an absorption solvent in a closed system in the manufacture of Maleic Anhydride

ii. Use in propellants

iii. Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

For discussion/agreement

14. Two uses of DEHP submitted by *VINYLOOP FERRARA S.p.A.*, *Stena Recycling AB* and *Plastic Planet srl* (DEHP 4):

iii. Formulation of recycled soft PVC containing DEHP in compounds and dryblends

iv. Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles

For discussion

c) Authorisation application -outcome of conformity check

1. Diarsenic trioxide 1 submitted by *Boliden Kokkola Oy*
2. Diarsenic trioxide 2 submitted by *Nordenhamer Zinkhütte GmbH*
3. Diarsenic trioxide 3 submitted by *Linxens France*
4. C.I. Pigment Yellow 34 and C.I. Pigment Red 104 submitted by *DCC Maastricht B. V. OR*

For agreement

8.2 Capacity building

a) ECHA project on carcinogenicity dose-response analysis of Trichloroethylene

RAC/28/2014/07

RAC/28/2014/08

For discussion/agreement

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

RAC/28/2014/09 (restricted room document)

For agreement

Item 9 – AOB

Item 10 – Action points and main conclusions of RAC-28

Table with Conclusions and Action points from RAC-28 ***For adoption***

ANNEX II (RAC-28)

Documents submitted to the members of the Committee for Risk Assessment for the RAC-28 meeting.

Document number	**Title**
RAC/A/28/2014	Final Draft Agenda
RAC/28/2014/01	Report from other ECHA bodies and activities
RAC/28/2014/02 Room document	Administrative document
RAC/28/2014/03 Restricted	Update on stakeholder participation
RAC/28/2014/04 Room document	Appointment of RAC (co-) Rapporteurs for CLH dossiers
RAC/28/2014/05	Revision of the restriction process
RAC/28/2014/06 Room document	Appointment of (co-) Rapporteurs for restriction dossiers
RAC/28/2014/07	ECHA project on carcinogenicity dose-response analysis of Cr (VI)-containing substances
RAC/28/2014/08	ECHA project on carcinogenicity dose-response analysis of As -containing substances

The following participants, including those for whom the Chairman declared the interest on their behalf, declared potential conflicts of interest with the agenda items (according to Art 9 (2) of RAC RoPs)

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
ALREADY DECLARED AT RAC 26 and 27		
CLH: Flocoumafen (NL)	Betty HAKKERT[4]	Working for the CA submitting the CLH dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Marja PRONK[4]	Working for the CA submitting the CLH dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Warfarin (IE)	Thomasina BARRON	Working for the CA submitting the CLH dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Brodifacoum (IT)	Paola di PROSPERO	Working for the CA submitting the CLH dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Coumatetralyl (DK)	Peter SOERENSEN	Working for the CA submitting the CLH dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Frank JENSEN	Working for the CA submitting the CLH dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Bromadiolone (SE)	Bert-Ove LUND	Working for the CA submitting the CLH dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Difenacoum (FI)	Riitta LEINONEN	Working for the CA submitting the CLH dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Difethialone (NO)	Marianne van der HAGEN	Working for the CA submitting the CLH dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation

[4] Potential CoI declared by the Chairman, member disagreed

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
		measures applied.
	Christine BJØRGE	Working for the CA submitting the CLH dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR. Nonylphenol (SE)	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR: 1-Methyl-2-pyrrolidone (NMP; NL)	Betty HAKKERT[4]	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Marja PRONK[4]	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

New dossiers

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
CLH: Disodiumoctaborate anhydrate (NL)	Betty HAKKERT[5]	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Marja PRONK[5]	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Disodiumoctaborate tetrahydrate (NL)	Betty HAKKERT[5]	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Marja PRONK[5]	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Boric acid (PL)	Boguslaw BARANSKI	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: PHMB (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied
CLH: HICC (SE)	Anne-Lee GUSTAFSSON	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Bupirimate (ISO) (NL)	Betty HAKKERT[5]	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Marja PRONK[5]	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

[5] Potential CoI declared by the Chairman, member disagreed

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
CLH: Flumioxazin (ISO) (CZ)	Marian RUCKI	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Bisphenol A (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied
CLH: Chlorobenzene (PL)	Boguslaw BARANSKI	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Bromadiolone (SE)	Anna-Lee GUSTAFSSON	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Chlorophacinone (ES)	Miguel A.SOGORB	Collaborated with the CA for the assessment of the biocide dossier for this rodenticide; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR. Ammonium salts (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR. Bisphenol A (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR. Cadmium in Artist paints (SE)	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Anne-Lee GUSTAFSSON	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR. Nonyl phenol (SE)	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Anne-Lee GUSTAFSSON	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
		measures applied.

RAC members' advisers

AP/Dossier / DS	RAC member adviser	Reason for potential CoI / Working for
CLH: Warfarin (IE)	Brendan MURRAY	Working for the CA submitting the CLH dossier

ANNEX IV

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-27 Action Points

The RAC-27 action points due for RAC-28 are completed.

2 Outcome of written procedures & other consultations

2.1 Written procedures for adoption of RAC opinions

Opinions adopted via written procedure	Deadline	Report on the Outcome
-	-	-

2.2 Written dossier consultations (status by 3 March 2014)

Subject / Document	Deadline	Status / follow-up
1st draft opinion on **Disodiumoctaborate anhydrate**	10 February 2014	closed
1st draft opinion on **Disodiumoctaborate tetrahydrate**	10 February 2014	closed
1st draft opinion on **boric acid**	10 February 2014	closed
1st draft opinion on **PHMB** (**Polyhexamethylene biguanide hydrochloride**)	14 February 2014	closed
1st draft opinion on **HICC** (**Hydroxyisohexyl 3-cyclohexene carboxaldehyde**)	10 February 2014	closed
1st draft opinion on **Bupirimate (ISO)**	24 January 2014	closed
1st draft opinion on **Direct Blue FC 57087**	7 February 2014	closed
1st draft opinion on **Flumioxazin (ISO)**	10 February 2014	closed
1st draft opinion on **Bisphenol A (BPA)**	14 February 2014	closed
1st draft opinion on **Chlorobenzene**	14 February 2014	closed
Anticoagulant rodenticides*		
1st draft opinion on **Difethialone (ISO)**	14 February 2014	closed
1st draft opinion on **Coumatetralyl (ISO)**	14 February 2014	closed
1st draft opinion on **Difenacoum (ISO)**	14 February 2014	closed

1st draft opinion on **Bromadiolone (ISO)**	14 February 2014	closed
1st draft opinion on **Chlorophacinone (ISO)**	14 February 2014	closed
Revised draft opinion on **Flocoumafen (ISO)**	14 February 2014	closed
Revised draft opinion on **Brodifacoum (ISO)**	14 February 2014	closed

*1st draft opinion on Warfarin (ISO) was subject to the RAC consultation 29/10/2013 – 18/11/2013

2.3 Other written consultations of RAC (last update: 3 March 2014)

Other written consultations	Deadline	Status / follow-up
Written procedure for adoption of the minutes of RAC-27	14 February 2014	Closed
CLH: AVKs (Coumatetralyl): Comments on the interpretation of the prolonged fish study	31 January 2014	closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
CLH: Call for expression of interest for rapporteurship	20–28 January 2014	Volunteers for three dossiers; appointment via WP
Restriction: call for expression of interest for rapporteurship for Methanol - N,N-dimethylformamide; dimethyl formamide	11- 28 February	Two volunteers for methanol; One volunteer for DMF.

2.5 Written procedures for appointment of (co-)rapporteurs

Appointment (co-)RAP	For Substance	Deadline	Outcome
CLH: Written procedure for appointing a rapporteur and co-rapporteur	▪ Silver zinc zeolite ▪ Silicon dioxide ▪ Cyproconazole (ISO) ▪ Pymetrozine (ISO)	7 February 2014	Closed No comments were received from RAC members on the recommendation of the Chairman; the RAC rapporteurs and co-rapporteurs were appointed with tacit agreement.
▪ **Restriction**: Written procedure for appointing a rapporteur and co-rapporteur	▪ 4,4'-isopropylidenediphenol (bisphenol A) ▪ ammonium salts	20 January 2014 31 January 2014	Closed No comments were received from RAC members: the RAC rapporteurs and

			co-rapporteurs were appointed with tacit agreement for both dossiers in consensus

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 28 4 – 7 March 2014 and 11 – 14 March 2014

(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/28/2014**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-28 minutes.
3. Declarations of conflicts of interests to the Agenda	
SECR informed the Committee on the status of the discussion of the ECHA Conflicts of Interest Advisory Committee (CoIAC) on practice of declaring a potential conflict of interest.	**SECR** to inform the RAC on the outcome of the CoIAC discussion and the decision of ECHA
4. Report from other ECHA bodies and activities	
4.a. Report on other ECHA bodies **SECR** presented document **RAC/28/2014/01**	**SECR** to upload the document to the CIRCABC non-confidential website.
4.b. RAC work plan for all processes SECR presented update on the 2014 work plan for RAC covering the Classification and Labelling, Restriction and Authorisation processes.	**SECR** to upload the presentation to non-confidential folder of the RAC-28 meeting on CIRCABC.
5. Update of stakeholder participation in the work of RAC (closed session)	
SECR presented document **RAC/28/2014/03 restricted**	**RAC** agreed with the proposed amendments to the list of stakeholders. **SECR** to update list of RAC stakeholders and publish on ECHA's website. **SECR** will provide information to new Stakeholders on the rules governing their participation in the Committee.
6. Harmonised classification and labelling (CLH)	
6.1. **a) Disodium octaborate anhydrate,** **b) Disodium octaborate tetrahydrate and** **c) Boric Acid**	
RAC adopted <u>by consensus</u> the opinions with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B (H360FD) for boric acid, DOT and DOA; SCLs: none for boric acid, DOT and DOA (GCL applies); otherwise no further CLH was agreed for DOT]	**Rapporteurs** to revise the opinion in accordance with the discussions in RAC. **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.

6.1. d) Bupirimate (ISO) (ENV & HH up to Skin Sens.)	
RAC agreed on the classification and labelling for bupirimate (ISO) as indicated in bold in Table 2 below. [agreement on Skin Sens. 1B (H317); Aquatic Chronic 1 (H410), M=1]	**Rapporteurs** to revise the opinion in accordance with the discussions at RAC-28 and to include an evaluation for carcinogenicity and the remaining health hazards in the ODD. **SECR** to launch RAC consultation on the revised draft ODD.
6.1. e) Direct blue FC 57087	
RAC adopted by consensus the opinion with a proposal to remove current harmonised classification and labelling.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to the SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
6.1. f) Flumioxazin (ISO)	
RAC agreed to continue the debate on reproductive toxicity at RAC-29 as two aspects still need to be clarified with the help of the DS. RAC agreed on the M-factor for the aquatic classification as indicated in bold in Table 2 below. [agreement on M=1000 for Aquatic Chronic 1]	**Rapporteurs** to revise the opinion in accordance with the discussions in RAC. **SECR** to contact the DS for the provision, by 31 March 2014, of background information on reproductive toxicity. **SECR** to launch RAC consultation on reproductive toxicity, taking into account the information provided by the DS.
6.1. g) Bisphenol A	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Replace Repr. 2 (H361) in the existing classification with Repr. 1B (H360F)]	**Rapporteurs** to revise the opinion in accordance with the discussions in RAC. **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.
6.1. h) Anticoagulant rodenticides: RAC adopted by consensus the opinions on the eight anticoagulant rodenticides with proposals for the harmonised classification and labelling as specified below for each substance.	
▪ **Warfarin (ISO)** RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 1; H330, Acute Tox. 1; H310, Acute Tox. 2; H300, STOT RE 1; H372 (blood) – removal of **, Aquatic Chronic 2; H411	**Rapporteur** to revise the opinion on Warfarin (ISO) in accordance with the discussion in RAC. **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

SCLs: Repr. 1A; H360D: C ≥ 0,003%, STOT RE 1; H372 (blood): C ≥ 0,5% STOT RE 2; H373 (blood): 0,05% ≤ C < 0,5%]	ECHA website.
▪ **Flocoumafen (ISO)** RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360D, Acute Tox. 1; H330, Acute Tox. 1; H310, Acute Tox. 1; H300, STOT RE 1; H372 (blood) – removal of **, Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=10 SCLs: Repr. 1B; H360D: C ≥ 0,003% STOT RE 1; H372 (blood): C ≥ 0,05% STOT RE 2; H373 (blood): 0,005% ≤ C < 0,05%]	**Rapporteur** to revise the opinion on Flocoumafen (ISO) in accordance with the discussion in RAC. **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.
▪ **Difethialone (ISO)** RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360D, Acute Tox. 1; H300, Acute Tox. 1; H310, Acute Tox. 1; H330, EUH070, STOT RE 1; H372 (blood), Aquatic Acute 1; H400, M=100, Aquatic Chronic 1; H410, M=100 SCLs: Repr. 1B; H360D: C ≥ 0,003%, STOT RE 1; H372 (blood): C ≥ 0,02%, STOT RE 2; H373 (blood): 0,002% ≤ C < 0,02%]	**Rapporteur** to revise the opinion on Difethialone (ISO) in accordance with the discussion in RAC. **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.
▪ **Coumatetralyl (ISO)** RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360D, Acute Tox. 2; H330, Acute Tox. 2; H300, Acute Tox. 3; H311, STOT RE 1; H372 (blood) removal of **, Aquatic Chronic 1; H410, M=10 Repr. 1B; H360D: C ≥ 0,003%, STOT RE 1; H372 (blood): C ≥ 1,0%, STOT RE 2; H373 (blood) 0,1% ≤ C < 1,0%]	**Rapporteur** to revise the opinion on Coumatetralyl (ISO) in accordance with the discussion in RAC. **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.
▪ **Brodifacoum (ISO)** RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1A; H360D, Acute Tox. 1; H300, Acute Tox. 1; H330, STOT RE 1; H372 (blood) - removal of **, Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=10 SCLs: Repr. 1A; H360D:C ≥ 0,003%, STOT RE 1; H372 (blood):C ≥ 0,02%, STOT RE 2; H373 (blood): 0,002% ≤ C < 0,02%]	**Rapporteur** to revise the opinion on Brodifacoum (ISO) in accordance with the discussion in RAC. **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.
▪ **Difenacoum (ISO)** RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteur** to revise the opinion on Difenacoum (ISO) in accordance with the discussion in RAC. **SECR** to make an editorial check of the

[Repr. 1B; H360D, Acute Tox. 1; H300, Acute Tox. 1; H330, Acute Tox. 1; H310, STOT RE 1; H372 (blood) - removal of **, Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=10 SCLs: Repr. 1B; H360D: C ≥ 0,003% STOT RE 1; H372 (blood): C ≥ 0,02%, STOT RE 2; H373 (blood): 0,002% ≤ C < 0,02%]	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.
▪ **Bromadiolone (ISO)** RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360D, Acute Tox. 1; H300, Acute Tox. 1; H310, Acute Tox. 1; H330, STOT RE 1 (blood); H372, Aquatic Acute 1; H400, M=1, Aquatic Chronic 1; H410, M=1 SCLs: Repr. 1B; H360D: C ≥ 0,003% STOT RE 1; H372 (blood): C ≥ 0,005%, STOT RE 2; H373 (blood): 0,0005% ≤ C < 0,005%]	**Rapporteur** to revise the opinion on Bromadiolone (ISO) in accordance with the discussion in RAC. **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.
▪ **Chlorophacinone (ISO)** RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360D, Acute Tox. 1; H300, Acute Tox. 1; H310, Acute Tox. 1; H330, STOT RE 1; H372 (blood) - removal of **, Aquatic Acute 1; H400, M=1, Aquatic Chronic 1; H410, M=1 SCLs: Repr. 1B; H360D: C ≥ 0,003% STOT RE 1; H372 (blood): C ≥ 0,1%, STOT RE 2; H373 (blood): 0,01% ≤ C < 0,1%]	**Rapporteur** to revise the opinion on Chlorophacinone (ISO) in accordance with the discussion in RAC. **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.
6.1. i) PHMB RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [add Acute Tox 2; H330 (CLP) to the existing PHMB classification]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC. **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.
6.1. j) HICC RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Sens. 1A; H317, EUH208]	**Rapporteur** to revise the opinion on HICC in accordance with the discussion in RAC. **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.
6.1. k) Chlorobenzene RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur.

[Skin Irrit. 2; H315 Removal of (*) from Acute Tox. 4]	**SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
6.2 Appointment of RAC (co-)rapporteurs for CLH dossiers RAC appointed the new (co-)rapporteurs for CLH dossiers.	**SECR** to upload the list of appointed (co-)rapporteurs to CIRCA BC confidential.
7. Restrictions	
7.1 General Restriction Issues	
7.1.b) Revision of the restriction process RAC agreed on the revised working procedure on developing opinions on Annex XV restriction dossiers.	**SECR** to upload the revised procedure to CIRCA BC and to apply it starting from restriction dossiers submitted within the January 2014 submission window.
7.2 Restriction Annex XV dossiers	
7.2.a) Opinion Development	
▪ **Nonyl phenol – 2nd version of the draft opinion** Rapporteurs presented the 2nd version of the RAC draft opinion.	**Rapporteurs** to take the RAC discussion into account in the 3rd version of the draft opinion (within 3 weeks). **SECR** to open a written commenting round on this version.
▪ **1-Methylpyrrolidin-2-one (NMP) – 2nd version of the draft opinion** Rapporteurs presented the 2nd version of the RAC draft opinion.	**Rapporteurs** to take the RAC discussion into account in the 3rd version of the draft opinion (by end of March 2014). **SECR** to open a written commenting round on this version.
7.2.b) Conformity check	
1. Isopropylidenediphenol (bisphenol A) - outcome of conformity check RAC agreed by a majority that the dossier does not conform to the Annex XV requirements and took note of the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCA BC. **SECR** to inform the dossier submitter on the outcome of the conformity check.
2. Cadmium and its compounds in artist paints - outcome of conformity check RAC agreed that the dossier conforms to the Annex XV requirements and took note of the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCA BC. **Rapporteurs** together with Secretariat to finalise the recommendations to the dossier submitter. **SECR** to inform the dossier submitter on the outcome of the conformity check.
3. Chrysotile - outcome of conformity check RAC agreed that the dossier conforms to the Annex XV requirements and took note of the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCA BC. **SECR** to inform the dossier submitter on the outcome of the conformity check.
4. Ammonium salts- outcome of conformity check RAC agreed by majority that the dossier does not	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and

conform to the Annex XV requirements and took note of the recommendations to the dossier submitter.	upload this to CIRCABC. **SECR** to inform the dossier submitter on the outcome of the conformity check.
7.3 Appointment of (co-)rapporteurs for restriction dossiers RAC took note of the pools of (co-)rapporteurs for the methanol and dimethyl formamide restriction dossiers.	**RAC members** to come forward as volunteers for the (co-)rapporteurships for the two upcoming restriction dossiers.
8. Authorisation	
8.1 Authorisation applications	
8.1.a) Authorisation applications on Phthalates – 1st outline/version of the draft opinions (applications submitted within the August 2013 submission window) 15. Two uses of DEHP submitted by ARKEMA FRANCE (DEHP 2a):	**Co-rapporteurs** to consider plenary discussion and to prepare the first version of the RAC draft opinions before 1 April. **SECR** to upload to CIRCA BC the first version of the RAC draft opinions and to launch a RAC consultation on the first draft version of the RAC draft opinion. **RAC** members to provide written comments on the first version of the RAC draft opinion by 30 April. **Co-rapporteurs** to respond to comments received from other RAC members and to send the second version of the RAC draft opinion by 20 May. **SECR** to upload to CIRCA BC the second version of the RAC draft opinion and RCOM table to CIRCABC by 23 May.
16. Two uses of DEHP submitted by Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna (DEHP 2b):	**Co-rapporteurs** to consider plenary discussion and to prepare the first version of the RAC draft opinion before 1 April. **SECR** to upload to CIRCA BC the first version of the RAC draft opinion and to launch 28 calendar days RAC consultation on the first draft version of the RAC draft opinion. **RAC** members to provide written comments on the first version of the RAC draft opinion by 30 April. **Co-rapporteurs** to respond to comments received from other RAC members and to send the second version of the RAC draft opinion by 20 May. **SECR** to upload to CIRCA BC the second version of the RAC draft opinion and RCOM table to CIRCABC by 23 May.
17. Three uses of DEHP submitted by DEZA a.s. (DEHP 2c):	**Co-rapporteurs** to consider plenary discussion and to prepare the first version of the RAC draft opinion before 1 April. **SECR** to upload to CIRCA BC the first version of the RAC draft opinion and to launch 28 calendar days RAC consultation

	on the first draft version of the RAC draft opinion. **RAC** members to provide written comments on the first version of the RAC draft opinion by 30 April. **Co-rapporteurs** to respond to comments received from other RAC members and to send the second version of the RAC draft opinion by 20 May. **SECR** to upload to CIRCA BC the second version of the RAC draft opinion and RCOM table to CIRCA BC by 23 May.
18. Three uses of DBP and DEHP submitted by Roxel (UK Rocket Motors) Ltd (DEHP 3):	
Use 1 DEHP **Use 2 DPB** RAC agreed that the risk is adequately controlled for both uses and RAC adopted the Draft Opinions for both uses.	**SECR** to inform SEAC about adoption of the Draft Opinion **SECR** to send the Applicant the Draft Opinion (after SEAC agreement) with a request to indicate his intention to submit comments on the Draft Opinion. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman to approve the Final Opinion on behalf of RAC. **SECR** to send the Opinion to the Commission, the Member States and the Applicant. **SECR** to publish the Opinion on the ECHA website. *Option 2:* Should the Applicant wish to comment, SECR to make the Applicant's comments available on CIRCABC and to inform RAC. **SECR** to invite the co-rapporteurs to provide their views on the comments. **Co-rapporteurs** to preview the Applicant's comments and to prepare a draft version of the Final Opinion taking into account the Applicant's comments, and to send it to SECR. **SECR** to organise written commenting in RAC. **Co-rapporteurs** to revise the draft Final Opinion. **SECR** to initiate the adoption of the Final Opinion at the RAC plenary meeting or via written procedure.
Use 3 DBP Rapporteurs presented their opinion	**Co-rapporteurs** to consider plenary discussion and to prepare the first version

about the exposure assessment and the risk assessment done by the applicant for this use.	of the RAC draft opinion by 1 April. **SECR** to upload to CIRCA BC the first version of the RAC draft opinion and to launch 28 calendar days RAC consultation on the first draft version of the RAC draft opinion. **RAC** members to provide written comments on the first version of the RAC draft opinion by 30 April. **Co-rapporteurs** to respond to comments received from other RAC members and to send the second version of the RAC draft opinion by 20 May. **SECR** to upload to CIRCA BC the second version of the RAC draft opinion and RCOM table to CIRCA BC by 23 May.
19. The use of DBP submitted by Sasol-Huntsman GmbH & Co. KG (DBP 1):	**SECR** to send the Applicant the Draft Opinion with a request to indicate his intention to submit comments on the Draft Opinion. **SECR** to inform SEAC about adoption of the Draft Opinion *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman to approve the Final Opinion on behalf of RAC. **SECR** to send the Opinion to the Commission, the Member States and the Applicant. **SECR** to publish the Opinion on the ECHA website. *Option 2:* Should the Applicant wish to comment, SECR to make the Applicant's comments available on CIRCA BC and to inform RAC. **SECR** to invite the co-rapporteurs to provide their views on the comments. **Co-rapporteurs** to preview the Applicant's comments and to prepare a draft version of the Final Opinion taking into account the Applicant's comments, and to send it to SECR. **SECR** to organise written commenting in RAC. **Co-rapporteurs** to revise the draft Final Opinion. **SECR** to initiate the adoption of the Final Opinion at the RAC plenary meeting or via written procedure.

1. Three uses of DBP submitted by DEZA a.s. (DBP 2):	
Use 1 RAC agreed that the risk is adequately controlled for the use and RAC adopted the Draft Opinion for the use.	**SECR** to inform SEAC about adoption of the Draft Opinion **SECR** to send the Applicant the Draft Opinion (after SEAC agreement) with a request to indicate his intention to submit comments on the Draft Opinion. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman to approve the Final Opinion on behalf of RAC. **SECR** to send the Opinion to the Commission, the Member States and the Applicant. **SECR** to publish the Opinion on the ECHA website. *Option 2:* Should the Applicant wish to comment, SECR to make the Applicant's comments available on CIRCA BC and to inform RAC. **SECR** to invite the co-rapporteurs to provide their views on the comments. **Co-rapporteurs** to preview the Applicant's comments and to prepare a draft version of the Final Opinion taking into account the Applicant's comments, and to send it to SECR. **SECR** to organise written commenting in RAC. **Co-rapporteurs** to revise the draft Final Opinion. **SECR** to initiate the adoption of the Final Opinion at the RAC plenary meeting or via written procedure.
Use 2 Rapporteurs presented their opinion about the exposure assessment and the risk assessment done by the applicant for this use.	**Co-rapporteurs** to request applicant for additional clarifications and to prepare the first version of the RAC draft opinion by 1 April. **SECR** to upload to CIRCA BC the first version of the RAC draft opinion and to launch 28 calendar days RAC consultation on the first draft version of the RAC draft opinion. **RAC** members to provide written comments on the first version of the RAC draft opinion by 30 April. **Co-rapporteurs** to respond to comments received from other RAC members and to

	send the second version of the RAC draft opinion by 20 May. **SECR** to upload to CIRCA BC the second version of the RAC draft opinion and RCOM table to CIRCA BC by 23 May.
2. Two uses of DEHP submitted by VINYLOOP FERRARA S.p.A., Stena Recycling AB and Plastic Planet srl:	**Rapporteurs** to consider plenary discussion and to prepare the first version of the RAC draft opinion by 26 March. **SECR** to upload to CIRCABC the first version of the RAC draft opinion and to launch 28 calendar days RAC consultation on the first draft version of the RAC draft opinion. **RAC** members to provide written comments on the first version of the RAC draft opinion by 30 April. **SECR** to organise the second rapporteurs' dialogue in a time frame from 5 to 15 May. **Rapporteurs** to respond to comments received from other RAC members and to prepare and to send the second version of the RAC draft opinion by 20 May. **SECR** to upload to CIRCABC the second version of the RAC draft opinion and RCOM table to CIRCABC by 23 May.
7.1.b) Authorisation application – outcome of conformity check 5. Diarsenic trioxide 1 6. Diarsenic trioxide 2 **7.** Diarsenic trioxide 3	**SECR** in each case to upload to CIRCA BC the adopted Conformity Report. **SECR** in each case to inform SEAC about the outcome of the Conformity check **SECR** in each case to send the updated Conformity Report to the Applicant.
8. C.I. Pigment Yellow 34 and C.I. Pigment Red 104	**SECR** to upload to CIRCA BC the adopted Conformity Report. **SECR** to inform SEAC about the outcome of the Conformity check. **SECR** to send the updated Conformity Report to the Applicant.
8.2 Capacity building	
8.2.a) ECHA project on carcinogenicity dose-response analysis of Trichloroethylene ***RAC/28/2014/07*** ***RAC/28/2014/08***	**SECR** to launch the Written Procedure on the modified draft note. **SECR** to publish the note on the ECHA website, if adopted in the Written Procedure.
8.3 Appointment of (co-) rapporteurs for authorisation applications (closed session) ***RAC/28/2014/09 (restricted room document)***	**SECR** to upload the pool of Rapporteurs to CIRCABC confidential.
10. Action points and main conclusions of RAC-28	**SECR** to upload the adopted action points to CIRCA BC.

Note: In the table below, the classification codes for acute toxicity are often followed by a mention of the relevant route of exposure in brackets, in the rows pertaining to the Dossier Submitter's proposal and to the RAC opinion. This is necessary as in these rows, the pertinent hazard statement could not be mentioned because it was not subject to change in the same way as the classification code. Consequently, the route of exposure had to be clarified in the column for the classification code, which was included in brackets.

Disodiumoctaborate anhydrate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current annex VI entry										
Dossier submitters proposal	005-020-00-3	disodium octaborate anhydrate	234-541-0	12008-41-2	Repr. 1B	H360FD	GHS08 Dgr			Repr. 1B; H360FD: C ≥ 3,7%	
RAC opinion					Repr. 1B	H360FD	GHS08 Dgr				
Resulting Annex VI entry if agreed by COM					Repr. 1B	H360FD	GHS08 Dgr				

Disodiumoctaborate tetrahydrate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current annex VI entry										
Dossier submitters proposal	005-021-00-9	disodium octaborate tetrahydrate	234-541-0	12280-03-4	Repr. 1B	H360FD	GHS08 Dgr			Repr. 1B; H360FD: C ≥ 4,5%	
RAC opinion					Repr. 1B	H360FD	GHS08 Dgr				
Resulting Annex VI entry if agreed by COM					Repr. 1B	H360FD	GHS08 Dgr				

Boric acid

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	005-007-00-2	boric acid; [1] boric acid; [2]	233-139-2 [1] 234-343-4 [2]	10043-35-3 [1] 11113-50-1 [2]	Repr. 1B	H360FD	GHS08 Dgr	H360FD		Repr. 1B; H360FD: C ≥ 5,5 %	
Dossier submitters proposal	005-007-00-2	boric acid; [1] boric acid; [2]	233-139-2 [1] 234-343-4 [2]	10043-35-3 [1] 11113-50-1 [2]	**Modify:** Repr. 2	**Modify:** H361d	GHS08 Wng	**Modify:** H361d			
RAC opinion					Repr. 1B	H360FD	GHS08 Dgr	H360FD			
Resulting Annex VI entry if agreed by COM					Repr. 1B	H360FD	GHS08 Dgr	H360FD		Repr. 1B; H360FD: C ≥ 5,5 %*	

* The current SCL for boric acid was not discussed by the RAC as it was not proposed by the DS. Nevertheless, RAC noted that the current SCL is based on an outdated ('German') method and not on the new method included in harmonised ECHA guidance, namely the revised Guidance on the application of the CLP criteria(Version 4.0 – November 2013, section 3.7.2.5. Setting of specific concentration limits).

Polyhexamethylene biguanide hydrochloride (PHMB)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry*	616-207-00-X	polyhexamethylene biguanide hydrochloride	-	27083-27-8; 32289-58-0	Carc. 2 Acute Tox. 4 STOT RE 1 Eye Dam. 1 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H372 (respiratory tract) (inhalation) H318 H317 H400 H410	GHS05 GHS07 GHS08 GHS09 Dgr	H351 H302 H372 (respiratory tract) (inhalation) H318 H317 H410		M=10 M=10	
Dossier submitters proposal					**Add:** Acute Tox. 2	**Add:** H330		**Add:** H330			
RAC opinion					Acute Tox. 2	H330		H330			
Resulting Annex VI entry if agreed by COM					Carc. 2 Acute Tox. 4 Acute Tox. 2 STOT RE 1 Eye Dam. 1 Skin Sens. 1B	H351 H302 H330 H372 (respiratory tract)		H351 H302 H330 H372 (respiratory tract)			

					Aquatic Acute 1 Aquatic Chronic 1	(inhalation) H318 H317 H400 H410		(inhalation) H318 H317 H410		 M=10 M=10	

* 5th ATP to CLP Regulation (Commission Regulation (EU) No 944/2013, 2 Oct 2013)

Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	605-040-00-8	hydroxyisohexyl 3-cyclohexene carboxaldehyde (INCI); Reaction mass of 4-(4-hydroxy-4-methylpentyl)cyclohex-3-ene-1-carbaldehyde and 3-(4-hydroxy-4-methylpentyl)cyclohex-3-ene-1-carbaldehyde [1]; 4-(4-hydroxy-4-methylpentyl)cyclohex-3-ene-1-carbaldehyde [2]; 3-(4-hydroxy-4-methylpentyl)cyclohex-3-ene-1-carbaldehyde [3]	- [1]; 250-863-4 [2]; 257-187-9 [3]	- [1]; 31906-04-4 [2]; 51414-25-6 [3]	Skin Sens. 1A	H317	GHS07 Wng	H317		Skin Sens. 1A: C ≥ 0,01%	
RAC opinion					Skin Sens. 1A	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM					Skin Sens. 1A	H317	GHS07 Wng	H317			

Chlorobenzene

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	602-033-00-1	chlorobenzene	203-628-5	108-90-7	Flam. Liq. 3 Acute Tox. 4* Aquatic Chronic 2	H226 H332 H411	GHS02 GHS07 GHS09 Wng	H226 H332 H411			
Dossier submitters proposal	602-033-00-1	chlorobenzene	203-628-5	108-90-7	**Modify:** Acute Tox. 4 **Add** Skin. Irrit. 2	**Retain:** H332 **Add:** H315	**Retain:** GHS07 Wng	**Retain:** H332 **Add:** H315			
RAC opinion					Acute Tox. 4 Skin. Irrit. 2	H332 H315	GHS07 Wng	H332 H315			
Resulting Annex VI entry if agreed by COM					Flam. Liq. 3 Acute Tox. 4 Skin Irrit. 2 Aquatic Chronic 2	H226 H332 H315 H411	GHS02 GHS07 GHS09 Wng	H226 H332 H315 H411			

Bupirimate (ISO); 5-butyl-2-ethylamino-6-methylpyrimidin-4-yl dimethylsulphamate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	612-288-00-0	bupirimate(ISO); 5-butyl-2-ethylamino-6-methylpyrimidin-4-yl dimethylsulphamate	255-391-2	41483-43-6	Carc. 2 Skin Sens. 1B Aquatic Chronic 1	H351 H317 H410	GHS08 GHS07 GHS09 Wng	H351 H317 H410		M= 1	
RAC opinion					Carc. 2 Skin Sens. 1B Aquatic Chronic 1	H351 H317 H410	GHS08 GHS07 GHS09 Wng	H351 H317 H410		M= 1	
Resulting Annex VI entry if agreed by COM											

Flumioxazin (ISO); 2-[7-fluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Entry	613-166-00-x	flumioxazin (ISO); 2-[7-fluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione	-	103361-09-7	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360D*** H400 H410	GHS08 GHS09 Dgr	H360D*** H410		M=1000	
Dossier submitters proposal	613-166-00-x	flumioxazin (ISO); 2-[7-fluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3(2H)-dione	-	103361-09-7	**Remove**: Repr. 1B	**Remove:** H360D***	**Remove:** GHS08 **Modify:** Wng	**Remove:** H360D***		**Add:** M (chronic) = 1000	
RAC opinion					Repr. 2	H361d	Wng	H361d		M (chronic)= 1000	
Resulting Annex VI entry if agreed by COM											

4,4'-isopropylidenediphenol (Bisphenol A)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	604-030-00-0	bisphenol A; 4,4'-isopropylidenediphenol	201-245-8	80-05-7	Repr. 2 STOT SE 3 Eye Dam. 1 Skin Sens. 1	H361f*** H335 H318 H317	GHS05 GHS08 GHS07 Dgr	H361f H335 H318 H317			
Dossier submitters proposal	604-030-00-0	bisphenol A; 4,4'-isopropylidenediphenol	201-245-8	80-05-7	**Modify:** Repr. 1B	**Modify:** H360F		**Modify:** H360F			
RAC opinion					Repr. 1B	H360F		H360F			
Resulting Annex VI entry if agreed by COM					Repr. 1B STOT SE 3 Eye Dam. 1 Skin Sens. 1	H360F H335 H318 H317	GHS05 GHS08 GHS07 Dgr	H360F H335 H318 H317			

Lithium sodium 3-amino-10-{4-(10-amino-6,13-dichloro-4,11-disulfonatobenzo[5,6][1,4]oxazino[2,3- b]phenoxazine-3-ylamino)-6-[methyl(2-sulfonato-ethyl)amino]-1,3,5-triazin-2- ylamino}-6,13- dichlorobenzo[5,6][1,4]oxazino[2,3-b]phenoxazine-4,11-disulfonate (Direct blue FC 57087)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	609-066-00-0	lithium sodium 3-amino-10-{4- (10-amino-6,13-dichloro-4,11-disulfonatobenzo[5,6][1,4]oxazino[2,3-b]phenoxazine-3-ylamino)-6- [methyl(2-sulfonato- ethyl)amino]-1,3,5-triazin-2-ylamino}-6,13-dichlorobenzo[5,6][1,4]oxazino[2,3-b]phenoxazine-4,11-disulfonate	418-870-9	154212-58-5	Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * STOT SE 2 **	H332 H312 H302 H371 **	GHS08 GHS07 Wng	H332 H312 H302 H371 **			
Dossier submitters proposal	609-066-00-0	lithium sodium 3-amino-10-{4-(10-amino-6,13-dichloro-4,11-disulfonatobenzo[5,6][1,4]oxazino[2,3-b]phenoxazine-3-ylamino)-6-[methyl(2-sulfonato-ethyl)amino]-	418-870-9	154212-58-5	**Remove:** Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * STOT SE 2 **	**Remove:** H332 H312 H302 H371 **	**Remove:** GHS08 GHS07 Wng	**Remove:** H332 H312 H302 H371 **			
RAC opinion					~~Acute Tox. 4 *~~ ~~Acute Tox. 4 *~~ ~~Acute Tox. 4 *~~	~~H332~~ ~~H312~~ ~~H302~~	~~GHS08~~ ~~GHS07~~ ~~Wng~~	~~H332~~ ~~H312~~ ~~H302~~			

		1,3,5-triazin-2-ylamino}-6,13-dichlorobenzo[5,6][1,4]oxazino[2,3-b]phenoxazine-4,11-disulfonate			~~STOT SE 2~~ **	~~H371~~ **		~~H371 **~~			
Resulting Annex VI entry if agreed by COM	None										

Chlorophacinone (IS0); 2-[(4-chlorophenyl)(phenyl)acetyl]-*1H*-indene-1,3(2H)-dione

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	606-014-00-9	chlorophacinone (ISO); 2-(2-(4-chlorophenyl)phenylacetyl)indan-1,3-dione	223-003-0	3691-35-8	Acute Tox. 1 Acute Tox. 2 * Acute Tox. 3 * STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H310 H300 H331 H372** H400 H410	GHS06 GHS08 GHS09 Dgr	H310 H300 H331 H372 ** H410			
Dossier submitters proposal	606-014-00-9	chlorophacinone (ISO); 2-[(4-chlorophenyl)(phenyl)acetyl]-*1H*-indene-1,3(2H)-dione	223-003-0	3691-35-8	**Modify**: Acute Tox. 2 (oral) Acute Tox. 1 (inhalation) **Add:** Repr. 1A	**Modify**: H330 H372 (blood) **Add:** H360D		**Modify**: H330 H372 (blood) **Add:** H360D		**Add**: STOT RE 1; H372 (blood): C ≥ 0,1%, STOT RE 2; H373 (blood): 0,01% ≤ C < 0,1% M=1 M=1	
RAC opinion					Acute Tox. 1 Acute Tox. 1 Repr. 1B	H300 H330 H372 (blood) H360D		H300 H330 H372 (blood) H360D		Repr. 1B; H360D: C ≥ 0,003% STOT RE 1; H372	

										(blood): C ≥ 0,1%, STOT RE 2; H373 (blood): 0,01% ≤ C < 0,1% M=1 M=1	
Resulting Annex VI entry if agreed by COM					Repr. 1B Acute Tox. 1 Acute Tox. 1 Acute Tox. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H300 H310 H330 H372 (blood) H400 H410	GHS06 GHS08 GHS09 Dgr	H360D H300 H310 H330 H372 (blood) H410		Repr. 1B; H360D: C≥ 0,003% STOT RE 1; H372 (blood): C ≥ 0,1%, STOT RE 2; H373 (blood): 0,01% ≤ C < 0,1% M=1 M=1	

Bromadiolone (ISO); 3-[3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-chromen-2-one

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	607-716-00-8	bromadiolone (ISO); 3-[3-(4'-bromobiphenyl-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-chromen-2-one	249-205-9	28772-56-7	Repr. 1A Acute Tox. 1 Acute Tox. 1 Acute Tox. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H300 H310 H330 H372 H400 H410	GHS06 GHS08 GHS09 Dgr	H360D H300 H310 H330 H372 H410		STOT RE 1; H372 (blood): C ≥ 0,02%, STOT RE 2; H373 (blood): 0,01% ≤ C < 0,1% M=1 M=1	
RAC opinion					Repr. 1B Acute Tox. 1 Acute Tox. 1 Acute Tox. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H300 H310 H330 H372 (blood) H400 H410	GHS06 GHS08 GHS09 Dgr	H360D H300 H310 H330 H372 (blood) H410		Repr. 1B; H360D: C ≥ 0,003% STOT RE 1; H372 (blood): C ≥ 0,005%, STOT RE 2; H373 (blood):	

										0,0005% ≤ C < 0,005% M=1 M=1	
Resulting Annex VI entry if agreed by COM					Repr. 1B Acute Tox. 1 Acute Tox. 1 Acute Tox. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H300 H310 H330 H372 (blood) H400 H410	GHS06 GHS08 GHS09 Dgr	H360D H300 H310 H330 H372 (blood) H410		Repr. 1B; H360D: C ≥ 0,003% STOT RE 1; H372 (blood): C ≥ 0,005%, STOT RE 2; H373 (blood): 0,0005% ≤ C < 0,005% M=1 M=1	

Difenacoum (ISO); 3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-157-00-X	difenacoum (ISO); 3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	259-978-4	56073-07-5	Acute Tox. 2* STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H300 H372** H400 H410	GHS06 GHS08 GHS09 Dgr	H300 H372** H410			
Dossier submitters proposal					**Modify:** Acute Tox. 1 (oral) **Add:** Acute Tox. 1 (dermal) Acute Tox. 1 (inhalation) Repr. 1A	**Modify:** H372 (blood) **Add:** H310 H330 H360D		**Modify:** H372 (blood) **Add:** H310 H330 H360D		**Add:** STOT RE 1; H372 (blood): C ≥ 0,1%, STOT RE 2; H373 (blood): 0,01% ≤ C < 0,1% M=10 M=10	
RAC opinion					Acute Tox. 1 (oral) Acute Tox. 1 (dermal) Acute Tox. 1 (inhalation) Repr. 1B	 H310 H330 H372 (blood) H360D		 H310 H330 H372 (blood) H360D		Repr. 1B; H360D: C≥ 0,003% STOT RE 1; H372 (blood): C ≥ 0,02%, STOT RE	

										2; H373 (blood): 0,002% ≤ C < 0,02% M=10 M=10	
Resulting Annex VI entry if agreed by COM					Repr. 1B Acute Tox. 1 Acute Tox. 1 Acute Tox. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H330 H310 H300 H372 (blood) H400 H410	GHS06 GHS08 GHS09 Dgr	H360D H330 H310 H300 H372(blood) H410		Repr. 1B; H360D: C ≥ 0,003% STOT RE 1; H372 (blood): C ≥ 0,02%, STOT RE 2; H373 (blood): 0,002% ≤ C < 0,02% M=10 M=10	

Difethialone (ISO); 3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydronaphthalen-1-yl]-4-hydroxy-2H-1-benzothiopyran-2-one

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	607-717-00-3	difethialone (ISO); 3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydronaphthalen-1-yl]-4-hydroxy-2H-1-benzothiopyran-2-one	-	104653-34-1	Repr. 1A Acute Tox. 1 Acute Tox. 1 Acute Tox. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H300 H310 H330 H372 H400 H410	GHS06 GHS08 GHS09 Dgr	H360D H300 H310 H330 H372 H410	EUH070	STOT RE 1; H372 (blood): C ≥ 0,02%, STOT RE 2; H373 (blood): 0,002% ≤ C < 0,02% M=100 M=100	
RAC opinion					Repr. 1B Acute Tox. 1 Acute Tox. 1 Acute Tox. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H300 H310 H330 H372 (blood) H400 H410	GHS06 GHS08 GHS09 Dgr	H360D H300 H310 H330 H372 (blood) H410	EUH070	Repr. 1B; H360D: C ≥ 0,003%, STOT RE 1; H372 (blood): C ≥ 0,02%,	

										STOT RE 2; H373 (blood): 0,002% ≤ C < 0,02% M=100 M=100	
Resulting Annex VI entry if agreed by COM					Repr. 1B Acute Tox. 1 Acute Tox. 1 Acute Tox. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H300 H310 H330 H372 (blood) H400 H410	GHS06 GHS08 GHS09 Dgr	H360D H300 H310 H330 H372 (blood) H410	EUH070	Repr. 1B; H360D: C ≥ 0,003%, STOT RE 1; H372 (blood): C ≥ 0,02%, STOT RE 2; H373 (blood): 0,002% ≤ C < 0,02% M=100 M=100	

Flocoumafen (ISO); reaction mass of: cis-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin and trans-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-375-00-5	flocoumafen (ISO); reaction mass of: cis-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin and trans-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin	421-960-0	90035-08-8	Acute Tox. 2 * Acute Tox. 1 Acute Tox. 2 * STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H330 H310 H300 H372 ** H400 H410	GHS06 GHS08 GHS09 Dgr	H330 H310 H300 H372 ** H410			
Dossier submitters proposal					**Modify:** Acute Tox. 1 (oral) Acute Tox. 1 (inhalation) **Add:** Repr. 2	**Modify:** H372 (blood) **Add:** H361d		**Modify:** H372 (blood) **Add:** H361d		**Add:** Repr. 2; H361d: C ≥ 0,003%, STOT RE 1; H372 (blood): C ≥ 0,05%, STOT RE 2; H373 (blood): 0,005% ≤ C < 0,05%	

										M=10 M=10	
RAC opinion					Acute Tox. 1 (oral) Acute Tox. 1 (inhalation) Repr. 1B	 H372 (blood) H360D		 H372 (blood) H360D		Repr. 1B; H360D: C ≥ 0,003% STOT RE 1; H372 (blood): C ≥ 0,05% STOT RE 2; H373 (blood): 0,005% ≤ C < 0,05% M=10 M=10	
Resulting Annex VI entry if agreed by COM					Repr. 1B Acute Tox. 1 Acute Tox. 1 Acute Tox. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H330 H310 H300 H372 (blood) H400 H410	GHS06 GHS08 GHS09 Dgr	H360D H330 H310 H300 H372 (blood) H410		Repr. 1B; H360D: C ≥ 0,003% STOT RE 1; H372 (blood): C ≥ 0,05% STOT RE 2; H373 (blood): 0,005% ≤ C < 0,05% M=10 M=10	

Warfarin (ISO); 4-hydroxy-3-(3-oxo-1-phenylbutyl)-2H-chromen-2-one

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-056-00-0	warfarin (ISO); 4-hydroxy-3-(3-oxo-1-phenylbutyl)-2H-chromen-2-one	201-377-6	81-81-2	Repr. 1A STOT RE 1 Aquatic Chronic 3	H360D *** H372 ** H412	GHS08 Dgr	H360D *** H372 ** H412			
Dossier submitters proposal					**Modify:** Aquatic Chronic 2 **Add:** Acute Tox. 1 (inhalation) Acute Tox. 1 (dermal) Acute Tox. 2 (oral)	**Modify:** H372 (blood) H411 **Add:** H330 H310 H300	**Add:** GHS06 GHS09	**Modify:** H372 (blood) H411 **Add:** H330 H310 H300		**Add:** Repr. 1A; H360D: C ≥ 0,0003%; STOT RE 1; H372 (blood): C ≥ 0,2% STOT RE 2; H373 (blood): 0,02% ≤ C < 0,2%	
RAC opinion					Acute Tox. 1 (inhalation) Acute Tox. 1 (dermal) Acute Tox. 2 (oral) Aquatic Chronic 2	H330 H310 H300 H372 (blood) H411	GHS06 GHS09	H330 H310 H300 H372 (blood) H411		Repr. 1A; H360D: C ≥ 0,003%, STOT RE 1; H372 (blood): C ≥ 0,5% STOT RE	

										2; H373 (blood): 0,05% ≤ C < 0,5%	
Resulting Annex VI entry if agreed by COM					Repr. 1A Acute Tox. 1 Acute Tox. 1 Acute Tox. 2 STOT RE 1 Aquatic Chronic 2	H360D H330 H310 H300 H372 (blood) H411	GHS06 GHS08 GHS09 Dgr	H360D H330 H310 H300 H372 (blood) H411		Repr. 1A; H360D: C ≥ 0,003%, STOT RE 1; H372 (blood): C ≥ 0,5% STOT RE 2; H373 (blood): 0,05% ≤ C < 0,5%	

Brodifacoum (ISO); 4-hydroxy-3-(3-(4'-bromo-4-biphenylyl)-1,2,3,4-tetrahydro-1-naphthyl)coumarin

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-172-00-1	brodifacoum (ISO); 4-hydroxy-3-(3-(4'-bromo-4-biphenylyl)-1,2,3,4-tetrahydro-1-naphthyl)coumarin	259-980-5	56073-10-0	Acute Tox. 1 Acute Tox. 2 * STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H310 H300 H372** H400 H410	GHS06 GHS08 GHS09 Dgr	H310 H300 H372 ** H410			
Dossier submitters proposal		brodifacoum (ISO); 4-hydroxy-3-(3-(4'-bromo-4-biphenylyl)-1,2,3,4-tetrahydro-1-naphthyl)coumarin	259-980-5	56073-10-0	**Modify:** Acute Tox. 1 (oral) **Add:** Acute Tox. 1 (inhalation) Skin Sens. 1 Repr. 1B	**Modify:** H372 (blood) **Add:** H330 H317 H360D	**Add:** GHS07	**Modify:** H372 (blood) **Add:** H330 H317 H360D		**Add:** STOT RE 1; H372 (blood) C ≥ 0.25%, STOT RE 2; H373 (blood): 0.025% ≤ C < 0.25% M=10 M=10	
RAC opinion					Acute Tox. 1 (oral) Acute Tox. 1	H330		H330		**Add:** Repr. 1A; H360D:	

					(inhalation) Repr. 1A	H372 (blood) H360D		H372 (blood) H360D		C ≥ 0,003%, STOT RE 1; H372 (blood): C ≥ 0,02%, STOT RE 2; H373 (blood): 0,002% ≤ C < 0,02% M=10 M=10	
Resulting Annex VI entry if agreed by COM					Repr. 1A Acute Tox. 1 Acute Tox. 1 Acute Tox. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H300 H310 H330 H372 (blood) H400 H410	GHS06 GHS08 GHS09 Dgr	H360D H300 H310 H330 H372 H410		Repr. 1A; H360D: C ≥ 0,003%, STOT RE 1; H372 (blood): C ≥ 0,02%, STOT RE 2; H373 (blood): 0,002% ≤ C < 0,02% M=10 M=10	

Coumatetralyl (ISO); 4-hydroxy-3-(1,2,3,4-tetrahydro-1-naphthyl)coumarin

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-059-00-7	coumatetralyl (ISO); 4-hydroxy-3-(1,2,3,4-tetrahydro-1-naphthyl)coumarin	227-424-0	5836-29-3	Acute Tox. 1 Acute Tox. 2 * STOT RE 1 Aquatic Chronic 3	H310 H300 H372 ** H412	GHS06 GHS08 Dgr	H310 H300 H372 ** H412			
Dossier submitters proposal					**Modify:** Acute Tox. 3 (dermal) Acute Tox. 2 (oral) STOT RE 1 Aquatic Chronic 1 **Add:** Acute Tox. 2 (inhalation) Repr. 1A	**Modify:** H311 H372 (blood) H410 **Add:** H330 H360D	**Add:** GHS09	**Modify:** H311 H372 (blood) H410 **Add:** H330 H360D		**Add:** STOT RE 1; H372 (blood): C ≥ 0,2%, STOT RE 2; H373 (blood) 0,02% ≤ C < 0,2% M=10	
RAC opinion					Acute Tox. 2 (inhalation) Acute Tox. 3 (dermal) Acute Tox. 2 (oral) STOT RE 1 Repr. 1B	H330 H311 H372 (blood) H360D	**Add:** GHS09	H330 H311 H372 (blood) H360D		**Add:** Repr. 1B; H360D: C ≥ 0,003%, STOT RE 1; H372 (blood): C ≥ 1,0%,	

					Aquatic Chronic 1	H410		H410		STOT RE 2; H373 (blood) 0,1% ≤ C < 1,0% M=10	
Resulting Annex VI entry if agreed by COM					Repr. 1B Acute Tox. 2 Acute Tox. 2 Acute Tox. 3 STOT RE 1 Aquatic Chronic 1	H360D H330 H300 H311 H372 (blood) H410	GHS06 GHS08 GHS09 Dgr	H360D H330 H300 H311 H372 (blood) H410		Repr. 1B; H360D: C ≥ 0,003%, STOT RE 1; H372 (blood): C ≥ 1,0%, STOT RE 2; H373 (blood) 0,1% ≤ C < 1,0% M=10	