RAC/M/27/2013
Final
14 February 2014

Minutes of the 27th Meeting of the Committee for Risk Assessment (RAC-27) 2-5 December 2013

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 27th meeting of the Committee for Risk Assessment (RAC). Apologies were received from three members. The Chairman welcomed three new RAC members, and informed the Committee that one RAC member had resigned. The participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed after the adoption of the minutes. The Chairman noted that the minutes would be published on the ECHA website and would include a full list of participants as given in Part III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the week's agenda.

One member raised the question of the confidentiality of the information contained in applications for authorisation, and access to such documents.

The Final Draft Agenda (RAC/A/27/2013) was adopted without further modification. The agenda and the list of all meeting documents are attached to these minutes as Annexes I and II, respectively.

3. Declarations of conflicts of interests to the Agenda

The Chairman informed the Committee in relation to the question raised by two RAC members during the RAC 26 meeting who had questioned the practice of declaring a potential conflict of interest when the dossier is submitted by a Member State Competent Authority or executing agency by whom the member is employed and when this member has not been personally involved in the preparation or evaluation of the dossier. In their view, excluding the member from voting in case there is a potential conflict of interest declared on any dossier submitted by the respective Competent Authority would not be in line with the request towards the Competent Authorities to provide support to their nominated Committee members. The issue was also brought to the attention of the Management Board by one of its members at its September 2013 meeting. The Management Board referred the question to the ECHA Conflicts of Interest Advisory Committee (CoIAC) who would consider the issue and advise the Executive Director of ECHA accordingly. Pending the recommendation of the CoIAC, the current practice will be maintained.

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.

The two RAC members that had raised the issue summarised above, repeated their objection to the declaration, indicating that their written comments on one of the substances concerned further illustrated their independence, as their opinion deviated from that of the dossier submitter proposal. It was further argued that the current practice might lead to a non-existing "conflict" of interest for many substances when a member is working at a large Agency.

The Chairman reiterated that members with concurrent employment at a CA submitting a dossier to the Committees were required to declare a potential conflict of interest in RAC and SEAC on that specific case and that this applies to all members evenly. The RAC will be informed of the outcome of the CoIAC discussion and the decision of ECHA if available at RAC 28 in March 2014.

4. Report from other ECHA bodies and activities

a) Report on RAC-26 action points, written procedures and other ECHA bodies

The Chairman informed the Committee that all action points of RAC-26 had been completed, or were on-going. He also informed the Committee that the final minutes of RAC-26 had been adopted via written procedure and were uploaded to CIRCABC and on the ECHA website on 22 November, and thanked those members who had provided comments on the draft. The Chairman informed the Committee that the draft minutes from RAC-27 will be compiled and sent for the RAC comments by 10 January 2014.

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 41 opinions in 2013 to ca. 71 in 2014 (40 CLH, 11 restrictions and 20 or more authorisations) and noted that holding longer meetings (4.5 instead of 3.5 days) would not be sufficient to meet this demand. Additional meetings would be needed.

The meeting dates listed on the RAC page of the ECHA website would be maintained he noted and assuming some gains in efficiency, the extra 30 dossiers could be fitted into 6 regular meetings (3.5 day; Tuesday 09:00 to Friday 13:30), instead of the usual 4.

Meetings 'in between' were considered to be problematic for the following reasons: the timelines for restrictions and applications for authorisation are tied to very tight legal deadlines, while the submission windows are synchronised to Committee dates. Already moving at a fast pace, the quarterly meeting pattern suits the rhythm of CLH and gains the maximum efficiency by allowing enough time for all parties, including rapporteurs to prepare for each meeting and carry out the necessary follow-up afterwards.

ECHA therefore proposed to add the additional meetings immediately following the planned March and December RAC meetings, making them in effect double meetings. In order to provide some flexibility, the secretariat would ensure differentiation into partly separate REACH (e.g. RAC 28A) and CLH (e.g. RAC 28B) agendas. A positive aspect of this would be that the Authorisation process would be given more room to grow and mature, while the CLP and Restriction processes would be able to gain further focus and efficiency.

The June and September meetings would remain unchanged, with normal mixed agendas for all processes. The Chairman concluded that the amended schedule for the March meetings would be announced before the end of the year.

5. Harmonised classification and labelling (CLH)

5.1 CLH dossiers

a) Sulfoxaflor

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

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

The Chairman noted that at RAC-26, the Committee had already agreed on harmonised classifications as Acute Tox. 4 (H302) and as Aquatic Acute 1 (H400) and Chronic 1 (H410), with an M-factor of 1 in both cases. At RAC-27 carcinogenicity and reproductive toxicity were the only endpoints left over for discussion. For both endpoints, several toxicity studies and a series of mechanistic studies needed to be evaluated, including a late mechanistic study on reproductive toxicity that was provided by the applicant under the EFSA process and which had previously been announced during the ECHA Public Consultation.

Where carcinogenicity was concerned, the Committee discussed the liver cell tumours observed in male and female mice and male rats and the mechanistic studies on the constitutive androstane receptor (CAR)(/pregnane X receptor (PXR)) mediated mode of action (MoA). The DS considered this MoA not relevant for humans. The absence of hepatocellular proliferation in a mechanistic study using humanised and knock-out CAR/PXR mice, was considered further evidence for the non-relevance to humans. The Committee questioned the use of the humanised mice model as only one gene has been changed in these mice and the model would not necessarily represent the full mechanism in humans. It was also noted that although liver tumours were likely formed via the CAR(/PXR) mediated mechanism, with key events in this MoA shown in male and female rats and mice, there were also some different responses between these species and between the sexes. It was pointed out that humans may be less sensitive to liver tumour formation via this MoA, but that this does not necessarily mean the absence of hazard to humans.

As RAC did not have any detailed data on phenobarbital, it was considered difficult to use this as a reference substance for the above mode of action. As a result, it was proposed not to refer to phenobarbital in the discussions.

It was noted that in the experiment with humanised mice there was a lack of positive controls showing that increased liver cell proliferation led to liver tumours in the same animals. A delayed proliferation was also considered as possible in humanised CAR/PXR mice, but this could not be concluded as the length of the experiment was only seven days. Some members commented that the CAR mediated mechanism in liver tumour formation is not relevant for humans. The key question was therefore whether other mechanisms could be excluded. According to the Rapporteur the mode of action was not genotoxic and other mode of actions were shown to be unlikely. Although the increased liver tumour incidences may have warranted classification for carcinogenicity, the Committee in the end concluded on no classification based on the totality of mechanistic evidence presented for sulfoxaflor. RAC considered a CAR-mediated, mitogenic MoA behind the liver tumours most likely for sulfoxaflor, but as humans do not seem to undergo the sulfoxaflor-induced proliferative response (as shown in humanised mice), liver tumours are not expected to occur in humans. RAC pointed out that this case was unique and should not be seen as a precedent for similar cases in the future: when a CAR-mediated MoA is claimed for a substance, sufficient and good quality data will have to be provided showing the presence or absence of key events supporting the MoA and the (non-)relevance to humans. While industry noted that the case against human relevance of the CAR-mediated MoA was strong enough even without the knock-out and humanised mice studies, the RAC felt that the evidence could have been stronger and further confirmatory studies would be desirable in future.

The overall evidence of Leydig cell tumours and preputial gland tumours observed only in male rats appeared too weak to justify classification. Therefore, the RAC agreed that classification for carcinogenicity was not warranted.

With regard to reproductive toxicity, the RAC agreed not to classify sulfoxaflor for this hazard class, despite the substance inducing some very specific foetal abnormalities together with reduced postnatal survival. RAC concluded that the mechanistic studies into the MoA behind these effects presented sufficient evidence for the non-relevance to humans.

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

b) Phenol, dodecyl-, branched (TPP)

The Chairman welcomed representatives of the two industry dossier submitters. He reported that phenol, dodecyl, branched was a UVCB substance, i.e. a complex mixture of branched alkyl-substituted phenols which is widely used by the chemical industry for the synthesis of polymers from monomers.

He noted that TPP currently had no harmonised classification in Annex VI to the CLP Regulation and that a harmonised classification would apply to any substance which predominantly contained C12 (branched) alkyl-substituted phenols.

One dossier submitter had proposed to classify the substance for Skin Irrit. 2 (H315), Eye Irrit. 2 (H319), Repr. 2 (H361f), and for Aquatic Acute 1 (H400) with an M-factor of 1, and Aquatic Chronic 1 (H410) with an M-factor of 10. On the basis of the information contained in their dossier, the Committee had already agreed at RAC-26 to classify the substance as Skin Corr. 1C, and as Aquatic Acute 1 and Chronic 1, with an M-factor of 10 for both aquatic hazard classes.

The Chairman informed the Committee that the two dossiers were being tabled for a second discussion in the RAC, in order to discuss toxicity to reproduction which was also proposed by the second industry dossier submitter, but with a different classification than the first one, namely as Repr. 1B (H360F) with a specific concentration limit (SCL) of 1.5 %.

The Chairman clarified that the information contained in both dossiers as well as the comments received under PC would have to be discussed together in order to decide on reproductive toxicity.

The Rapporteur presented the data on reproductive toxicity, as well as the argumentation from the two dossier submitters for the classification proposals, Repr. 2 versus 1B (the latter with a SCL of 1.5 %).

During the discussion, several RAC members expressed support for Repr. 1B, considering the existing database presented in the CLH dossiers, including several reproductive toxicity studies as well as supporting studies. It was stated that the effects seen, on e.g. female reproduction, could not be explained by the reduced body weight gain compared to concurrent controls, and it was noted that adverse effects on reproduction were also seen where there were no effects on body weight. Following a question from one RAC member, it was further clarified that in the studies on TPP, there was a reduction in body weight gain and final body weight compared to controls, but not an actual body weight loss. Hence, it was concluded that the feed restriction studies could not support the argumentation of one dossier submitter that the reproductive effects could be a non-specific secondary effect caused by the effects on body weight.

The Rapporteur further presented calculations on the concentration limit, and concluded that the proposed SCL of 1.5 % was not appropriate. According to the calculations, made according to the Guidance on the application of CLP criteria, TPP is of medium potency, and hence the general concentration limit would apply.

It was agreed to classify TPP into Repr. 1B (H360F) without assigning a SCL. It was further agreed not to classify TPP for developmental toxicity and for effects on or via lactation. The Committee adopted the opinion on phenol, dodecyl, branched by consensus. The Chairman thanked the Rapporteur(s) for their presentation of the arguments and the Committee for their participation in the discussions.

c) Lead

The Chairman welcomed an expert accompanying the Eurometaux stakeholder observer. He reported that lead had a variety of uses, both for industrial purposes as well as in consumer products.

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

While the RAC had already agreed at RAC-26 to classify lead (all forms) as Repr. 1A for both development and fertility (H360DF) as well as for effects on or via lactation (Lact., H362), the discussion on specific concentration limits and the overall scope of the lead entry in Annex VI still needed to be finalised.

The Chairman invited the Rapporteur to present the options related to both questions.

The Rapporteur proposed a SCL of 0.03% for development based on a drop of 1-5 IQ points at a blood lead level of 100 µg/l, both maternally and post-natally. This blood lead level is achieved at external doses from 330 µg/kg/day. No SCL was proposed by the Rapporteur for fertility effects. The Rapporteur also noted the option of having two entries for lead, one for lead powder with the proposed SCL and one for the massive form without SCL. During the

subsequent discussions, the Committee recognised that lead was a highly potent substance which needed to be reflected by a specific concentration limit. The RAC was of the opinion that on the basis of the bioavailability data presented for particulate lead, estimates of doses for massive forms were unclear. Additionally, small particles would be expected to form during reasonable handling and use of massive lead. Splitting the entry for lead with regard to the assignment of SCL's was therefore not considered justified and the RAC agreed on a SCL of 0.03% for developmental effects.

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

d) Anti-coagulant rodenticides

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and reported that the eight dossiers submitted by eight different dossier submitters (Ireland, Italy, the Netherlands, Sweden, Norway, Denmark, Spain, Finland) would be considered in detailed substance-by-substance analyses, taking all available data into account including data on warfarin, in a weight of evidence assessment (in accordance with the CLP criteria) as agreed upon at RAC 26 when the general discussion on AVKs had taken place. The substances belong to a group of anticoagulant rodenticides, i.e. those with an anti-vitamin K mode of action (AVKs) and are used mainly as the active substances in biocidal products for pest control of rats, mice and other rodents.

Some substances already have a harmonised classification in Annex VI to the CLP Regulation, however only Warfarin is classified for toxicity to reproduction as Repr. 1A (H360D).The discussion on developmental toxicity of the 7 other AVKs were never finalised by the TC C&L and were handed-over to ECHA.

Toxicity to reproduction of the first two dossiers (Brodifacoum and Flocoumafen) for which first draft opinions were prepared was discussed together and the following issues were considered: mode of action (MoA), animal data, human data, placental transfer and toxicokinetics.

One RAC member stressed that a common understanding of the interpretation of human data on Warfarin and other AVK substances/agents and the animal data on Warfarin would be needed for further discussion on individual dossiers, which was supported by other RAC members. Also, the predictability of the standard developmental toxicity study (OECD TG 414) of the effects seen in humans (including the typical warfarin embryopathy syndrome) would need to be clarified in order to provide adequate weight to the animal data in the weight of evidence analysis. In addition, it was noted that both maternal toxicity and developmental effects in the animal studies have to be evaluated in detail if a comparison should be made between Warfarin and the other AVKs with regard to available animal data.

The RAC agreed that both substances, as well as Warfarin, act with an identical mode of action. However, for some members a common / identical MoA on its own was not seen as sufficient for classification and they stated that a broader assessment would be needed before a final conclusion could be made.

Although one RAC member was of the opinion that developmental toxicity is clearly shown in the rat warfarin studies, several RAC members commented that the results from these studies, in particular the study by Kubaszky (2009), were weak and/or equivocal (e.g. because of low incidences, lack of dose response and severe/unclear maternal toxicity). Two RAC members reminded the Committee that the typical human nasal skeletal malformations have only been demonstrated in the rat after post-natal exposure with concurrent supplement of vitamin K (Howe and Webster, 1992). This statement was challenged by the expert from ECPA who noted that the post-natal nasal elongation measured in Howe and Webster represented a different growth process than the cellular and tissue reorganisation and migration that occurs during the critical window of teratogenesis. The Chairman summarised that several RAC members considered that the animal data on warfarin had weaknesses and that no firm conclusion could be drawn. However, the warfarin data could be considered again in the context of each AVK case.

Concerning the human data on Warfarin, several RAC members underlined that the effects seen in the foetuses were irreversible and severe (malformations and death) in contrast to the maternal therapeutic effects (including prolongation of blood coagulation time).

The RAC agreed that in case of a direct effect on the embryo/foetus, both substances have a potential to cross the placenta in the rat although the extent of the transfer may differ. Flocoumafen has a higher binding affinity to the maternal liver than warfarin but also a much longer half time in the maternal liver.

1. Brodifacoum

Brodifacoum already has a harmonised classification in Annex VI to the CLP, the current entry being Acute Tox. 1; H310, Acute Tox. 2*; H300, STOT RE 1; H372**, and environmental hazards Aquatic Acute 1; H400 and Aquatic Chronic 1; H410.

As to reproduction, the Rapporteur supported the DS proposal (which originally was to add Repr. 1B for developmental toxicity but was revised to addition of Repr. 1A after the public consultation (PC)). There were 5 experimental animal studies (rats and rabbits), all of them "negative", one case report on an accidental exposure of a dog with foetotoxic findings (7 out of 13 pups died of haemorrhage at birth or within 2 days after birth) and in addition 3 clinical cases of exposure of pregnant women with Brodifacoum, of which two showed evidence of developmental toxicity. According to the Rapporteur, the proposal was justified by a) an identical MoA as for Warfarin and other therapeutic coumarins which are teratogenic in the human, b) by the two human cases where the offspring were more severely affected than the mothers even if they were treated with vitamin K, c) by the dog case study and finally, d) by uncertainties in relation to the reliability of the experimental animal data in predicting effects in humans.

Considering the 3 clinical reports with regard to brodifacoum exposure, the expert from ECPA pointed out that the level of toxicity to the mothers was sufficiently high and that all women were treated with vitamin K to prevent anticoagulation. He noted that effects on human foetuses were observed in the presence of severe maternal toxicity. In his view, the quality of the clinical reports did not meet the criteria for Cat 1 A. Further, the expert from ECPA noted that according to his interpretation of the criteria (i.e. Table 3.7.1(a) of Annex 1 to the Regulation), such 'uncertainty' could only be used for "downgrading" the classification (and not the other way round).In the discussion, several RAC members commented that the human and dog data on Brodifacoum seemed to fit with the developmental toxicity profile related to Warfarin and other human medicinal drugs with the same MoA/mechanism of action. Other members questioned whether these cases were well enough reported to provide the necessary weight of evidence. The RAC finally agreed on the proposed classification for developmental toxicity (Repr. 1A; H360D) based on the set of evidence as summarised by the Rapporteur. Other proposed hazard classes (modification of Acute toxicity and Skin sensitisation) will be discussed at the next meeting.

2. Flocoumafen

Flocoumafen already has a harmonised classification in Annex VI to the CLP, the current entry being Acute Tox. 2*; H330, Acute Tox. 1; H310, Acute Tox. 2*; H300, STOT RE 1; H372**, and environmental hazards Aquatic Acute 1; H400 and Aquatic Chronic 1; H410.

The Rapporteur supported the DS proposal for modifications of the minimum classification for Acute toxicity for oral, and inhalation routes (Acute Tox. 1; H300, Acute Tox. 1; H330) based on the results of the studies in rats (oral), resp. rats and mice (inhalation). The RAC agreed on the proposed modifications.

The Rapporteur supported the DS proposal for modification of the hazard statement for classification for specific target organ toxicity after repeated exposure (STOT RE 1) i.e. to delete the "**" for H372 in the current Annex entry, in order to indicate that all routes are of concern, based on the outcome of a 90-day study in rats. The RAC agreed to this modification of the hazard statement of H372.

The developmental toxicity of Flocoumafen and the DS's proposal to add a Repr. 2 classification for this endpoint were not discussed in detail due to time constraints and will be resumed at the next meeting. The Committee also agreed - due to time constraints – to deal with environmental classification for all eight anticoagulant rodenticides via written procedure.

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

e) Triflusulfuron methyl

The Chairman welcomed an expert accompanying the ECPA stakeholder observer The Chairman reported that the substance is an herbicide to be used in agriculture under field conditions and the dossier was submitted by France. In the EU Plant Protection Products (PPP) dossier, representative uses are for sugar and fodder beets. The substance has no harmonised classification in the Annex VI to the CLP Regulation. The dossier submitter proposed to classify triflusulfuron methyl as Carc. 2 (H351), Aquatic Acute 1 (H400, M-factor 100), and Aquatic Chronic 1 (H410, M-factor 10). During the public consultation, comments from seven Member State Competent Authorities were received and were addressed in the second draft opinion. The Chairman stated that all hazard classes proposed in the dossier would be discussed in the meeting and invited the Rapporteurs to present the draft opinion and the comments received during the public consultation.

In the Rapporteurs' presentation, covering all physico-chemical and human health endpoints, it was concluded that the proposal by the dossier submitter to classify the substance as Carc. 2 (H351) was justified. Increase in incidences of interstitial cells hyperplasia (Leydig cells, testes) and adenomas were seen at the two highest dose levels in male rats and a slight increase in hepatocellular adenomas were seen in male mice. The Rapporteur also noted that late in the process (the week before the RAC plenary) industry had submitted additional data, challenging the proposal on carcinogenicity by the dossier submitter and the RAC Rapporteur. The Chairman noted that the aforementioned information had only been provided to ECHA shortly before the meeting and further pointed out that the appropriate time to provide such information was during the public consultation. While it had been passed on to the Rapporteurs and the RAC, it was too short notice to assess its significance and consider it properly. After brief discussion RAC decided not to delay the process, and to base its decision on the data already available.

RAC also agreed with the recommendation of the Rapporteurs to classify the substance for the environmental toxicity endpoints. In accordance with the dossier submitter's proposal, the classification should be Aquatic Acute 1 (H400, M-factor 100) and Aquatic Chronic 1 (H410, M-factor 10), confirmed despite minor corrections, i.e. recalculation of initial measured concentrations and preference of 7d values, the other duckweed test then turning out as the key study for chronic classification.

The Committee adopted the opinion on triflusulfuron methyl by consensus. The Chairman thanked the Rapporteurs for their presentation of the arguments and the Committee for their participation in the discussion.

f) Bifenazate

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that bifenazate is a new active substance, for use as an acaricide in crops and ornamentals and that it has no Annex VI entry. The CLH dossier was submitted by the Netherlands.

The dossier submitter had proposed to classify the substance for Skin sensitisation 1B; H317, for STOT RE 2; H373, for Aquatic Acute 1; H400 with an M-factor of 1 and for Aquatic Chronic 1; H410 with an M-factor of 1.

Based on a negative Buehler test and a positive guinea pig maximisation test (GPMT) the DS proposed to classify bifenazate as Skin Sens 1B. With specific reference to the results in the GPMT (which does not preclude classification for 1A since a sensitisation rate of >60% at 1% concentration cannot be excluded) the RAC decided to classify the substance without a sub-categorisation, i.e. as Skin Sens. 1.

Concerning repeated dose toxicity, the Rapporteurs proposed to classify bifenazate as STOT RE 2, based on mortality observed in the 28-d oral studies in mouse and rat, supported by haematotoxicity. In longer-term studies, the haematology effects were confirmed in the dog only. No specific target organ was proposed for the CLP classification because the blood

system could not be unequivocally identified as the target organ responsible for mortality. The criteria for classification were fulfilled under CLP but not under DSD and this conclusion was supported by the RAC.

Although the DS had not proposed classification for the following hazard classes, the Rapporteur presented the data concerning: mutagenicity, carcinogenicity and reproductive toxicity. After a careful and detailed analysis of this data, RAC agreed with the DS and the Rapporteur's conclusion to not classify the substance for these endpoints.

The co-Rapporteur agreed with the original proposal of the dossier submitter to classify bifenazate according to the CLP criteria as Aquatic Acute 1 (H400) with an M-factor acute of 1 and Aquatic Chronic 1 (H410) with an M-factor chronic of 1. The RAC agreed with the proposed classification.

In summary, the RAC agreed to classify the substance as STOT RE 2; H373, Skin Sens. 1; H317 (without subcategory), Aquatic Acute 1; H400, M=1, Aquatic Chronic 1; H410, M=1.

The opinion on bifenazate was adopted by consensus. The Chairman thanked the Rapporteurs for their presentation of the arguments and the Committee for their participation in the discussions.

g) Fenpyroximate

The Chairman reported that fenpyroximate was an active substance used as a PPP. Therefore, RAC needed to evaluate all hazard classes for which the dossier submitter (Germany) has provided appropriate information.

Fenpyroximate currently has no harmonised classification in Annex VI to the CLP Regulation. The dossier submitter proposed to classify the substance as Acute Tox. 3; H301, Acute Tox. 2; H330, Skin Sens. 1B; H317, Eye Irrit. 2; H319, Aquatic Acute 1; H400, M=100, Aquatic Chronic 1; H410, M=1000. The originally proposed classification for Eye Irritation 2 was withdrawn by the dossier submitter after the public consultation.

The Rapporteurs guided the Committee through all hazard classes for which the dossier submitter provided information. Concerning eye irritation, the Rapporteur noted that the available human data from humans was insufficient for classification and the most relevant primary eye irritation study with the active substance fenpyroximate in rabbits was negative. The RAC therefore agreed that classification for eye irritation was not appropriate.

The RAC asked the Rapporteur to make additions to the STOT RE section of the opinion, i.e. to include information on whether there were findings in the organs of those dogs that were not sacrificed before the end of the study and in addition, a minor clarification to the reproductive toxicity section. However, classification was not considered appropriate for either of these endpoints.

The RAC agreed to classify the substance as proposed by the DS.

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

h) Lenacil

The Chairman reported that the substance is an herbicide used in agriculture and that it has no harmonised classification. The CLH dossier was submitted by Belgium.

The dossier submitter proposed to classify the substance as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with M factors of 10. No classification was proposed for human health hazards.

The Rapporteur presented all hazard classes related to human health and carcinogenicity was discussed in detail. The RAC analysed the data related to increased incidences of thyroid (follicular and c-cells) and mammary gland tumours in female rats and of lung and liver tumours in male mice. There was no mechanism of action presented. Single and combined

incidences of tumours (adenomas, adenocarcinomas and carcinomas) occurring in rats and mice were compared with historical control data (HCD). At the request of the Chairman, the industry expert (ECPA) provided additional information on the origin of the 'updated' set of HCD. RAC members also asked for additional information on the mean values of the HDC data because only ranges had been presented. The Rapporteur then provided additional details to RAC regarding some of the mean values. Based on that, RAC concluded that for one tumour type, i.e. those in mammary gland of female rats, the incidences were higher than could be expected from the HCD. RAC therefore agreed to classify lenacil as carcinogen Cat 2.

For the environment, it was concluded that lenacil is not readily/rapidly degradable, has a low potential to bioaccumulate and that there are adequate acute and chronic toxicity data available on fish, daphnia, algae and aquatic plant *Lemna*. The RAC agreed to the proposal by Belgium to classify lenacil as very toxic to aquatic life with long lasting effects (Aquatic Acute 1 and Aquatic Chronic 1, M=10 in both cases).

RAC adopted the opinion on lenacil by consensus. The Chairman thanked the Rapporteurs for their presentation of the arguments and the Committee for their participation in the discussions.

i) Tributyltin Compounds

The Chairman reported that tributyltin chloride and tributyltin oxide are used as an intermediate for production of other organotin compounds. The current entry in Annex VI of the CLP Regulation covers 'tributyltin compounds with the exception of those specified elsewhere in this Annex' and comprises (along with relevant SCLs and M factors) Acute toxicity (minimum classifications for oral and dermal route), STOT RE 1; H372**, Eye Irrit. 2; H319 and Skin Irrit. 2; H315 and environmental hazards Aquatic Acute 1; H400 and Aquatic Chronic 1; H410.

The DS (Germany) proposed to classify the substance as Repr. 1B; H360Fd and to modify the existing minimum classifications for acute toxicity to Acute Tox. 3; H301 and Acute Tox. 3; H311.

The RAC agreed with the DS to modify the classification for acute toxicity via the oral route, but considered the data for modifying the classification for acute toxicity via the dermal route insufficient and therefore agreed to leave the current minimum classification unchanged.

The RAC agreed with the proposal of the DS to classify the substance for toxicity to reproduction – fertility as Repr 1B, based on the evidence for adverse effects on fertility in males and females in animal studies.

The discussion then focused on developmental toxicity for which the DS proposed classification as Repr. 2 (H360Fd). Several effects were observed, and whereas most findings were considered by the DS to be secondary non-specific effects related to maternal toxicity (mainly decreased maternal body weight), this was not so clear for the malformations (including cleft palate) observed in two species (rats and mice), hence the proposal for Repr. 2. During the discussion it was noted that a dose-response relationship in the increase in cleft palates was observed in several studies and that cleft palate was a rare malformation and this warranted classification as Repr. 1B for developmental toxicity. The RAC agreed to classify the substance for developmental toxicity as Repr. 1B. The opinion on tributyltin compounds was adopted by consensus.

The Chairman thanked the Rapporteur for his presentation of the arguments and the Committee for their participation in the discussion and pointed out that final revision to reflect the discussion at RAC 27 and an editorial check would be performed before the opinion would be published on the ECHA website.

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

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

5.3 General and procedural CLH issues

a) New template for a CLH report

At the request of one RAC member, the Secretariat updated the Committee about the status of the new CLH report template which had been sent to CARACAL for information for their November meeting.

One member argued that should the new template be implemented in its current form, for every CLH dossier, its use (production and subsequent assessment) would have significant time and resource-related implications for the CAs, RAC and ECHA. This increased burden would not according to the RAC member outweigh the benefits the ECHA hoped would be gained by requesting additional information for all dossiers and all endpoints (Section *13. Detailed Study Summaries* of the template).

In addition, in his view, this additional information would not facilitate really complicated cases, as for such dossiers the experience of the committee has shown how scrutiny of the original study reports is often preferred. This RAC member requested that ECHA reconsider their proposal, noting that the implications of the changes had not been explained in full to Member State Competent Authorities. As a possible compromise, the suggested application of the new Section 13 could be made optional. This position was supported by three other RAC members, in particular with reference to transferring information from Biocides CAR documents.

In response to these comments the Secretariat explained the background to the preparation of the new template which was mainly driven by the need to increase the efficiency of the CLH process, and on recent experience with the opinion development process. The Secretariat noted the members' comments and reiterated an earlier offer of assistance to the CAs in the preparation of CLH proposals.

In a final comment, the RAC member explained that his motivation was to ensure that the CLH working process remained efficient and productive, as well as robust.

6. Restriction

6.1 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:

- **Ammonium salts** in cellulose wadding insulation materials used in buildings. ECHA has received a registration of intent for the submission of an Annex XV restriction proposal. In August 2013, France informed the Commission, ECHA and the other MSs, in accordance with Article 129(1) of the REACH Regulation (safeguard clause), it had justifiable grounds for believing that urgent action was essential to protect the public from exposure to ammonia released from ammonium salts in such building materials. France adopted a provisional measure in June and in September 2013, the Commission authorised this provisional measure. Article 129(1) of REACH states that if the provisional measure taken by the MS consists in a restriction on the placing on the market or use of a substance, the MS concerned shall initiate a Union restriction procedure by submitting to ECHA a dossier, in accordance with Annex XV, within 3 months of the date of the Commission decision. The expected submission date is 15 January 2014.
- **Chrysotile** in diaphragms for the use in the chloralkali industry (to be submitted by ECHA on request of the Commission in January 2014);
- **Cadmium and its compounds** in plastics (to be submitted by ECHA on request of the Commission in January 2014 - however, ECHA has not been able to get information based on which it could be able to finalise an Annex XV restriction report by 17 January 2014);

- **Cadmium and its compounds** in artist paints (to be submitted by Sweden in January 2014);
- **Bisphenol A** in thermal paper (to be submitted by France in January 2014);
- **Bis(pentabromophenyl) ether (DecaBDE)** (to be submitted by ECHA on request of the Commission in August 2014).

b) Revision of the restriction process

The ECHA secretariat informed RAC that concerns have been raised about the workload relating to the preparation of restriction proposals and the efficiency of the opinion making process. In addition, the Commission services and ECHA secretariat have discussed to what extent the output of the restriction process, i.e. opinions provided by the two scientific committees of ECHA, satisfies the needs of the Commission for its decision making. In response to these discussions, the Commission and ECHA propose to first carry out a survey to better identify some of the problems. The Committee was informed that during December 2013, a questionnaire would be sent to the members, MSCAs and accredited stakeholder observers of RAC and SEAC. It was also proposed to establish a task force to discuss the issues raised in the questionnaire, to analyse the results, identify the core issues and suggest solutions by spring 2014. The RAC members interested in taking part in the work of this task force were encouraged to express their interest to ECHA by 21 December 2013.

In relation to the discussion on the streamlining of the REACH restriction process and in light of the growing workload of RAC and SEAC, the Secretariat proposed to review and simplify the current Committees' working procedures for processing of restriction dossiers. Several RAC members welcomed the initiative of the Secretariat.

The Committee agreed to the revised working procedure on the conformity check of Annex XV restriction dossiers as proposed by the Secretariat with one additional modification (the initial commenting round to last until Day 12), as part of the above review.

RAC was then informed that the Secretariat would also revise the working procedure for developing opinions on restriction dossiers and schedule it for discussion and agreement at the next plenary meeting.

6.2 Restriction Annex XV dossiers

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

The Chairman welcomed the dossier submitter's representative (SE), as well as the SEAC (co-) Rapporteur, who both followed the discussion remotely via WebEx.

He then introduced the state of play with the development of the opinion for the proposed restriction, on the placing on the market of lead and its compounds in articles intended for consumer use and that the opinion should be adopted at this meeting based on the modified fourth version (i.e. amendments made based on two written commenting rounds in October and November) of the RAC draft opinion. The Chairman restated that the proposal is targeted at consumer articles that could be placed in the mouth by children, considering that children are the most vulnerable population group when exposed to lead. Lead has been shown to be a non-threshold substance for neurotoxic and neurodevelopmental effects. The main route through which small children (between ages of 6 and 36 months) are exposed to lead from consumer articles is by mouthing. The key negative effect from such exposure is the impairment of the development of the Central Nervous System.

The RAC Rapporteurs presented the modified fourth version of the draft RAC opinion, with a focus on the minor modifications on the wording of the scope, and clarification of terms such as the 'tip' of pens, as well as specific changes made to the opinion (e.g. referring to the expression of mouthing times and the justification for the proposed exemptions based on risk).

The RAC discussed how to deal with outdoor articles; it was pointed out that in southern parts of Europe, the likelihood of exposure from mouthing outdoor articles would be higher due to

the fact that children spend a longer time outdoors, e.g. in the garden in warmer climates. After a short exchange of views, RAC concluded that outdoor articles would be left in the scope (as already agreed at RAC-26). However as a result, one member considered that there was insufficient information in the dossier to conclude that there would be a risk with respect to all outdoor articles.

In addition, RAC discussed how to deal with musical instruments, keys, locks and padlocks which were originally proposed by the dossier submitter to be exempted from the proposed restriction. The Secretariat explained that in order to avoid challenges on procedural grounds, even if they posed a risk, they could not now be included in the restriction, as they were not considered during the public consultation on the original Annex XV dossier.

The Secretariat agreed to prepare a note on how to deal with scope/derogation issues during opinion making (including public consultation) in the future.

In conclusion, the RAC agreed to the proposed restriction by a simple majority. Four members reserved their position pending the final wording of the text. The Secretariat was requested to launch a written procedure to adopt the modified text of the opinion, which would close by 10 December 2013.

The Chairman thanked the Rapporteurs and all those who had contributed to an intense and fruitful debate in preceding weeks.

b) Nonylphenol – 1st version of the draft opinion

The Chairman welcomed the dossier submitter representatives (SE) who followed the discussion remotely via WebEx.

The RAC Rapporteurs explained in relation to the environmental hazards that the application of Assessment Factors (AF) and Species Sensitivity Distribution (SSD) approaches to standard end point data led to very similar Predicted No Effect Concentrations (PNEC), consistent with those from the REACH Chemical Safety Reports (CSR). The dossier derived a marine PNEC separately from the freshwater PNEC, but the RAC Rapporteurs thought that this created an artificial distinction in the levels of toxicity and therefore recommend merging marine and freshwater data. Several RAC members supported the Rapporteurs' suggestion to have a combined PNEC with the value of 0.39 µg/L.

In relation to the Endocrine Disrupting (ED) effects of NP, the Rapporteurs noted that the dossier concludes that it is too uncertain to reflect such effects adequately in a PNEC. The Rapporteurs, however, contended that aquatic PNECs, based on both standard AF and SSD approaches were well supported by reliable experimental data in this case and that in the absence of any guidance to the contrary, the justification would have to be based on the available scientific (NP specific) data. The Rapporteurs noted that there were no doubts about the evidence for the ED properties of NP at least in fish, and that vitellogenin (VTG) induction and secondary sex characteristics were well known ED indicative endpoints. In this regard, the SVHC dossier for NP indicates that the lowest reliable ED effect data is for VTG induction in rainbow trout with a LOEC of 1.05 µg/L. The Rapporteurs noted that VTG induction is an indicator of endocrine modulation but is *per se* not necessarily adverse in terms of population stability. OECD and other test method validation work with small fish species (medaka, fathead minnow, zebra fish) provide however evidence that in the same treatments of full life cycle tests, VTG induction during earlier parts of the exposure period precede adverse effects later on in the same test. For the frequently most sensitive fish species rainbow trout, there is no adequate full life cycle test available with NP.

The Rapporteurs proposed three options to the Committee on how to deal with ED effects in terms of the risk assessment: a) by using a lower margin of safety, b) by including an additional ED assessment factor to the standard PNEC data, or c) by basing the PNEC on clearly ED indicative endpoints. The Committee supported the option for a lower margin of safety. Several members pointed out that although there is a working definition for endocrine disruption, there are no criteria and therefore, the wording in this respect needs to be very careful.

In relation to environmental hazards of other relevant NPEO degradation products, the Rapporteurs explained that the submitted dossier refers to evidence showing that ecotoxicity

and estrogenicity increase with decreasing chain length, the most toxic substances being those with one or two ethoxylate or carboxyethoxylate units. This evidence is based on four acute tests, one chronic *Daphnia* study, and *in vitro* receptor binding assays. On this basis, Environment Canada has derived a Toxic Equivalence Factor (TEF) approach, which has been proposed in the dossier. The RAC Rapporteurs agree that the TEF would help to estimate combined effects, however, given the poor data set, they considered that the proposed TEFs add significant uncertainties to combined hazard estimates – for NP(3-8)EO the Rapporteurs proposed that QSAR modelling might help to bridge the gap and consolidate the TEFs analysis (at least for acute toxicity). The Committee supported the proposal of the Rapporteurs. A 'best case' *vs* 'worst case' approach might also be possible as a sensitivity analysis.

NP is a Water Framework Directive (WFD) Priority Hazardous Substance and it is therefore subject to monitoring by the EU MS. Relevant data have been reported to the Commission and the dossier submitter has referred to these data to draw conclusions about the risk. Many of the reported concentrations are below the limit of detection. The dossier submitter used a median of 'country-specific' PECs, based in turn on a median of 90th percentiles of individual water bodies, to derive an overall EU PEC of 0.085 µg/L. A similar approach has been used for the marine PEC (four MSs only) of 0.05 µg/L. In the view of the RAC Rapporteurs this approach is too simplistic and uncertain for assessing the magnitude or extent of NP contamination in a risk assessment context. Members of RAC were encouraged, if they have access to any additional monitoring data, to submit it through the ongoing public consultation on this restriction proposal. The RAC Rapporteur confirmed that the UK will submit additional monitoring data via this route. One member confirmed that such data are also available to his Member State's competent authority.

With regard to short chain NPEO/NPEC exposure in EU water bodies, the Rapporteurs noted that the dossier presents data to show that NPEOs degrade to NP and short chain NPEOs in Waste Water Treatment Plants (WWTP). In the view of the RAC Rapporteurs, the derived ratio of NP to short chain NPEOs in WWTP effluent is uncertain, and the uncertainty is increased by the use of the "overall EU PEC" for NP to derive possible concentrations of short chain NPEOs in receiving waters using this ratio. In addition, the approach assumes that the NP concentration is solely related to NPEO release, which is not correct based on the evidence of WWTP influent data. The Rapporteurs explained that hopefully more reliable monitoring information would help to draw more reliable conclusions about the levels of short chain NPEOs in receiving waters. Several RAC members supported the Rapporteurs' approach and highlighted a possibility that industry might also provide some further information through the public consultation.

With regard to the occurrence of NPEO in textiles, the Rapporteurs informed the participants that the dossier presents data from 11 studies that clearly show that NPEO is present in some textile articles, but the representativeness of the data is unknown. The large number of 'non-detects' and the large skew in the data make it difficult to decide what an appropriate 'average' measure of NPEO content is. The Rapporteurs asked the RAC members to consult, if possible, the statisticians in their countries and come up with possible suggestions (also SEAC will be asked to look into this issue).

For NPEO releases from textile washing, the Rapporteurs noted that they consider the assumed quantity of NPEO released from textile laundering on an annual basis highly uncertain. In the dossier, the EU trade statistics (6 million tonnes) and estimated arithmetic mean concentration (107 mg/kg) are used to derive the likely release of NPEO (642 tonnes/year). However, the Rapporteurs flagged that the figure could be substantially less (e.g. 60 tonnes/year, if the overall geometric mean concentration in clothing is assumed to represent textiles in general).

In addition, many other sources of NPEO and NP exist besides textiles (e.g. paints, resins, construction industry, etc.). The dossier suggests that textile laundering may contribute about 50% of the amount of NP in EU surface waters. Given the large number of untested assumptions, the comparison of releases of NP/NPEO from different sources is highly uncertain. The RAC Rapporteurs noted that the assumptions about the relative contribution of textiles to NP/NPEO concentrations in water bodies are important in the context of the risk reduction capacity of the proposal. Given the uncertainties, they therefore believe that further work is needed to establish relative contributions with more confidence before risk reduction

capacity can be reliably assessed. A preliminary estimate can be provided by comparing estimated influent and effluent d concentrations on a per capita release basis with measured concentrations, but the Rapporteurs would prefer more comprehensive monitoring data to be available before drawing any conclusions on this issue. Several RAC members expressed support to the approach proposed by the Rapporteurs.

The Chairman summarised the discussion and encouraged RAC members to provide further comments to the ongoing written commenting round on the 1st version of the RAC draft opinion. The Rapporteurs were asked to take comments into account in the next version of the RAC draft opinion that would be discussed at the next plenary meeting.

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

The Chairman welcomed the dossier submitter representatives (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. The public consultation was launched on 18 September 2013.

The Chairman informed the Committee that ECHA had recently received a letter from the Commission regarding the NMP restriction proposal referring in particular to the potential divergence between Derived No Effect Level (DNEL) and the Indicative Occupational Exposure Level (IOEL). This letter was made available to both RAC and SEAC on 28 November, 2013. The Chairman invited the Commission observers to introduce this letter and their views to the participants.

In the view of the Commission, any proposal for adoption of an exposure limit value at an occupational premise should not be implemented under REACH but under the appropriate workers' protection legislation, which is specifically designed to establish and implement IOELs. As REACH does not contain provisions to stop the discussion on the Annex XV dossier, the proposal should receive a proper assessment by both RAC and SEAC. Based on their final outcome, the Commission will decide whether the issue needs to be transferred to SCOEL for further consideration.

The representative of the Commission (DG Employment) confirmed that this issue was also on the agenda of the 90th meeting of the Scientific Committee on Occupational Exposure Limits (SCOEL), scheduled for 11 and 12 December 2013. RAC agreed to continue work on this restriction proposal in the normal way. Several members also highlighted the importance of communication and collaboration between RAC and SCOEL, to identify potential discrepancies and find ways to deal with them.

The Rapporteurs presented the 1st version of the draft opinion. In the proposal, the dossier submitter has used data from the registration dossiers. The dossier submitter had calculated inhalatory (5 mg/m³) and dermal (2.4 mg/kg bw/day) DNELs, which by comparison with the exposure estimates of the registration dossiers indicated a risk for most scenarios. In the dossier, a NOAEC of 247 mg/m³ was set based on a statistically significant 5% decrease of the foetal body weight at the LOAEC 494 mg/m³. The body weight gain of the dams was decreased by 19% over the whole gestation period at 247 and 494 mg/m³. The RAC Rapporteurs explained that they supported 247 mg/m³ as a NOAEC and as the basis for DNEL, to which the RAC agreed.

The Rapporteurs noted that for intraspecies differences, the dossier submitter used an assessment factor of 5 for workers, in line with the REACH guidance. For pregnant workers, however, the same assessment factor was used as normally used for the general population (i.e., 10), based on the argument that children belong rather to the general population than to the population of workers. Although the guidance does not specifically mention pregnant workers; the Rapporteurs supported this approach. RAC discussed the choice of intraspecies assessment factors for pregnant workers and identified that whereas there is some sympathy for an AF of 10 for pregnant workers it was not supported by all members, nor is this number supported by the REACH guidance. It was concluded that the Rapporteurs should for the time being use both the REACH-supported AF of 5 and the AF of 10 used by the dossier submitter to illustrate the calculations of the RCRs, and RAC members should provide their comments on the issue by the 11th December 2013.

With regard to exposure, the Rapporteurs explained that the dossier submitter had used data from the registration dossiers for the different exposure scenarios and gave a brief description of the input data for the exposure modelling. However, the Rapporteurs questioned how relevant and reliable the modelled data really were. If the modelling could be interpreted as if the registration dossiers describe current working practices as far as possible in the exposure scenarios, then the exposure estimates from the registration dossiers seem to be a proper basis for the restriction proposal. It was recognised that the range of industrial uses of NMP was very diverse. On the other hand, it is possible that the exposure scenarios have not been created based on real workplace information, but rather have been developed using only those RMMs needed to achieve RCRs<1 and without using higher tier models. It was agreed that the Rapporteurs would proceed with information from the registration dossiers, acknowledging at the same time that further information that might affect the exposure assessments might be received in the public consultation.

Following the request of the RAC members, it was agreed to extend the deadline for the written commenting round by one day (until 11 December 2013). The Rapporteurs were asked to take comments into account in the next version of the RAC draft opinion that would be discussed at the next plenary meeting.

d) Cadmium in paints – outcome of conformity check

The Chairman presented a general approach to the Committee for dealing with an amendment to an existing restriction entry as requested by the Commission. He noted that it was expected that other similar 'amendment' dossiers may follow in the future. According to legal advice, non-editorial modifications to an existing Annex XVII entry can only be done via the restriction procedure initiated by an Annex XV report. Therefore, a standard procedure for conformity check was launched on 14 November.

The representative of the dossier submitter (ECHA) then presented the main elements of the proposed restriction to the Committee. The Commission requested ECHA to propose and justify extending the existing restriction to the placing on the market of paints with certain Integrated Community Tariff (TARIC) codes. For enforceability reasons, the dossier should also propose specific limit values of cadmium for such paints.

The ECHA restriction report proposes to modify the restriction such that 'placing on the market' of cadmium in paints, TARIC codes (3208)(3209), would also be restricted if the level of cadmium in those paints exceeds the limit value of 0.01%. Based on ECHA's consultation with the relevant industry representatives it is apparent that concentrations of cadmium in paints in the EU, including copper-based anti-fouling paints, are currently well below the proposed concentration limit of 0.01% and are expected to stay so in the future. The positive limit value allows continuing use of recycled copper and having the same limit value as elsewhere in the entry simplifies both entry and the enforcement efforts.

The RAC Rapporteur then presented the outcome of the RAC conformity check and recommended that the dossier should be considered in conformity. He explained that the amendment of an existing restriction is introduced for enforcement reasons only and there is no need to re-evaluate the risk by RAC. Some members stated that RAC should not spend too much time on these types of dossiers; they could be handled for example via written procedure or other means to process them efficiently.

Following several questions from members, the Chairman confirmed that this case was unique, as all RAC restrictions so far had involved a full risk assessment. However RAC would assume that the risk was assessed properly in the first restriction. Only the wording needed to be amended in the existing entry. The Commission representative noted that the Commission is content with the approach taken by ECHA.

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

The Secretariat was asked to amend the conformity check template to better reflect the requirements for any similar amendments to existing restrictions in the future.

6.3 Appointment of (co-) Rapporteurs for restriction dossiers

The Secretariat presented the recommendation of the Chairman for the pool of Rapporteurs for the restriction dossier on Bis(pentabromphenyl) ether (DecaBDE), as well as for the appointment of (co-) Rapporteurs for chrysotile as outlined in the meeting document RAC/27/2013/05 CONFIDENTIAL. RAC agreed to the appointment of (co-) Rapporteurs for chrysotile as proposed in the recommendation.

The Chairman then informed that despite several calls for bisphenol-A (only one volunteer in the pool) as well as ammonium salts (both dossiers submitted by France) to be submitted in January 2014, it was not possible to appoint the (co-) Rapporteurs for these dossiers. Therefore, RAC members were encouraged to come forward urgently for (co-) Rapporteurs of the restriction dossiers on bisphenol-A and ammonium salts.

7. Authorisation

7.1 Authorisation application

a) Authorisation application on the use of DEHP in a stop-off formulation in manufacturing of aero engines – first version of the draft opinion

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

The Chairman announced that the discussion on the first version of the draft opinion should take place in an observed session. However, should a need arise to discuss any confidential business information, he would close the session as a precaution.

The Rapporteurs then presented the first version of the draft opinion of the application for authorisation for the processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades. Regarding the workplace inhalation exposure assessment, the Rapporteurs explained that for three out of four contributing scenarios quantitative inhalation exposure data had been provided: all air concentration measurements were below the limit of detection. The applicant had used the limit of detection as the highest "measured" airborne concentration of 10 µg/m³. The Rapporteurs further elaborated on the workplace dermal exposure assessment, explaining that for three out of four contributing scenarios, quantitative dermal exposure data had been provided: actual exposure (wiping of the skin after removal of gloves) being monitored, DEHP was found to be below the limit of detection of 1 µg in all samples. Thus "actual" exposure per sample could be considered to be lower than estimated. The Rapporteurs recommended the addition of all dermal exposure incidents over the full shift by considering all repetitions of the relevant task-based activity per shift with up to six dermal exposure incidents per activity.

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 ca. 0.01, which is around 100 times lower than the reference RCR of 1. He also noted that the actual external dermal exposure RCR value is probably lower than calculated. The Rapporteurs explained that the possible risks associated with the other components of about 95% of the stop-off formulation were not considered, since they fell outside the scope of the authorisation procedure; none of the other components are included in Annex XIV of the REACH Regulation.

The Rapporteurs concluded that in order to control the risks at the workplace the RMMs and OCs outlined in the application need to be strictly observed.

The RAC concluded that no specific conditions or monitoring arrangements over and above the RMMs and OCs that have already been included in the application need to be established, noting a well-controlled workplace, very specific and low quantity usage, the availability of quantitative monitoring data for inhalation and dermal exposure measured at the facility, and the fact that very few workers were engaged in these tasks.

After a short discussion on the exposure assessment RAC supported the exposure assessment presented by the co-Rapporteurs and agreed on the exposure values in the Draft Opinion. RAC considered that adequate control had been demonstrated by the Applicant.

Therefore, RAC agreed the draft opinion on the application for authorisation, recommending granting of the application.

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

b) Authorisation applications on Phthalates (submitted within the August submission window) - outcome of the conformity check

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

1) Application for authorisation submitted by *ARKEMA FRANCE* on the following uses of Bis(2-ethylhexyl) phthalate (DEHP): Use 1: Formulation of DEHP in compounds, dry-blends and Plastisol formulations, Use 2: Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles [except erasers, sex toys, household items <10cm, clothing intended to be worn against bare skin; toys, cosmetics, Food Contact materials (FCM)];
2) Application for authorisation submitted by *Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna* on the following uses of DEHP: Use 1: Formulation of DEHP in compounds, dry-blends and Plastisol formulations, Use 2: Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles except erasers, sex toys, household items <10cm, clothing intended to be worn against bare skin; toys, cosmetics, FCM;
3) Application for authorisation submitted by *DEZA a.s.* on the following uses of DEHP: Use 1: Formulation of DEHP in compounds, dry-blends and Plastisol formulations, Use 2: Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles [except erasers, sex toys, household items <10cm, clothing intended to be worn against bare skin; toys, cosmetics, FCM], Use 3: Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements;
4) Application for authorisation submitted by *Sasol-Huntsman GmbH & Co. KG* on the following use of dibutyl phthalate (DBP): Use as an absorption solvent in a closed system in the manufacture of Maleic Anhydride;
5) Application for authorisation submitted by *DEZA a.s.* on the following uses of DBP: Use 1: Use as an absorption solvent in a closed system in the manufacture of Maleic Anhydride, Use 2: Use in propellants, Use 3: Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements;
6) Application for authorisation submitted by *Roxel (UK Rocket Motors) Ltd* on the following uses of DEHP and DBP: Use 1: Industrial use in manufacture of solid propellants and motor charges for rockets and tactical missiles (DEHP), Use 2: Industrial use in manufacture of solid propellants and motor charges for rockets and tactical missiles (DBP), Use 3: Industrial use within a specialty paint in manufacture of motors for rockets and tactical missiles (DBP);
7) Application for authorisation submitted by *VINYLOOP FERRARA S.p.A.*, *Stena Recycling AB* and *Plastic Planet srl* on the following uses of DEHP: Use 1: Formulation of recycled soft PVC containing DEHP in compounds and dry blends, Use 2: Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles;

The RAC agreed with the Rapporteurs that all seven 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.

7.2 Capacity building

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

The ECHA Secretariat presented the outcome of the project and two draft notes concerning the publication of dose response relationships for Cr(VI)- and inorganic As-containing substances.

The RAC members pointed out that the dose response relationships were derived by linear extrapolation. Extrapolating outside the range of observation inevitably introduces uncertainties. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that the excess risks in the low exposure range might be an overestimate.

Moreover, the members recommended adding information to the notes 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 agreed on the notes and the Secretariat will upload them on the ECHA website.

b) Trichloroethylene

The invited expert presented the ECHA project: *Services to support remaining cancer risks, or adequate control, related to the use of trichloroethylene in Applications for Authorisation*. The project contains two work packages:

- Review the relevant scientific literature related to carcinogenicity of trichloroethylene and seek information related to cancer mechanisms and exposure
- Prepare relevant dose-response curves or threshold-type risk estimates for trichloroethylene

The presentation of a final report and the end of the project is foreseen in April 2014.

7.3 Appointment of (co-) Rapporteurs for authorisation applications

During the plenary meeting the Committee members expressed their interest by applying to the pool of Rapporteurs and by indicating the absence of conflict of interest. The pool of Rapporteurs as outlined in the amended confidential room document RAC/27/2013/08 Rev.1 will be agreed in the written procedure after the plenary meeting.

Other issues

As a general comment, a Member suggested to check and decide on the conformity of the applications for authorisation via a written procedure, instead of discussing them at a plenary meeting. The Secretariat will consider this suggestion for future applications for authorisation, bearing in mind that it may be useful to present a brief overview of the application for the members to familiarise themselves with the case.

With regard to the public consultations on the applications for authorisation, one stakeholder observer asked ECHA to publish the complete chemical safety report and keep only the business-threatening information as confidential.

8. AOB

8.1 Update on Guidance activities

An update on Guidance activities was made available to the members.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 27, 2-5 December 2013

(Adopted at the meeting)

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/27/2013**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-27 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 at RAC 28
4. Report from other ECHA bodies and activities	
4.a. Report on other ECHA bodies **SECR** presented document **RAC/27/2013/01**	**SECR** to upload the document to the CIRCABC non-confidential website.
4.b. RAC work plan for all processes SECR presented update on the 2013-2014 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-27 meeting on CIRCABC.
5. Harmonised classification and labelling (CLH)	
5.1. a) Sulfoxaflor	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4 (H302); Acute Aquatic 1 and Chronic 1; M=1 both; EUH401 (see Art. 25(2) CLP)]	**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.
5.1. b) Phenol, dodecyl-, branched (TPP)	
RAC adopted <u>by consensus</u> the two opinions with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Corr. 1C; Repr. 1B (H360F); Aquatic Acute 1 and Chronic 1; M=10 both]	**Rapporteurs** to revise the opinions in accordance with the discussions in RAC and to provide them to the SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinions and their annexes to COM and publish it on the ECHA website.
5.1. c) Lead	
RAC adopted <u>by consensus</u> the opinion with a proposal for one sole entry in Annex VI pertaining to all forms of lead, and the harmonised classification and labelling and specific concentration limits as indicated in Table 1 below.	**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

[Repr. 1A, SCL_{dev}=0.03%; Lact.]	the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and to publish it on the ECHA website.
5.1. d) Anti-coagulant rodenticides	
	SECR to launch written procedure for the agreement on environmental hazard classes of 8 anticoagulant rodenticides.
▪ **brodifacoum (ISO)**	
RAC agreed on the classification and labelling for developmental toxicity of brodifacoum (ISO) as indicated in bold in Table 2 below. [classification agreed at RAC 27: Repr. 1A; H360D)]	**Rapporteur** to revise the opinion on brodifacoum (ISO) in accordance with the discussion in RAC and to add the other hazard classes (Acute Tox. and Skin Sens.) and SCLs for discussion at the next RAC meeting. **SECR** to launch RAC consultation on the revised draft opinion.
▪ **flocoumafen (ISO)**	
RAC agreed on the classification and labelling for acute toxicity and on extension of STOT RE 1 to other routes of exposure on flocoumafen (ISO) as indicated in bold in Table 2 below. [classification agreed at RAC 27: Acute Tox 1; H300, Acute Tox. 1; H310, Acute Tox. 1; H330]	**Rapporteur** to revise the opinion on flocoumafen (ISO) in accordance with the discussion in RAC and forward it to SECR for discussion at the next RAC meeting. **SECR** to launch RAC consultation on the revised draft opinion.
5.1. e) Triflusulfuron methyl	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351 Aquatic Acute 1; H400, M=100 Aquatic Chronic 1; H410, M=10]	**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.
5.1. f) Bifenazate	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [STOT RE 2; H373 Skin Sens. 1; H317 (without subcategory) Aquatic Acute 1; H400, M=1 Aquatic Chronic 1; H410, M=1]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to the SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1. g) Fenpyroximate	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 3; H301 Acute Tox. 2; H330 Skin Sens. 1B ; H317	**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

Aquatic Acute 1; H400, M=100 Aquatic Chronic 1; H410, M=1000]	the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1. h) Lenacil	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351 Aquatic Acute 1; H400, M=10 Aquatic Chronic 1; H410, M=10]	**Rapporteur** 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 Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1. i) Tributyltin compounds	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox.3; H301, Repr. 1B; H360FD]	**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.
5.2 Appointment of RAC (co-)rapporteurs for CLH dossiers	
Call for expression of interest of (co-)rapporteurship for CLH dossiers listed in document **RAC/27/2013/02 (CONFIDENTIAL room document)**	**SECR** to upload the list of appointed (co-)rapporteurs to CIRCABC confidential.
6. Restrictions	
6.1 General Restriction Issues	
6.1.b) Revision of the restriction process	
RAC agreed on the revised working procedure on conformity check of Annex XV restriction dossiers with one additional modification (12 days for initial commenting round).	**SECR** to upload the revised procedure to CIRCABC and to apply it starting from restriction dossiers submitted within the January 2014 submission window. **SECR** to revise the opinion development procedure and table it for agreement at RAC-28.
6.2 Restriction Annex XV dossiers	
6.2.a) Lead in consumer articles – 4th version of the RAC draft opinion	
RAC Rapporteurs presented the modified fourth version of the RAC opinion. RAC discussed the main changes made to the draft opinion of RAC. RAC adopted the opinion on the proposed restriction by simple majority. Dissenting views will be reflected in the RAC27 minutes.	**Rapporteurs** to make final editorial changes to the justification of the opinion based on the discussions held at RAC-27. **Rapporteurs** to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to launch an urgent written procedure for the adoption of the justification. **SECR** to forward the adopted opinion and

	its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and CIRCABC IG.
6.2.b) Nonylphenol - 1st version of the draft opinion	
RAC Rapporteurs presented the 1st version of the RAC draft opinion.	**Rapporteurs** to take comments into account in the 2nd version of the draft opinion (due by mid-February 2014). **Rapporteurs** in cooperation with the SECR to submit a response to comments for distribution to RAC members.
6.2.c) 1-Methylpyrrolidin-2-one (NMP) - 1st version of the draft opinion	
RAC Rapporteurs presented the 1st version of the RAC draft opinion.	**Rapporteurs** to take comments into account in the 2nd version of the draft opinion (due by mid-February 2014). **Rapporteurs** in cooperation with the SECR to submit a response to comments for distribution to RAC members.
6.2.d) Cadmium in 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 CIRCABC. **SECR** to inform the dossier submitter on the outcome of the conformity check. **SECR** to consider amending the conformity check template for future purposes to be used for similar dossiers.
7. Authorisation	
7.1 Authorisation applications	
7.1.a) Authorisation application on the use of DEHP in a stop-off formulation in manufacturing of aero engines – first version of the draft opinion	
RAC supported the exposure assessment presented by the co-rapporteurs and agreed on the exposure values in the Draft Opinion. RAC supported that DEHP is a threshold substance, and adequate control has been demonstrated by the Applicant. RAC agreed to recommend granting the authorisation in accordance with the application has been made to the Commission.	**SECR** to send the Applicant the Draft Opinion 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.
7.1.b) Authorisation applications on Phthalates (submitted within the August submission window) - outcome of the conformity check	
Rapporteurs presented seven applications for authorisation (DEHP and DBP) and the draft conformity reports. RAC agreed on the conformity of all seven applications for authorisation.	**SECR** to upload the adopted Conformity Report for the first application for authorisation on CIRCA BC. **SECR** to send the updated Conformity Report to the Applicant.
7.2 Capacity building	
7.2.a) ECHA project on carcinogenicity dose-response analysis of Cr (VI)-and As-containing substances	**SECR** to upload the document on ECHA website.
7.2.b) ECHA project on carcinogenicity dose response analysis of Trichloroethylene	
9. Action points and main conclusions of RAC-27	
	SECR to upload the adopted action points to CIRCABC.

Table 1. Adopted by RAC 27 - proposed new or revised classification in Annex VI, CLP[1]

Sulfoxaflor

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	616-217-00-4	sulfoxaflor (ISO); [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ6-sulfanylidene]cyanamide	-	946578-00-3	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410		M=1 M=1	
RAC opinion			-	946578-00-3	**Acute Tox. 4** **Aquatic Acute 1** **Aquatic Chronic 1**	**H302** **H400** **H410**	**GHS07** **GHS09** **Wng**	**H302** **H410**		**M=1** **M=1**	
Resulting Annex VI entry if agreed by COM			-	946578-00-3	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410		M=1 M=1	

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

Classification and labelling in accordance with the criteria of Directive 67/548/EEC (DSD)

	Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Classification**	**Labelling**	**Concentration Limits**	**Notes**
Current Annex VI entry	**No current Annex VI entry**							
Dossier submitters proposal	616-217-00-4	sulfoxaflor (ISO); [methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ6-sulfanylidene]cyanamide	-	946578-00-3	Xn; R22 N; R50-53	Xn; N R: 22-50/53 S: (1/2-)46-60-61	N; R50/53: C ≥ 25 % N; R51/53: 2,5 % ≤ C < 25 % R52/53: 0,25 % ≤ C < 2,5 %	
RAC opinion			-	946578-00-3	**Xn; R22** **N; R50-53**	**Xn; N** **R: 22-50/53** **S: (2-)60-61**	**N; R50-53: C ≥ 25 %** **N; R51-53: 2,5 % ≤ C < 25 %** **R52-53: 0,25 % ≤ C < 2,5 %**	
Resulting Annex VI entry if agreed by COM			-	946578-00-3	Xn; R22 N; R50-53	Xn; N R: 22-50/53 S: (2-)60-61	N; R50-53: C ≥ 25 % N; R51-53: 2,5 % ≤ C < 25 % R52-53: 0,25 % ≤ C < 2,5 %	

Lead

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	082-013-00-1	lead	231-100-4	7439-92-1	Repr. 1A	H360FD	GHS08 Dgr	H360FD		Repr. 1A; H360FD: C ≥ 0,03 %	
RAC opinion					**Repr. 1A Lact.**	**H360FD H362**	**GHS08 Dgr**	**H360FD H362**		**Repr. 1A; H360D: C ≥ 0,03 %**	
Resulting Annex VI entry if agreed by COM					Repr. 1A Lact.	H360FD H362	GHS08 Dgr	H360FD H362		Repr. 1A; H360D: C ≥ 0,03 %	

Classification and labelling in accordance with the criteria of Directive 67/548/EEC (DSD)

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	**No current Annex VI entry**							
Dossier submitters proposal	082-013-00-1	lead	231-100-4	7439-92-1	Repr. Cat. 1; R60-61	T R: 60-61 S: (1/2-)13-35-45-53	Repr. Cat. 1; R60-61: C ≥ 0,03 %	
RAC opinion					**Repr. Cat. 1; R60-61** **R64**	**T** **R: 60-61-64** **S:45-53**	**Repr. Cat. 1; R61: C ≥ 0,03 %**	
Resulting Annex VI entry if agreed by COM					Repr. Cat. 1; R60-61 R64	T R: 60-61-64 S: 45-53	Repr. Cat. 1; R61: C ≥ 0,03 %	

Phenol, dodecyl-, branched

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 proposals (denoted as (1) and (2))	604-092-00-9	Phenol, dodecyl-, branched [1]; Phenol, 2-dodecyl-, branched; Phenol, 3-dodecyl-, branched; Phenol, 4-dodecyl-, branched; Phenol, (tetrapropenyl) derivatives [2]	310-154-3 [1]	121158-58-5 [1] 74499-35-7 [2]	Repr. 2 (1) Repr. 1B (2) Skin Irrit. 2 (1) Eye Irrit. 2 (1) Aquatic Acute 1 (1) Aquatic Chronic 1 (1)	H361f (1) H360F (2) H315 (1) H319 (1) H400 (1) H410 (1)	GHS08 (1),(2) GHS07 (1) GHS09 (1) Wng (1) Dgr (2)	H361f (1) H360F (2) H315 (1) H319 (1) H410 (1)		Repr. 1B; H360F: C ≥ 1,5 % (2) M=1 (1) M=10 (1)	
RAC opinion					**Repr. 1B Skin Corr. 1C Aquatic Acute 1 Aquatic Chronic 1**	**H360F H314 H400 H410**	**GHS05 GHS08 GHS09 Dgr**	**H360F H314 H410**		**M=10 M=10**	
Resulting Annex VI entry if agreed by COM					Repr. 1B Skin Corr. 1C Aquatic Acute 1 Aquatic Chronic 1	H360F H314 H400 H410	GHS05 GHS08 GHS09 Dgr	H360F H314 H410		M=10 M=10	

Classification and labelling in accordance with the criteria of Directive 67/548/EEC (DSD)

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	**No current Annex VI entry**							
Dossier submitters proposal	604-092-00-9	Phenol, dodecyl-, branched [1]; Phenol, 2-dodecyl-, branched; Phenol, 3-dodecyl-, branched; Phenol, 4-dodecyl-, branched; Phenol, (tetrapropenyl) derivatives [2]	310-154-3 [1]	121158-58-5 [1] 74499-35-7 [2]	Repr. Cat. 3 (1) Repr. Cat. 2 (2) Xi; R36-38 (1) N; R50-53 (1)	C, Xn, N (1) T (2) R: 36/38-62(1)-50/53 (1) R: 60 (2) S: 26-36/37/39-60-61	N; R50-53: C ≥ 25 % N; R51-53: 2,5 % ≤ C < 25% R52-53: 0,25 % ≤ C < 2,5 % (1) Repr. Cat. 2; R60: C < 1,5 % (2)	
RAC opinion					**Repr. Cat. 2; R60** **C; R34** **N; 50-53**	**C, T, N** **R: 34-50/53-60** **S: 26-36/37/39-45-53-60-61**	N; R50-53: C ≥ 2,5 % N; R51-53: 0,25 % ≤ C < 2,5 % R52-53: 0,025 % ≤ C < 0,25 %	
Resulting Annex VI entry if agreed by COM					Repr. Cat. 2; R60 C; R34 N; 50-53	C, T, N R: 34-50/53-60 S: 26-36/37/39-45-53-60-61	N; R50-53: C ≥ 2,5 % N; R51-53: 0,25 % ≤ C < 2,5 % R52-53: 0,025 % ≤ C < 0,25 %	

Flocoumafen

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	5 reaction mass of: *cis*-4-hydroxy- 3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin; 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					**Add:** Repr. 2 **Modify:** Acute Tox. 1 Acute Tox. 1	**Add:** H361d **Modify**: H330 H300 **Remove:** **for		**Add:** H361d **Remove:** **for H372		**Add**: STOT RE 1; H372: C ≥ 0,05 % STOT RE 2; H373: 0,005 % ≤ C < 0,05 %	

						H372				Repr. 2;H361d: C≥0.003% M=10 M=10	
RAC opinion					**Add:** Repr. 2 **Modify:** **Acute Tox. 1** **Acute Tox. 1**	**Add:** H361d **Modify:** **H330** **H300** **Remove:** ****for H372**		**Add:** H361d **Remove:** ****for H372**		STOT RE 1; H372: C ≥ 0,05 % STOT RE 2; H373: 0,005 % ≤ C < 0,05 % Repr. 2; H361d: C ≥ 0,003 % M=10 M=10	
Resulting Annex VI entry if agreed by COM					Repr. 2 Acute Tox. 1 Acute Tox. 1 Acute Tox 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H361d H330 H310 H300 H372 H400 H410	GHS06 GHS08 GHS09 Dgr	H361d H330 H310 H300 H372 H410		STOT RE 1; H372: C ≥ 0,05 % STOT RE 2; H373: 0,005 % ≤ C < 0,05 % Repr. 2; H361d: C ≥ 0,003 % M=10 M=10	

Classification and labelling in accordance with the criteria of Directive 67/548/EEC (DSD)

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry								
Dossier submitters proposal								
RAC opinion								
Resulting Annex VI entry if agreed by COM								

Brodifacoum

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	4-hydroxy-3-(3-(4'-bromo-4-biphenylyl)-1,2,3,4-tetrahydro-1-naphthyl)coumarin; Brodifacoum (ISO)	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					**Add**: Repr. 1B[2] **Modify** : Acute Tox. 1 **Add**: Acute Tox. 1 **Add** : Skin Sens 1	H360D H300 H330 H317 **Remove:** **for H372		H360D H300 H330 H317 **Remove:** **for H372		**Add:** STOT RE 1; H372: C ≥ 0,25 % STOT RE 2; H373: 0,025 % ≤ C < 0,25 % M=10 M=10	

[2] After the public consultation of the proposal, the dossier submitter revised their proposal to Repr. 1A; H360D.

RAC opinion					**Add: Repr. 1A** **Modify** : Acute Tox. 1 **Add**: Acute Tox. 1 **Add** : Skin Sens 1	**H360D** H300 H330 H317 **Remove:** **for H372		**H360D** H300 H330 H317 **Remove:** **for H372		**Add:** STOT RE 1; H372: C ≥ 0,25 % STOT RE 2; H373: 0,025 % ≤ C < 0,25 % 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 Skin Sens 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H310 H300 H330 H372 H317 H400 H410	GHS06 GHS08 GHS09 Dgr	H360D H310 H300 H330 H372 H317 H410		STOT RE 1; H372: C ≥ 0,25 % STOT RE 2; H373: 0,025 % ≤ C < 0,25 % M=10 M=10	

Classification and labelling in accordance with the criteria of Directive 67/548/EEC (DSD)

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry								
Dossier submitters proposal								
RAC opinion								
Resulting Annex VI entry if agreed by COM								

Triflusulfuron methyl

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	607-714-00-7	triflusulfuron-methyl; methyl 2-({[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]carbamoyl}sulfamoyl)-3-methylbenzoate	N/A	126535-15-7	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		M=100 M=10	-
RAC opinion					**Carc. 2** **Aquatic Acute 1** **Aquatic Chronic 1**	**H351** **H400** **H410**	**GHS08** **GHS09** **Wng**	**H351** **H410**		**M=100** **M=10**	-
Resulting Annex VI entry if agreed by COM					Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		M=100 M=10	-

Classification and labelling in accordance with the criteria of Directive 67/548/EEC (DSD)

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	**No current Annex VI entry**							
Dossier submitters proposal	607-714-00-7	triflusulfuron-methyl; methyl 2-({[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]carbamoyl}sulfamoyl)-3-methylbenzoate	N/A	126535-15-7	Carc. Cat. 3; R40 N; R50-53	Xn; N R: 40-50/53 S: 36/37-60-61	N; R50-53: C ≥ 0,25 % N; R51-53: 0,025 % ≤ C < 0,25 % R52-53: 0,0025 % ≤ C < 0,025 %	-
RAC opinion					**Carc. Cat. 3; R40** **N; R50-53**	**Xn; N** **R: 40-50/53** **S: (2-)36/37-60-61**	**N; R50-53: C ≥ 0,25 %** **N; R51-53: 0,025 % ≤ C < 0,25 %** **R52-53: 0,0025 % ≤ C < 0,025 %**	-
Resulting Annex VI entry if agreed by COM					Carc. Cat. 3; R40 N; R50-53	Xn; N R: 40-50/53 S: (2-)36/37-60-61	N; R50-53: C ≥ 0,25 % N; R51-53: 0,025 % ≤ C < 0,25 % R52-53: 0,0025 % ≤ C < 0,025 %	-

Bifenazate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	607-715-00-2	bifenazate (ISO); Isopropyl 2-(4-methoxybiphenyl-3-yl)hydrazinecarboxylate	442-820-5	149877-41-8	STOT RE 2 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H373 H317 H400 H410	GHS07 GHS08 GHS09 Wng	H373 H317 H410		M=1 M=1	
RAC opinion					**STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1**	**H373 H317 H400 H410**	**GHS07 GHS08 GHS09 Wng**	**H373 H317 H410**		**M=1 M=1**	
Resulting Annex VI entry if agreed by COM					STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H373 H317 H400 H410	GHS07 GHS08 GHS09 Wng	H373 H317 H410		M=1 M=1	

Classification and labelling in accordance with the criteria of Directive 67/548/EEC (DSD)

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	**No current Annex VI entry**							
Dossier submitters proposal	607-715-00-2	bifenazate (ISO); Isopropyl 2-(4-methoxybiphenyl-3-yl)hydrazinecarboxylate	442-820-5	149877-41-8	R43 N; R50/53	Xi; N R: 43-50/53 S: 24-37-60-61	N; R50/53: C ≥ 25 % N; R51/53: 2,5 % ≤ C < 25 % N; R52/53: 0,25 % ≤ C < 2,5 %	
RAC opinion					**R43** **N; R50-53**	**Xi; N** **R: 43-50/53** **S: (2-)24-37-60-61**	**N; R50-53: C ≥ 25 %** **N; R51-53: 2,5 % ≤ C < 25 %** **N; R52-53: 0,25 % ≤ C < 2,5 %**	
Resulting Annex VI entry if agreed by COM					R43 N; R50-53	Xi; N R: 43-50/53 S: (2-)24-37-60-61	N; R50/53: C ≥ 25 % N; R51/53: 2,5 % ≤ C < 25 % N; R52/53: 0,25 % ≤ C < 2,5 %	

Fenpyroximate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	607-713-00-1	fenpyroximate (ISO); tert-butyl 4-[({(E)-[(1,3-dimethyl-5-phenoxy-1*H*-pyrazol-4-yl)methylene]amino}oxy)methyl]benzoate	-	134098-61-6	Acute Tox. 3 Acute Tox. 2 Eye Irrit. 2 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H301 H330 H319 H317 H400 H410	GHS06 GHS07 GHS09 Dgr	H301 H330 H319 H317 H410		M=100 M=1000	
RAC opinion					**Acute Tox. 3** **Acute Tox. 2** **Skin Sens. 1B** **Aquatic Acute 1** **Aquatic Chronic 1**	**H301** **H330** **H317** **H400** **H410**	**GHS06** **GHS09** **Dgr**	**H301** **H330** **H317** **H410**		**M=100** **M=1000**	
Resulting Annex VI entry if agreed by COM					Acute Tox. 3 Acute Tox. 2 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H301 H330 H317 H400 H410	GHS06 GHS09 Dgr	H301 H330 H317 H410		M=100 M=1000	

Classification and labelling in accordance with the criteria of Directive 67/548/EEC (DSD)

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	**No current Annex VI entry**							
Dossier submitters proposal	607-713-00-1	fenpyroximate (ISO); tert-butyl 4-[({(E)-[(1,3-dimethyl-5-phenoxy-1H-pyrazol-4-yl)methylene]amino}oxy)methyl]benzoate	-	134098-61-6	Xn; R22 T+; R26 R43 N; R50-53	T+; N R: 22-26-43-50/53		
RAC opinion					**T+; R26 Xn; R22 R43 N; R50-53**	**T+; N R: 22-26-43-50/53 S: (1/2-)28-36/37-45-60-61-63**		
Resulting Annex VI entry if agreed by COM					T+; R26 Xn; R22 R43 N; R50-53	T+; N R: 22-26-43-50/53 S: (1/2-)28-36/37-45-60-61-63		

Tributyltin compounds

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	050-008-00-3	tributyltin compounds, with the exception of those specified elsewhere in this annex	-	-	Acute Tox. 3 * Acute Tox. 4 * STOT RE 1 ** Skin Irrit. 2 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H301 H312 H372 H315 H319 H400 H410	GHS06 GHS08 GHS09 Dgr	H301 H312 H372** H315 H319 H410	-	* STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,25 % ≤ C < 1 % Skin Irrit. 2; C ≥ 1 % Eye Irrit. 2; C ≥ 1 % M=10	 A 1
Dossier submitters proposal		tributyltin compounds, with the exception of those specified elsewhere in this annex	-	-	**Add** Repr. 1B **Modify** Acute Tox. 3 Acute Tox. 3	**Add** H360Fd **Modify** H301 H311	GHS06 GHS08 GHS09 Dgr	**Add** H360Fd **Modify** H301 H311			
RAC opinion			-	-	**Add** **Repr. 1B** **Modify** **Acute Tox. 3** **Retain** **Acute Tox. 4 ***	**Add** **H360FD** **Modify** **H301** **Retain** **H312**	**GHS06** **GHS08** **GHS09** **Dgr**	**Add** **H360FD** **Modify** **H301** **Retain** **H312**			
Resulting Annex VI entry if agreed by COM			-	-	Repr. 1B Acute Tox. 3 Acute Tox. 4* STOT RE 1 Skin Irrit. 2 Eye Irrit. 2	H360FD H301 H312 H372** H315 H319	GHS06 GHS08 GHS09 Dgr	H360FD H301 H312 H372** H315 H319	-	* STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,25 % ≤ C < 1 % Skin Irrit. 2; C ≥ 1 %	A 1

					Aquatic Acute 1 Aquatic Chronic 1	H400 H410		H410		Eye Irrit. 2; C ≥ 1 % M=10	

Classification and labelling in accordance with the criteria of Directive 67/548/EEC (DSD)

	Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Classification**	**Labelling**	**Concentration Limits**	**Notes**
Current Annex VI entry	050-008-00-3	tributyltin compounds, with the exception of those specified elsewhere in this annex	-	-	T; R25-48/23/25 Xn; R21 Xi; R36/38 N; R50-53	T; N R: 21-25-36/38-48/23/25-50/53 S: (1/2-)36/37/39-45-60-61	T; R25: C ≥ 2,5 % Xn; R22: 0,25 % ≤ C < 2,5 % Xn: R21: C ≥ 1 % T; R48/23/25: C ≥ 1 % Xn; R48/20/22: 0,25 % ≤ C < 1 % Xi; R36/38: C ≥ 1 % N; R50-53: C ≥ 2,5 % N; R51-53: 0,25 % ≤ C < 2,5 % R52-53: 0,025 % ≤ C < 0,25 %	A 1
Dossier submitters proposal			-	-	**Add** Repr. Cat. 22; R60 Repr. Cat. 3; R63	**Add** R: 60-63	T; R25: C ≥ 2,5 % Xn; R22: 0,25 % ≤ C < 2,5 % Xn: R21: C ≥ 1 % T; R48/23/25: C ≥ 1 % Xn; R48/20/22: 0,25 % ≤ C < 1 % Xi; R36/38: C ≥ 1 % N; R50-53: C ≥ 2,5 % N; R51-53: 0,25 % ≤ C < 2,5 % R52-53: 0,025 % ≤ C < 0,25 %	
RAC opinion			-	-	Add Repr. Cat. 2; R60 Repr. Cat. 3; R63	Add R: 60-63		
Resulting Annex VI entry if agreed by COM			-	-	Repr. Cat. 2; R60 Repr. Cat. 3; R63 T; R25-48/23/25 Xn; R21 Xi; R36/38 N; R50-53	T; N R: 21-25-36/38-48/23/25-50/53-60-63 S: 36/37/39-45-53-60-61	T; R25: C ≥ 2,5 % Xn; R22: 0,25 % ≤ C < 2,5 % Xn: R21: C ≥ 1 % T; R48/23/25: C ≥ 1 % Xn; R48/20/22: 0,25 % ≤ C < 1 % Xi; R36/38: C ≥ 1 % N; R50-53: C ≥ 2,5 % N; R51-53: 0,25 % ≤ C < 2,5 %	A 1

							R52-53: 0,025 % ≤ C < 0,25 %	

Lenacil

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	613-320-00-6	lenacil (ISO); 3-cyclohexy-6,7-dihydro-1H-cyclopenta[d]pyrimidine-2,4(3H,5H)-dione	218-499-0	2164-08-1	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=10 M=10	
RAC opinion			218-499-0	2164-08-1	**Carc. 2** **Aquatic Acute 1** **Aquatic Chronic 1**	**H351** **H400** **H410**	**GHS08** **GHS09** **Wng**	**H351** **H410**		**M=10** **M=10**	
Resulting Annex VI entry if agreed by COM			218-499-0	2164-08-1	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		M=10 M=10	

Classification and labelling in accordance with the criteria of Directive 67/548/EEC (DSD)

	Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
Current Annex VI entry	**No current Annex VI entry**							
Dossier submitters proposal	613-320-00-6	lenacil (ISO); 3-cyclohexy-6,7-dihydro-1H-cyclopenta[d]pyrimidine-2,4(3H,5H)-dione	218-499-0	2164-08-1	N; R50-53	N R: 50/53 S: 35-57	N; R50-53: C ≥ 2,5% N; R51-53: 0,25% ≤ C <2,5% R52-53: 0,025% ≤ C < 0,25%	
RAC opinion			218-499-0	2164-08-1	**Carc. Cat. 3; R40** **N; R50-53**	**Xn; N** **R: 40-50/53** **S: (2-)36/37-60-61**	**N; R50-53: C ≥ 2,5 %** **N; R51-53: 0,25 % ≤ C <2,5 %** **R52-53: 0,025 % ≤ C < 0,25 %**	
Resulting Annex VI entry if agreed by COM			218-499-0	2164-08-1	Carc. Cat. 3; R40 N; R50-53	Xn; N R: 40-50/53 S: (2-)36/37-60-61		

Part III. List of Attendees of the RAC-27 meeting

02-05 December 2013

RAC members	ECHA staff
BARANSKI Bogusław	ATLASON Palmi
BARRON Thomasina	BERGES Markus
BIRO Anna	BLAINEY Mark
BJORGE Christine	BOWMER Tim, Chairman
BRANISTEANU Radu	BROECKAERT Fabrice
CARVALHO João	DE BRUIJN Jack
Di PROSPERO FANGHELLA Paola	DVORAKOVA Dana
DUNAUSKIENĖ Lina	ERICSSON Gunilla
DUNGEY Stephen	FUHRMANN Anna
GREIM Helmut (2-3.12)	HELLSTEN Kati
GRUIZ Katalin	HONKANEN Jani
HAKKERT Betty	JOVER BUSTILLO Vanessa
ILIE Mihaela	KANELLOPOULOU Athanasia
JENSEN Frank	KARJALAINEN Ari
KADIĶIS Normunds	KLAUK Anja
KAPELARI Sonja	KOKKOLA Leila
KORATI Safia	KOSK-BIENKO Joanna
LEINONEN Riitta	LOGTMEIJER Christiaan
LUND Bert-Ove	LUDBORŽS Arnis
MULLOOLY Yvonne	LUSCHUTZKY Evita
PARIS Pietro	MAGGIORE Angelo
PASQUIER Elodie	MARQUEZ-CAMACHO Mercedes
PINA Benjamin	MOSSINK Jos
PRONK Marja	NYGREN Jonas
RUCKI Marian	ORISPÄÄ Katja
RUPPRICH Norbert	PELTOLA Jukka
SCHLÜTER Urs (3-5.12.)	RIVERO Debora
SCHULTE Agnes	RODRÍGUEZ IGLESIAS Pilar
SMITH Andrew	ROGGEMAN Maarten
SOERENSEN Peter	SADAM Diana
STASKO Jolanta	SOSNOWSKI Piotr
STOLZENBERG Hans-Christian	SPJUTH Linda
TADEO José Luis	STOYANOVA Evgenia

TSITSIMPIKOU Christina		THUVANDER Ann
Van der HAGEN Marianne		VAINIO Matti
VARNAI Veda Marija		VAN HAELST Anniek
VIVIER Stéphanie		**Industry experts**
Invited expert		BINKS Steve, Eurometaux, ILA (Lead CLH and restriction)
LARSEN Poul Bo (4.12.)		BILLINGTON Richard ECPA, DAS (sulfoxaflor)
SOGORB Miguel Angel		CROUDACE Charlotte, ECPA, Chemtura (bifenazate)
Dossier submitters		FRAME Steven, ECPA, DuPont (triflusulfuron methyl, lenacil)
MÜLLER Severin, SI Group (TPP)		WARREN Simon, ECPA, Exponent (AVKs)
ROBERTS Linda Chevron (TPP)		
Advisers to the RAC members		**Remote participants**
ESPOSITO Dania adviser to Pietro Paris		ARMSTRONG Keith, IE dossier submitter (warfarin)
HERINGA Minne adviser to Betty Hakkert (remote)		BEEKMAN Martijn, NL dossier submitter (NMP)
MURRAY Brendan adviser to Thomasina Barron		BRIGNON Jean-Marc, SEAC member (AfA)
PAPPONEN Hinni adviser to Riitta Leinonen		DANTINNE Catheline , SEAC member (AfA9
PECZKOWSKA Beata adviser to Boguslaw Baranski, CLHadviser for TPP		FOCK Lars, SEAC member (NMP)
PRUTNER Wiebke adviser to Norbert Rupprich, CLH adviser for bifenazate		IVARSSON Jenny, SE dossier submitter (NP/NPE)
EU Commission observers		KIISKI Johanna, SEAC member (lead restriction)
BINTEIN Sylvain, DG ENV		LESTANDER Dag, SE dossier submitter (NP/NPE)
LEFEBRE Remi, DG ENV		LUTTIKHUIZEN Cees, SEAC member (AfA)
MORRIS Alick DG EMPL, SCOEL		MULLER Andre, NL dossier submitter (AVKs)
ROZWADOWSKI Jacek, DG ENTR		STARK Christiane, DE dossier submitter (fenpyroximate, tributyltin compounds), adviser to Hans-Christian Stolzenberg
SCAZZOLA Roberto, DG ENTR		TER BURG Wouter, NL dossier submitter (NMP)
Stakeholders observers		VASS Anne Marie, SE dossier submitter (lead Restriction)
ANNYS Erwin, CEFIC		**Excuses**
BARRY Frank, ETUC		LOSERT Annemarie, RAC member ~~(~~
MERCKEL Dan, OECD		POLAKOVICOVA Helena RAC member
MUNARI Tomaso, EuCheMS		SPETSERIS Nikolaos, RAC member
ROMANO Dolores, EEB		TAYLOR Katy (ECEAE)
ROWE Rocky, ECPA		

VEROUGSTRAETE Violaine, Eurometaux	

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-27 meeting

ANNEX II List of documents submitted to the members of the Committee for Risk Assessment for the RAC-27 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-27 meeting

2 December 2013
RAC/A/27/2013

Final Agenda
27th meeting of the Committee for Risk Assessment

2-5 December 2013
ECHA Conference Centre, Annankatu 18, Helsinki
2 December: starts at 9:00
5 December: ends at 14:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/27/2013
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Report from other ECHA bodies and activities

a) Report on RAC 26 action points, written procedures and other ECHA bodies

RAC/27/2013/01
For information

b) RAC workplan for all processes

For information

Item 5 – Harmonised classification and labelling (CLH)

5.1 CLH dossiers

a) Sulfoxaflor
b) Phenol, dodecyl-, branched (TPP)
c) Lead
d) Anti-coagulant rodenticides
    a. Flocoumafen
    b. Warfarin

c. Brodifacoum

e) Triflusulfuron methyl

f) Bifenazate

g) Fenpyroximate

h) Lenacil

i) Tributyltin compounds

For discussion/adoption

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

RAC/27/2013/02 (confidential room document)

For agreement

5.3 General and procedural CLH issues

a) State of play of CLH dossiers

RAC/27/2013/03

For information

Item 6 – Restrictions

6.1 General restriction issues

a) Update on intended restriction dossiers

For information

b) Revision of the restriction process

RAC/27/2013/04

For discussion/agreement

RAC/27/2013/09

For information

6.2 Restriction Annex XV dossiers

a) Lead in consumer articles – 4th version of the draft opinion

For adoption

b) Nonyl phenol – 1st version of the draft opinion

For discussion

c) 1-Methyl-2-pyrrolidone (NMP) – 1st version of the draft opinion

For discussion

d) Cadmium in paints- outcome of conformity check

For agreement

6.3 Appointment of (co-) Rapporteurs for restriction dossiers

RAC/27/2013/05 (confidential room document)

For information/agreement

Item 7 – Authorisation

7.1 **Authorisation applications**

c) Authorisation application on the use of DEHP in a stop-off formulation in manufacturing of aero engines – first version of the draft opinion

For discussion/agreement

d) Authorisation applications on Phthalates (submitted within the August submission window) - outcome of the conformity check

For agreement

7.2 Capacity building

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

RAC/27/2013/06

RAC/27/2013/07

For discussion/agreement

d) ECHA project on carcinogenicity dose response analysis of Trichloroethylene

For information

7.3 Appointment of (co-) Rapporteurs for authorisation applications

RAC/27/2013/08 (confidential room document)

For agreement

Item 8 – AOB

- Update on Guidance activities

Item 9 – Action points and main conclusions of RAC-27

- Table with Conclusions and Action points from RAC-27

For adoption

ANNEX II (RAC-27)

Documents submitted to the members of the Committee for Risk Assessment for the RAC-27 meeting.

Document number	**Title**
RAC/A/27/2013	Final Draft Agenda
RAC/27/2013/01	Report from other ECHA bodies and activities
RAC/27/2013/02 Room document	Appointment of RAC (co-) Rapporteurs for CLH dossiers
RAC/27/2013/03	Status Report on Harmonised Classification and Labelling proposals (CLH Dossiers)
RAC/27/2013/04	Revision of the working procedure for RAC and SEAC on conformity check of Annex XV restriction dossiers
RAC/27/2013/05 Room document	Appointment of (co-) Rapporteurs for restriction dossiers
RAC/27/2013/06	ECHA project on carcinogenicity dose-response analysis of Cr (VI)-containing substances
RAC/27/2013/07	ECHA project on carcinogenicity dose-response analysis of As -containing substances
RAC/27/2013/08 Room document	Appointment of (co-) Rapporteurs for authorisation applications
RAC/27/2013/09	Questionnaire and setting task force in relation to efficiencies in Annex XV dossier preparation for restrictions proposals and subsequent opinion making

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		
CLH: Sulfoxaflor (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: Lead (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: Flocoumafen (NL)	Betty HAKKERT[3]	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[1]	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

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

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
		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 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. Lead in consumer articles (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. 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.

New dossiers

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
NEW		
CLH: Triflusulfuron methyl (FR)	Elodie PASQUIER	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: Bifenazate (NL)	Betty HAKKERT[1]	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[1]	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: Fenpyroximate (DE)	Urs SCHUELTER	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.
	Norbert RUPPRICH	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.
	Agnes SCHULTE	Collaborated with the CA submitting the CLH dossier
	Hans-Christian STOLZENBERG	His employer collaborated with the CA submitting the CLH dossier
CLH: Lenacil (BE)	Safia KORATI	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: Tributyltin compounds (DE)	Urs SCHUELTER	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.
	Norbert RUPPRICH	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.
	Agnes SCHULTE	Collaborated with the CA submitting the CLH dossier

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

RAC members' advisers

AP/Dossier / DS	RAC member adviser	Reason for potential CoI / Working for
CLH: Sulfoxaflor (IE)	Brendan MURRAY	Working for the CA submitting the CLH dossier
CLH: Warfarin (IE)	Brendan MURRAY	Working for the CA submitting the CLH dossier
CLH: Chlorophacinone (ES)	Miguel SOGORB	Collaborated with the CA for the assessment of the biocide dossier for this rodenticide

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