RAC/M/24/2013
FINAL
29 April 2013

Minutes
of the 24th Meeting
of the Committee for Risk Assessment (RAC-24)
05-08 March 2013

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 24th meeting of the Committee for Risk Assessment (RAC). He informed the meeting that a new RAC member, Stéphanie Vivier, had been appointed by the Management Board in December 2012 and asked her to briefly introduce herself. The Chairman then informed the meeting that former RAC member Annick Pichard will carry on as an invited expert acting as the rapporteur for the CLH dossier mandipropamid, and as the co-rapporteur for the CLH dossier potassium sorbate. Apologies were received from four members. .

The participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed after the adoption of the minutes. He noted that the minutes would be published on the ECHA website and would include a full list of participants as given in Part III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the week's agenda for the Committee, highlighting some of the more difficult dossiers and highlighting the joint session with the SEAC on the Friday in which the valuation of PBT's would be considered. The Final Draft Agenda (RAC/A/24/2013) was adopted without modifications. The agenda and the list of all meeting documents are attached to these minutes as Annexes I and II, respectively.

3. Declarations of conflicts of interests to the Agenda

The Chairman requested all participants to declare any potential conflicts of interest to any of the agenda items. Six members and one invited expert declared potential conflicts of interest, each to specific agenda items. These meeting participants did not participate in voting under the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

He added that in accordance with the updated Conflict of Interest policy (ED/08/2013; General Principles and Guidance for Committee members of ECHA), some changes in the current practice of the declarations of the absence of conflict of interest were introduced which RAC members should be aware of:

- When accepting the (co-)rapporteurship of the RAC to provide an opinion on a CLH dossier, members also need to declare right away the absence of any conflict of interest (in a specific column in the table of the document circulated during the plenary meeting).
- Once a member has been appointed by the agreement of the RAC as the (co-) Rapporteur and the dossier has been submitted to ECHA, the Secretariat sends the actual declaration of the absence of any conflicts of interest to be signed by the member; this is then followed by the letter of appointment.
- Should any conflict of interest become evident in the meantime, the appointment will become null and void (and the new call for expression of interest will be initiated).

4. Report from other ECHA bodies and activities

a) Report on RAC 23 action points, written procedures and other ECHA bodies

The Secretariat informed the Committee on administrative issues as set out in room document RAC/2324/20123/01, which included an overview of the adoptions, consultations, and agreements undertaken by written procedure since the last RAC meeting and on the reports from the last meetings of the ECHA bodies namely the Management Board, the Member State Committee, the Committee for Socio- Economic Analysis and the Forum for Exchange of Information on Enforcement (Forum) as

summarised in document RAC/24/2013/02. In addition, the Secretariat presented the outcome of the Annual Satisfaction Survey of RAC members and RAC Accredited stakeholder observers held in November 2012.

b) Appointment of co-opted members pursuant to Art. 85.4 of REACH

The RAC had previously discussed the general and specific needs for co-opting additional members to its Committee during RAC 21 in June 2012. It was concluded at that time that further discussion on the area of expertise would be needed and additional clarification of financial aspects of co-opting members were requested. In addition, the RAC Chairman discussed this topic in his interviews with the members between October and November 2012, receiving indications that the members generally support the need to increase the Committees expertise in certain areas.

As a follow-up to the discussion at RAC 21 and the Chairman's recent interviews, the Secretariat presented a paper providing further clarification of financial aspects and seeking agreement as to the proposed complementary scientific expertise required and the procedure for selection and appointment of co-opted members for the RAC.

In the discussion, several RAC members expressed a strong preference for creating a pool of experts by using the existing Rules of procedure with regard to 'invited experts' rather than co-option. To ensure a proper discussion on specific topics, experts from the pool with detailed knowledge of the topic in question could be invited to strengthen the RAC on an ad hoc basis; one member recalled the already existing database of experts and invited for its update. Potential weakening of the transparency and independence of the Committee, combined with a still unclear reimbursement policy for the co-opted members were mentioned among the reasons against the co-option of RAC members.

Other members pointed out that the critical issue for the RAC was not so much specialised expertise but more the mobilisation of enough committed members and in particular experienced rapporteurs, sufficient to manage the oncoming workload. The Chairman pointed to the need to agree on ca. 40 CLH opinions in 2013, several restrictions and an as yet unknown number of authorisations from RAC 27 onwards, confirming that the number of rapporteurs available would be critical.

None-the-less, several members supported the idea of co-opting RAC members in line with the option given by the legislation and the actual need for sharing the increasing workload the RAC was facing. Having expressed this position, they did not exclude an option of using a pool of experts in parallel to co-opted members. The option (currently not fully used) to nominate more regular members by a Member State was also raised. In reaction to this one member pointed out the resource limits of esp. smaller Member States and supported the use of the pool of experts.

In conclusion, the Chairman informed the RAC that the suggestion for a pool of experts would be followed up by the secretariat. The proposal for co-option of members would be revised in the light of members' comments and in the context of the overall workload of the RAC and presented again at RAC 25 for considerations and adoption.

5. Harmonised classification and labelling (CLH)

5.1 CLH dossiers

a) Etridiazole

The Chairman reported that etridiazole is an active substance used as a fungicide in the treatment of glasshouse grown tomato, cucumber, pepper and ornamentals. This CLH dossier was submitted by the Netherlands. The legal deadline for adoption of the opinion is 27 August 2013.

Etridiazole has a harmonised classification in Annex VI as Carc. 2, H351, Acute Tox. 3*, H331 (inhalation), Acute Tox. 4*, H312 dermal, Acute Tox. 4*, H302 oral, Aquatic Acute 1, H400, Aquatic Chronic 1, H410. The Dossier Submitter (DS), the Netherlands, had

proposed the following modifications to the classification following the review of the dataset:

- to remove the classification Acute Tox. 3*, H331 and Acute Tox. 4*, H312;
- to remove the "*" in Acute Tox. 4*, H302;
- to add the classification of STOT SE 3, H335 and Skin Sens. 1B, H317, and;
- to add multiplication factors to the Aquatic Acute and Aquatic Chronic classifications with an M-factor of 1 respectively (CLP).

The Chairman reported that this is the first discussion in the RAC plenary meeting and invited the Rapporteurs to present their draft opinion. The Rapporteurs had evaluated all hazard classes for which there was information in the dossier.

The RAC discussed the proposed classification of STOT SE 3, H335 for respiratory tract irritation, recognising that the proposed classification is based on relatively little data from only two studies. One was a sub-acute repeated dose inhalation study in which nasal discharge (rhinitis) and minimal squamous metaplasia of the larynx mucosa were reported. The other was an acute inhalation study in which reversible laboured and rapid breathing were observed. It could not be concluded if the observed effects in the sub-acute study occurred after single dose and if they were reversible effects. One RAC member mentioned that the low pH in water could be the reason for the observed effects. It was also pointed out that the observed breathing difficulties could be attributed to the high dust concentrations. The RAC concluded that the observed effects were not sufficient for classification with STOT SE 3.

Classification as STOT RE was not proposed, as no serious adverse effects occurred below the guidance values.

The RAC agreed to remove the classification for Acute Tox. 3*, H331, Acute Tox. 4*; H312 and the "*" in Acute Tox. 4*, H302, and to add Skin Sens. 1B, H317. The discussion of the data for the carcinogenicity, reproductive toxicity and environmental classification endpoints were to be continued via written comments and in the next RAC meeting due to the limited time available at this plenary meeting.

The RAC agreed to the proposed classifications on the hazard classes as indicated in the table 2 in part 2 of these minutes. Following the revision of the draft opinion the Secretariat will launch a RAC commenting round on the remaining endpoints.

b) Mandipropamid

The Chairman reported that mandipropamid is a fungicide used against leaf blight in grapes, tomatoes and potatoes and is not currently harmonised on Annex VI of the CLP Regulation. The legal deadline for adoption of the opinion is 28 August 2013.

The DS (Austria) proposed to classify the substance as Aquatic Acute 1; H400 and Aquatic Chronic 2; H411 according to the CLP Regulation. As it is an active substance, in accordance with Art. 36(2) of the CLP Regulation, all physical and chemical properties, human health and environmental endpoints are considered in the CLH report.

The Chairman informed the RAC that an additional aquatic toxicity study on Daphnia magna had been introduced to the opinion development process during the public consultation (PC). He reported that the substance was being discussed at a RAC plenary meeting for the first time and invited the Rapporteurs to present the draft opinion.

The Rapporteurs noted that mandipropamid was considered non-rapidly degradable with a low bioaccumulation potential. They agreed with the DS proposal for the harmonised classification for Aquatic Acute 1 (M=1) but proposed to have long-term hazard classification as Aquatic Chronic 1 (M=1) based on the new study that was submitted during the PC.

Based on the detailed results of two studies a classification for STOT RE for liver and kidney effects was discussed. It was concluded that although effects occurred within the

guidance value for STOT classification, they were not sufficiently significant or severe to warrant the classification.

In the discussion, the RAC supported the Rapporteurs' conclusions on both environmental and human health hazard classes and the opinion on mandipropamid was adopted by consensus.

c) Fenoxaprop-p-ethyl

The Chairman welcomed an expert accompanying the ECPA stakeholder observer.

The Chairman reported that fenoxaprop-p-ethyl is used as an herbicidal active substance for post-emergence use in certain crops. This CLH dossier was submitted by Austria; legal deadline for adoption of the opinion is 15 October 2013.

Fenoxaprop-p-ethyl currently has no harmonised classification in Annex VI. The DS had proposed to classify fenoxaprop-p-ethyl as Skin Sens. 1B, Aquatic Acute 1; Aquatic Chronic 1 and STOT RE 2 – H373 (kidney).

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

The Rapporteurs had evaluated all hazard classes for which there was information in the dossier. They proposed no classification for reproductive toxicity and carcinogenicity, which was supported by all RAC members. The Rapporteur, as well as all RAC members, agreed to the DS's proposal to classify the substance as STOT RE 2 (H373) for effects on kidneys. In relation to skin sensitisation, the Rapporteur proposed to classify fenoxaprop-p-ethyl as Skin Sens. 1, but without stating the sub-category as there was insufficient information about induction concentrations and potency to distinguish between category 1A and 1B. This view was shared by the RAC. The RAC also agreed to classify the substance as Aquatic Acute 1 and Chronic 1 with an M-factor of 1 for both as proposed by the DS.

RAC adopted the opinion on fenoxaprop-p-ethyl by consensus. It was agreed that the rapporteur would revise the opinion in line with the discussions at RAC-24 before the document is prepared for publication on ECHA's website.

d) Isoxaflutole

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and reported that isoxaflutole is used as an herbicide in maize crops. This CLH dossier was submitted by the Netherlands and the legal deadline for adoption of the opinion is 11 November 2013.

Isoxaflutole has a harmonised classification in Annex VI as Repr. 2, Aquatic Acute 1 and Aquatic Chronic 1. The DS proposed to add M-factors (CLP) and specific concentrations limits (DSD) taking the new classification criteria into account that were introduced by the 2nd ATP[1]. The proposal addressed only the environmental classification.

The Rapporteur presented the revised draft opinion that addressed comments made during public consultation and during the RAC commenting round. The RAC members confirmed their support for the revised draft opinion and the RAC adopted the opinion on isoxaflutole by consensus as indicated in the table 1 in part 2 of these minutes. Following an editorial revision the opinion including its Annexes will be sent to the Commission and uploaded to the ECHA website.

e) Tembotrione

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and reported that the substance is used as a herbicide against grasses and broad leaved weeds

[1]2nd ATP, "Commission Regulation (EU) No 286/2011 of 10 March 2011amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures", http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:083:FULL:EN:PDF

and that it currently has no entry on Annex VI of the CLP Regulation. The legal deadline for the adoption of the opinion is 11 November 2013.

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

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

The Rapporteurs agreed with the DS proposal for the harmonised classification for environmental hazards but based on the results of the acute tests with *Lemna gibba* being the most sensitive species they proposed a higher acute M-factor (M=100).

The Rapporteurs agreed with the DS proposal on skin sensitisation in category 1 (based on a study in Guinea pigs - Magnusson and Kligman Maximisation test performed in accordance with the OECD guideline 406), however proposed not to specify a sub-category as only the intradermal induction concentrations of 2.5 % were tested and therefore the data are in principle not sufficient to decide on the sub-category. Rapporteurs' proposal was generally supported by the RAC but one member raised a concern that if the criterion is interpreted to support category 1 in this case, then it could mean that 1B will be rarely applied. It was agreed that the Rapporteurs would look at the severity of the effects in the Guinea pig study to find out more information on the potency of the substance if available.

The Rapporteurs presented the proposal for STOT RE 2 classification based on kidney effects and also discussed the general conclusion made by the DS that tyrosinaemia in tested species (rat) would not be relevant to humans. This issue was brought up by one RAC member during the RAC consultation and the Rapporteurs agreed that this needs further assessment and therefore it was not possible to conclude on this endpoint. In addition, the ECPA expert also promised to provide more detailed information on the studies referred to in the CLH report (kidney assessment). The Rapporteurs will prepare a revised version of the opinion and it will be circulated for RAC comments before the next plenary meeting.

The RAC agreed with the conclusions of the Rapporteurs with regard to the environmental hazards. The RAC will further discuss other evaluated hazard classes of tembotrione based on the revised draft opinion.

f) Potassium sorbate

The Chairman welcomed the German DS who participated remotely in the meeting and reported that potassium sorbate is a biocide; the deadline for adoption of the opinion is 11 November 2013.
The substance does not currently have an entry in Annex VI to the CLP Regulation for harmonised classification and labelling.
The Chairman invited the Rapporteurs to present the revisions in the draft opinion and replies to the RAC comments.
The classification Eye Irrit. 2, as proposed by the DS, was supported by the RAC. Concerning skin irritation, arguments for and against classification with Skin Irrit. 2 as proposed by the DS were raised. The proposal was supported by read across from sorbic acid, which is known as a potent skin irritant. However, given the negatives studies on potassium sorbate (the Draize test on skin irritation and the OECD 404 rabbit study), the RAC decided not to support the proposal for classification as skin irritant.

Other human health endpoints were not addressed by the rapporteurs, since no proposal for classification had been received from the DS. In the absence of an evaluation, RAC did not endorse the 'no classification' for the other human health endpoints.

During the RAC discussion, the environmental classification of potassium sorbate was raised and as no proposal for classification had been received from the DS, the rapporteur decided not to include it in the presented opinion.

The RAC agreed to classify potassium sorbate as eye irrit. 2 and not to classify for skin irritation.

The RAC adopted the opinion on potassium sorbate by consensus.

g) Nitric acid

The Chairman welcomed an expert accompanying the CEFIC stakeholder observer and reported that nitric acid is a chemical which is mainly used to produce fertiliser but also in explosives, nylon precursors, specialty organic compounds and in household cleaning products. The CLH dossier was submitted by Germany and the legal deadline for the adoption of the opinion is 19 December 2013. Nitric acid already has a harmonised classification as Ox. Liq. 3 – H272; with specific concentration limits (SCLs) and as Skin Corr. 1A – H314; with SCLs.

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

The Rapporteurs agreed with the proposal from the DS to classify nitric acid with a more severe category for oxidising liquids (Ox. Liq. 2) and to revise the pertinent specific concentration limits (Oxid. Liq. 2; H272: C ≥ 99%; Ox. Liq. 3; H272: 99% > C ≥ 65 %). This view was shared by the RAC. However, the applicability of the 99% threshold was questioned by a RAC member; the Secretariat was requested to clarify the issue by contacting ECHA experts.

In relation to health hazards, the Rapporteurs, as well as the other RAC members, agreed with the DS to assign the supplemental labelling EUH071'corrosive to the respiratory tract'.

As to inhalation toxicity where a classification for Acute Tox. 1 (H330) was proposed, the question was raised whether NO_2 should be seen as chiefly responsible for the toxicity. One RAC member reminded the Committee that in the study with the lowest LC_{50} value (Gray et al, 1954) NO_2 was also present in the test substances (red and white fuming nitric acid, respectively). The expert accompanying the ECPA stakeholder observer noted that the exposure duration in the Gray study needed to be extrapolated to 4h in order to provide valid results which are directly comparable to the classification criteria.

RAC agreed on classification as Acute Tox. 1 (H330) subject to clarification of the questions raised in relation to the setting of SCLs for hazard class oxidising liquids. A final decision on the harmonised classification would be taken either through written procedure or at the next RAC plenary.

h) Flonicamid

The Chairman reported that flonicamid is an insecticide used on e.g. potatoes, wheat and apples. The CLH dossier was submitted by France and the legal deadline for the adoption of the opinion is 19 December 2013.

Flonicamid does not currently have an entry in Annex VI to the CLP Regulation. The DS proposed classification as Acute Tox. 4 - H302. During the public consultation, consideration of the following hazard classes was proposed by third parties: Carcinogenicity, Repr. 2 (dev. tox) and STOT RE.

In his presentation, the Rapporteur presented the key data relevant for the classification, agreeing with the proposal of the DS to classify the substance as Acute Tox. 4 - H302, based on the reported acute oral toxicity LD_{50} values in rats. He also agreed that the substance should not be classified for skin and eye irritation or skin sensitization and further supported the DS conclusion that no specific target organ toxicity had been identified. In his opinion flonicamid did not meet the criteria for classification as germ cell mutagenicity. The RAC agreed with the above mentioned proposal.

In the CLH dossier, no classification for carcinogenicity was proposed, and the rapporteur supported with this. Effects have been seen in studies using CD-1 mice, namely pulmonary neoplastic lesions, and focal hyperplasia. In the opinion of the Rapporteur those are not relevant for classification because CD-1 mice are particularly susceptible to chemically induced lung tumours but that this does not generally apply to other rodent species. Therefore, the Rapporteur agreed with the DS proposal not to classify for carcinogenicity.

The RAC members asked for clarification concerning historical control data of the lung tumors in the CD-1 strain. The Rapporteur replied that the historical control data was mentioned in the CLH dossier without information on the source. During the public consultation third parties provided information on historical controls (higher than those included in the CLH dossier) which was properly documented and in the Rapporteur's opinion more reliable.

The RAC members were not confident that the fact that the lung tumours produced by flonicamid in CD-1 mice were not seen in other rodent species provided a strong enough justification to exclude that the effects might be relevant for humans. They asked if there are any data which can exclude that the genes thought to be responsible for the CD-1 mice's extra sensitivity are not present in humans, or that flonicamid can cause similar effects in humans through other genes or mechanisms. . One RAC member further questioned the justification to dismiss the relevance to humans as there is no clear understanding of the mode of action (what gene is involved, where it is expressed etc.).

The Rapporteur replied that the proposal for no classification is justified since the mechanism of action for lung tumour induction in the CD-1 mouse by flonicamid requires lung epithelial cells proliferation. In two other mouse strains and in rats flonicamid does not induce such cell proliferation. The CD-1 mouse strain has a high frequency of spontaneous lung tumours which is comparable to those observed in the CD-1 mice treated with flonicamid. This frequency is much higher than in other strains of mice. Members asked the Rapporteur to rephrase the justification to focus mainly on the results of the animal studies, and the high spontaneous rate of lung tumours in the CD-1 mouse strain and the low incidence in other rodent species, rather than on the non-relevance to humans as this cannot be proven on the basis of the current information. The Rapporteur agreed to modify the justification but noted that this will not change the overall conclusion.

One of the RAC members offered information on the genetic background of the CD-1 mouse strain. The level of the spontaneous lung tumour in the CD-1 mouse strain (average 20%) justified that this strain cannot be considered reliable for lung tumour studies.

The RAC members requested more time to examine the data on carcinogenicity. They requested the Rapporteur to provide a better clarification on the historical controls and on the evidence that humans are not sensitive to the effects of the substance.

The RAC requested the industry expert present if he could provide any further information on the historical control data and its origin. Industry promised to use their best efforts to locate such data.

Concerning reproductive toxicity, the Rapporteur agreed with the DS for no classification. This opinion was supported by the RAC. The RAC also agreed with the proposal not to classify flonicamid for environmental hazards but the Rapporteur was asked to add information on the water-sediment study which confirms that the substance is not rapidly degradable instead of using the information on photo-degradation, as it is difficult to use for classification purposes.

The Chairman concluded that the classification of all hazard classes had been agreed except for carcinogenicity where no classification versus Carc. 2 were still under consideration. The justification for the conclusion on the carcinogenicity will be the subject of further work via written RAC consultation. The Rapporteur was requested to provide the

Secretariat with the new version of the draft opinion. The Secretariat will launch a written RAC consultation. The opinion is foreseen for adoption before or at RAC 25.

i) Tricalcium diphosphide

The Chairman reported that tricalcium diphosphide is an active substance used to control rodents, moles and other non-rodent vertebrates in cropland and non-cropland field situations. This CLH dossier was submitted by Germany and the legal deadline for adoption of the opinion is 19 December 2013.

Tricalcium diphosphide already has a harmonised classification as Water-react. 1, Acute Tox. 2* and Aquatic Acute 1 (M=100) and EUH029 'liberates toxic gas in contact with water'.

The DS (Germany) had proposed to add Acute Tox. 3, H311, and Skin Corr. 1A, H314 and to confirm the minimum classification Acute Tox. 2*, H300 based on the data included in the dossier by deleting the asterisk "*".

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

The Rapporteurs had evaluated all hazard classes for which information was provided in the dossier and during public consultation. The RAC agreed with the DS to classify as Acute Tox. 3 – H311 and Acute Tox. 2 – H300. In addition, the RAC agreed with comments received during PC that tricalcium diphosphide should be classified as Acute Tox 1 – H330.

The RAC did not agree with the DS to classify tricalcium diphosphide as Skin Corr. 1A. In the CLH report, the DS argued that the high pH of the hydrolysis product calcium dihydroxide would be sufficient to classify for Skin Corrosion. However, the RAC considered that the effects observed in the available studies on calcium hydroxide, as reported in the respective REACH registration dossier, are not severe enough to warrant classification for skin corrosion.

The RAC noted the deficiencies in the studies on calcium hydroxide; in one study the substance was applied as a powder without applying moisture. A RAC member added that according to OECD guidelines, moistening of the test substance is required as this would occur on the human skin due to sweat or dampness. In another study, the substance was applied in a "putty" form containing 40% calcium hydroxide mixed with water.

The RAC agreed that the slight effects seen in those studies on the hydrolysis product calcium dihydroxide are sufficient to classify calcium phosphide for skin irritation under DSD with R38. However, classification under CLP was not considered appropriate because the criteria require that the grade should be at least 2.3 to 4 for classification. In addition, the RAC agreed that the effects seen in two eye irritation studies with calcium hydroxide warranted classification of tricalcium diphosphide as Eye Dam. 1 – H318 (R41 under DSD).

The RAC adopted the opinion on tricalcium diphosphide by consensus. Following an editorial check, the opinion will be forwarded to the Commission and uploaded to the ECHA website.

j) 8:2 Fluorotelomer alcohol (FTOH)

The Chairman welcomed an expert accompanying the Cefic stakeholder observer and the DS (Norway) who followed the meeting via WEBEX connection. He reported that the substance is used as a raw material (one component in a mixture of fluorotelomer alcohols) to manufacture surfactant and polymeric products that have a range of commercial uses; the polymers are used for coating of textiles, paper and carpets to achieve oil, stain and water repellent properties. The substance is not currently harmonised in Annex VI of the CLP Regulation. The Chairman reminded the RAC that even though 8:2 FTOH is metabolised to PFOA to some extent in all mammalian species studied and that the RAC adopted an opinion on the latter in December 2011, proposing to classify PFOA as Repr. 1B; H360D, the discussion here should be primarily focussed on 8:2 FTOH

and the available data. The DS (Norway) proposed a harmonised classification for Repr. 1B; H360D according to the CLP Regulation based on the biotransformation of 8:2 FTOH to PFOA with evidence from several supporting studies.

The Chairman reported that the legal deadline for the adoption of the opinion is 15 October 2013 and that the substance was being discussed at a RAC plenary meeting for the first time; he then invited the Rapporteur to present the draft opinion.

The Rapporteur presented the summary of the DS proposal for classification of 8:2 FTOH as a presumed human reproductive toxicant based on the formation of the metabolite PFOA. He pointed out that the available data were rather limited and that quantitative comparisons of the kinetics would be needed in order to reach a conclusion but that there were many uncertainties. The RAC then discussed the level of metabolism of 8:2 FTOH and the severity of the observed effects in the available studies.

The validity of some studies for the classification of the substance was questioned due to the fact that these were carried out on a mixture containing only 27% of 8:2 FTOH. Industry confirmed that this mixture contained a wide range of other chain lengths than the 8:2. It was agreed that these studies should not be used as primary data for the classification.

Based on the discussion and particularly on the limited information on metabolism of 8:2 FTOH in relevant species the RAC agreed by consensus not to classify 8:2 FTOH for toxicity to reproduction due to insufficient data on the substance.

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

a) Gallium arsenide (GaAs)

The Chairman welcomed the expert accompanying the Eurometaux stakeholder observer and noted that GaAs is used as a semiconductor in the microelectronics industry. He noted that this was the fifth discussion at a RAC plenary meeting of the draft opinion on reproductive toxicity of gallium arsenide initiated by an Article 77(3)(c) request from the Executive Director of ECHA[2].

In its opinion[3] of 25 May 2010, the RAC supported the DS's proposal for classification of GaAs as Repr. 1B (CLP) for effects on fertility, based on clear evidence in repeated dose toxicity studies showing testicular toxicity in two species and supported by a potential for gallium to accumulate in rat testis following inhalation exposure.

During the public consultation held on the basis of a previous Art. 77(3)(c) request[4], which concerned the carcinogenicity of GaAs and in the information subsequently submitted by Eurometaux in December 2011, industry presented a hypothesis that GaAs induced lung toxicity may cause hypoxia which in turn may result in the observed effects in the testes (testicular atrophy, reduced sperm counts and abnormal spermatids). To support this hypothesis, industry referred to several studies. One of the referenced reports (Tanaka et al, 2000) showed some effects of GaAs in other organs than the testes (including the lung) in an intra-tracheal study using hamsters by Omura et al (1996a). Omura et al (1996a)

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

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

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

was one out of four key studies demonstrating testis toxicity of GaAs. Later on in the opinion development process industry drew the RAC's attention to a scientific publication on this issue (Bomhard and Gelbke, 2011).

The Rapporteurs had been requested at RAC 23 to revise the draft opinion based on the previous RAC discussions and the extensive written comments provided by the members. In order to facilitate the revision of the draft opinion, given its complexity and to ensure a balanced discussion in the Committee, it was further agreed at RAC 23 that the Secretariat should prepare a summary of the main evidence and arguments. A presentation of this summary had been given to RAC members by the Secretariat at a WebEx meeting on 15th February; a short report on the outcome had been made available via CIRCA BC and the Chairman summarised the discussion that had taken place, noting that 12 members had attended on line.

At RAC 24, this presentation with some additions was used to summarise all the key data and to structure the discussion. The Committee agreed that the data were well-reflected in the presentation and that it formed a good basis with which to reach agreement on the classification and to finalise the opinion. Industry also agreed that although their interpretation of the criteria for classification might be different from the majority of RAC members, it provided a good starting point for the discussion. It was also agreed by the Committee that the main question to be addressed was whether the testis toxicity of GaAs can be considered a secondary non-specific consequence of other toxic effects.

Referring to the industry hypothesis that the observed testis effects following GaAs exposure would not be primary effects but could be caused by lung toxicity induced hypoxia, one RAC member agreed that Ga and/or As may accumulate in the testis, but questioned whether the concentrations reached in this organ would be sufficiently high to cause the observed effects. He concluded that since there was clear lung toxicity (including a marked increase in lung weights) observed in some of the studies with testis toxicity, there was an uncertainty whether GaAs caused a primary or secondary non-specific effect on the testis. This uncertainty led him to suggest classification in category 2. This was supported by another RAC member.

One RAC member noted that no testis effects had been observed with another substance such as silica which caused increased lung weight, and therefore could not agree that increased lung weight per se would lead to testis toxicity.

Several RAC members repeated their positions presented at previous discussions, stating that the mode of action (MoA) proposed earlier – testis toxicity being caused by lung damage resulting in hypoxaemia in the blood and subsequent hypoxia in the testis, - is not sufficiently convincing and not the only possible explanation. It was considered that alternative mode(s) of action for the testis toxicity as proposed by RAC members could not simply be dismissed. It was also pointed out that certainty about the exact MoA was not needed in order to classify. Some members considered that if the alveolar proteinosis and anaemia led to the observed testicular effects, this would still be a very specific secondary effect and could lead to category 1B classification. In addition, based on calculated and estimated concentrations of Ga and/or As compounds in the testes in the studies where testis toxicity was observed in rats and mice (NTP, 2000; Pant 2001 and 2004) a direct effect of Ga and/or As could not be excluded. Thus, it could not be concluded that the testis toxicity is solely a secondary non-specific consequence of other toxicity (lung toxicity). In addition, a majority of RAC members were of the view that regardless of all the potential MoA(s) discussed, there was no doubt about the relevance to humans.

A clear majority of RAC members agreed that no change was warranted to the previous RAC opinion from March 2010 which concluded that gallium arsenide was recommended to be classified as a substance which may damage fertility (Repr. 1B), as originally proposed by the DS.

It was agreed that an ad-hoc drafting group will revise the draft opinion which should summarise the justification for the majority view of category 1 B on the basis of the

discussion and the presentation made by the Secretariat. Three members expressed their preference to classify the substance as Repr. 2; their minority positions will be made available in a separate document which will be published at the same time as the final opinion. In accordance with the mandate from the Executive Director of ECHA, the draft opinion will be subject to a public consultation before its final adoption.

The Chairman thanked the members for the detailed scientific discussion and for their efforts with this complex dossier. He also thanked the Secretariat for preparing the summary upon which the final discussion was based.

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

The Secretariat collected the names of volunteers for CLH dossiers and listed these in a room document. Due to time constraints the appointments will be made via the written procedure after the plenary meeting.

5.4 General and procedural CLH issues

a) State of play of CLH dossiers

The Secretariat informed the Committee that a paper with an indicative planning of the CLH dossiers and the timelines for RAC 25 (4-7 June 2013) and RAC 26 (10-13 September 2013) had been prepared and uploaded for the attention of the members on CIRCA BC.

b) Opinion development process – alignment with the ppp process

The Secretariat provided an update on the coordination of the pilot dossier concerning sulfoxaflor, which is subject to the ECHA CLH process and at the same time, to the EFSA approval process for this new active substance under the pesticides Regulation (EC) No 1107/2009.

In the subsequent discussions, it became clear that RAC members recognised the need to align both processes. RAC members encouraged further and regular dialogue on this issue and also recognised that there was some need for the CLH process, being the more flexible process, to adapt to the peer review process which is seen as having more rigid milestones. Nevertheless, and in view of the importance of harmonised classification for the approval decision on the active substance, any alignment needs should be carefully balanced with the need to optimise CLH planning within the legal time span of 18 months as granted under the CLP Regulation in order to arrive at a robust opinion.

One RAC member raised the question as to what ECHA could contribute to raising awareness of which dossiers would be subject to alignment, pointing out that in countries where the CAs for PPP/Biocides and CLP are separate (many EU MS), the CA for CLP might in a worst case only receive a few weeks' notice for the preparation of a CLH dossier. The Secretariat clarified that ECHA was aware of the problem and that a solution was being sought.

Finally the question was asked whether ECHA would be aligning with the biocides process in a similar way. The Secretariat informed that this would be further explored in-house in due course.

Overall, RAC members expressed the view that a regular update of the Committee on the status of regulatory alignment, including the sulfoxaflor pilot project and subsequent alignment considerations would be appreciated.

c) Opinion development process – implementation of the framework for CLH opinion development

The Secretariat presented a paper which introduced an approach to the implementation of the "Framework for the RAC opinion development on substances for harmonised classification and labelling". As part of a range of efficiency measures, the paper evaluated the usefulness of allowing Stakeholder experts to attend the Committee on a continuing basis. The concerns of industry and RAC members, as expressed at RAC 22 had been borne in mind. The main thrust of the paper therefore was the concern to create a

solid and stable information base for each substance early on in the process, so avoiding late submissions which disturb the process. ECHA would consider ways and means of offering fair and well publicised opportunities for all parties concerned to forward information that they deem relevant. In turn, they would be informed about the progress of the opinion development process. In this way, flexibility would be maintained and should the need arise; possibilities for the Committee to seek additional information would be retained. Finally, the Committee was reminded that under the current Rules of Procedure, all documents for consideration in a plenary meeting should be submitted 10 days in advance and that this would be strictly applied in the future.

RAC members expressed their appreciation for the approach and pointed out the diversity of CLH dossiers, both in terms of size, complexity and quality; they encouraged the secretariat to continue looking for efficiencies while maintaining a flexible system, so that any additional burden is avoided when not justified by the complexity of a dossier.

6. Restriction

6.1 General restriction issues

a) Update on intended restriction dossiers (joint RAC/SEAC session)

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

- 1-Methylpyrrolidin-2-one (NMP) in coatings and cleaners for consumers and professionals prepared by the Netherlands (expected submission date - 19 April 2013);
- Cadmium and its compounds in plastics and paints prepared by ECHA at the request of the Commission (expected submission date – 17 January 2014);
- Placing on the market and use of diaphragms containing chrysotile prepared by ECHA at the request of the Commission (expected submission date – 17 January 2014).

The Secretariat mentioned that calls for expressions of interest for (co-)rapporteurship of the chrysotile restriction dossier would be launched in both the RAC and SEAC shortly after RAC-24/SEAC-18.

6.2 Restriction Annex XV dossiers

a) Dichlorobenzene – fourth version of the draft opinion

The purpose of the proposed restriction is to ban the use of 1,4-dichlorobenzene (1,4 DCB) in toilet blocks and air fresheners used in toilets or other domestic or public indoor areas, or offices. The DS is ECHA.

The public consultation on the restriction dossier on 1,4 DCB took place between 19 June 2012 and 19 December 2012, with six comments received. The rapporteurs' 3rd dialogue took place on 17 January 2013 and a written RAC commenting round on the 4th version of the RAC opinion closed on 17 February, while a further meeting with interested RAC members took place on 19 February via WebEx. Based on all comments received, the Rapporteurs prepared a modified 4th version of the RAC opinion for discussion at RAC 24. The final Forum advice was made available to the RAC and SEAC on 26 February 2013. The deadline for adoption of the opinion is 19 March 2013.

The Chairman welcomed the DS and then invited the rapporteurs to present the modified 4th version of the RAC opinion. The rapporteurs started with a presentation on the hazard assessment, with a focus on DNEL derivation based on liver tumours observed in both sexes of BDF1 mice following a two year inhalation exposure and on liver effects in dogs (1 year oral exposure). RAC members supported the rapporteurs' proposal for choosing liver tumours as observed following inhalation exposure. The Chairman reminded the RAC that the DNEL derivation for other relevant but not leading endpoints could be described in

detail in the Background Document. The RAC agreed on carcinogenicity as the only endpoint to be taken forward for risk characterisation.

An assessment factor of three was used to calculate a DNEL for carcinogenicity based on a steep dose-response for liver tumours in mice. Different views were raised with regard to this choice; some members called for further justification. The RAC reached consensus on the assessment factor of three on the basis of steep dose response and the fact that the tumours observed in mice were rare/unusual.

It was subsequently clarified that the terminology to be used for the worst case scenarios should be "reasonable worst case". The average temperature used in the modelling of exposures was also discussed in detail, and the RAC considered whether the average temperature of 25°C would be more appropriate that the higher temperature of 30°C used in the exposure modelling.

While the RAC fully supported the RCRs established for the consumers, some discussion took place on the magnitude of RCRs for professionals. RAC members felt that where RCR's of greater than 1 had been established, then as a matter of principle, this could not be ignored. The Commission pointed out that if RCRs are above one, the options chosen to reduce this risk need to be duly justified.

An ad/hoc meeting with 12 RAC members (including the Rapporteurs), a Commission representative and five ECHA staff members further discussed the issues raised in plenary. The Rapporteur reported on the conclusions of the ad/hoc group to plenary, presenting some additional exposure calculations based on the average temperature of 25°C /7,5 hours a day, which also resulted in RCRs above 1 for professionals. Furthermore, RAC members had discussed the possible risk management options (such as job rotation, voluntary agreements by cleaning industry, personal protective equipment, increased ventilation, artificial temperature control, and the adjustment of the worker legislation in particular of occupational exposure limits) and concluded that restriction would be the most appropriate measure to reduce exposures and address the identified risk as expressed by RCRs above 1.

In response to a question from RAC members, the DS clarified that the scope of the restriction would also include hospitals and the nursing homes for the elderly people, where low ventilation and relatively high indoor temperatures might be expected to occur.

The RAC adopted the opinion and the text by consensus. The Chairman thanked the Rapporteurs and all those who had contributed to an intense and fruitful debate in preceding weeks. The Rapporteurs and the Secretariat were asked to make some specific editorial changes to the opinion based on the discussions in the plenary. The Rapporteurs will ensure that the supportive documentation (BD and RCOM) is in line with the adopted RAC opinion. The Secretariat will forward the adopted opinion and its supportive documentation to SEAC and will publish the adopted opinion and its supportive documentation on the ECHA website and CIRCA IG.

b) Nonylphenol - outcome of conformity check

The Chairman welcomed the SEAC (co-)rapporteurs and the DS representatives from the Swedish MSCA (the latter followed the discussions remotely as observers).

The Chairman reminded the Committee that the restriction dossier on nonylphenol (NP) and nonylphenol ethoxylates (NPE) had first been submitted by Sweden to ECHA in August 2012. In September 2012, both the RAC and SEAC concluded that the dossier did not conform to the requirements of Annex XV and the reasons for non-conformity were sent to the DS, who resubmitted the Annex XV restriction proposal on 26 November 2012. The conformity check process in the RAC and SEAC was launched on 7 February and the Committees were informed that they were expected to reach a conclusion on conformity by 8 March 2013 at the latest.

The Annex XV dossier proposed a restriction on the placing on the market of NP and NPE in clothing and household textile articles (including their prints) that can be washed in

water, if they contain these substances alone or in combination in concentrations equal or higher than 100 mg/kg textile. The use of NP and NPE in concentrations equal or higher than 0,1% is already restricted within the EU in products for among other the processing of leather and textiles, industrial and institutional cleaning, etc (REACH, Annex XVII, Entry 46). However, NP and NPE are still used outside the EU as detergents and auxiliaries in the manufacturing of textile articles. Following import to the EU, the textile articles will be washed and the residues of NP and NPE will be released into the environment via the waste water treatment.

The RAC (co-)Rapporteurs presented the outcome of the RAC conformity check and recommended that the dossier would be considered to be in conformity by the RAC. The Rapporteurs expressed their appreciation for the many improvements made in the dossier. They also made recommendations to the DS for further improvements.

The RAC (co-)Rapporteurs underlined the importance of monitoring data. They explained that since NP is a priority hazardous substance under the EU Water Framework Directive, much more monitoring data should be available. The Rapporteurs called upon their Committee colleagues to approach their respective MSCAs in order to obtain monitoring data for NP/NPE in rivers and the marine environment, as well as in WWTP influent/effluent.

Following this call for information by the rapporteurs, the Chairman informed that if RAC members could assist the DS in obtaining more recent monitoring data, they are invited to approach the RAC Secretariat via the RAC functional mailbox. The Chairman pointed out that as this was the first 'environmental' restriction dossiers for the RAC to consider, and with more potentially underway, it would be important for the RAC to develop working practises for the future; it was his understanding that the DS had already expressed their interest and willingness to improve the dossier further for which the RAC expressed its appreciation.

After a brief discussion, RAC agreed that the dossier on nonylphenol and nonylphenol ethoxylates conforms to the requirements of Annex XV of REACH.

Following the discussion in RAC, the SEAC (co-)rapporteurs informed the Committee that the interim results of the conformity check by SEAC, showed that the dossier would not be considered to be in conformity. The revised report would not allow a proper evaluation of the proposed restriction with regard to effectiveness, in particular its proportionality. The (co-)rapporteurs stressed that the conclusion on conformity by SEAC would be reached on the next day (7 March 2013) within SEAC-18.

c) Lead in consumer articles – outcome of conformity check

The Chairman welcomed the SEAC (co-)rapporteurs and the DS representatives from the Swedish MSCA (the latter followed the discussions remotely as observers).

The Chairman explained to the RAC that the restriction dossier on lead and lead compounds had been submitted to ECHA on 18 January 2013. The RAC and SEAC conformity check was launched on 7 February and the Committees are expected to reach a conclusion on conformity by 8 March 2013 at the latest.

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

The RAC Rapporteurs presented the outcome of the conformity check and recommended that the dossier should be considered in conformity. They noted that the proposal takes into account the earlier RAC opinion on the restriction dossier on lead in jewellery and that a similar set of arguments and risk assessment approach had been used. The Rapporteurs also listed the recommendations to the DS, which were related to information on hazards and risks, information on alternatives, justification that the restriction is the most appropriate EU wide action and information on stakeholder consultation. The RAC Rapporteurs mentioned that in the two written commenting rounds organised within the conformity check process, one comment was received from a RAC member, which was supportive to the rapporteurs' conclusions on conformity of this dossier.

The Eurometaux stakeholder observer noted that the lead manufacturing and recycling industry supports minimization of lead exposure to children, to which this restriction can contribute. She also mentioned that the source of lead as added material or impurity in articles is uncertain and not well described in the current proposal, potentially compromising the scope of the restriction. The observer pointed out that the most specialised uses of lead relate to specific downstream sectors, (e.g. brass industry) which are not aware of this restriction proposal and have not been covered in the stakeholder consultation presented in the dossier. She also questioned whether the derogation for lead in crystal and special glass has been considered in addition to derogations for musical instruments and keys/padlocks. In addition, the observer pointed out that all Pb compounds were covered under one CAS number and entry and wondered whether this is legally justifiable. The observer added that IND challenged the treatment of organic and inorganic Pb compounds in an equal way, as their health properties may be significantly different.

One RAC member pointed out that in order not to repeat the example of the opinion development on lead in jewellery, the Rapporteurs needed to be sure that the dossier contained sufficient information on all key aspects and that that they should not rely on the DS to improve the dossier further. The rapporteurs, however, confirmed that there is enough information available for the RAC to complete work on this restriction opinion.

The RAC agreed that the dossier on lead in consumer articles conforms to the requirements of Annex XV of REACH.

The Chairman informed the participants that the Secretariat would communicate the results of the conformity check and recommendations to the DS and that the public consultation on the proposal would be started shortly after RAC-24.

Joint RAC/SEAC session:

After the dossier was agreed to be in conformity by the RAC and SEAC, an introductory presentation was provided by the DS (Sweden) on the restriction proposal to both Committees within the joint RAC/SEAC session. One participant questioned why keys have been exempted from the scope, as keys are often put in the mouth by children. The DS representative replied that according to the consultation with industry, it is not technically feasible yet to substitute lead in keys. A relevant review clause, though, is foreseen in the restriction proposal. A question was also asked on lead uses in glass, enamels and ceramics relevant applications. A clarification was provided by the DS that the food contact related uses are handled within the framework of the Food Legislation.

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

a) Non-classified phthalates (DINP and DIDP)

The Chairman welcomed the observer from EuPC and the experts accompanying the Cefic and EuPC stakeholder observers.

He reminded the RAC that this is an Article 77(3)(c) request for an opinion on a draft review report prepared by ECHA, entitled: *Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to Regulation (EC) No 1907/2006*

(REACH). He informed that the Executive Director of ECHA had extended the deadline for the opinion to 31 March 2013.

He reminded that a WebEx teleconference with RAC members and observers was held on the 11th of February to discuss the 4th draft opinion. Based on the conclusions of the teleconference, the draft opinion was amended, and restructured so that it would only contain the response of the RAC to the questions listed in the mandate (with the details of the evaluation as an annex). The resulting 5th draft opinion was subjected to a 5 day commenting round.

The Rapporteur presented the 6th draft opinion, containing answers to the questions in the mandate. The Rapporteur and the Chairman stressed that all issues had been discussed in great length, and that the 6th draft opinion was an attempt to reflect the views of members and stakeholder observers from industry.

Several members commented that the opinion should be further limited to the scope of the mandate, i.e. to respond to the questions as listed in the mandate. Several members and the ECHA Secretariat considered it important that sufficient justification to the answers provided in the opinion is given.

An in-depth discussion was held on several issues as outlined in the following.

Concerning the toxicokinetics and absorption for DINP and DIDP, the Rapporteur concluded that the absorption both in adults and children is 100%, and this could warrant a modification of the dose descriptor with a factor of 2 to account for the differences in absorption between rats (50%) and humans (100%). He noted however that this could be questioned. Some questioned the need to apply such a factor, whereas most members supported a modification of the dose descriptor with a factor of 2.

The use of the absorption factor of 2 was criticized by stakeholder observers from industry who were of the opinion that McKee et al (2002) had shown that absorption in the rat ranges from 65 – 90%, and that human biomonitoring data showed that humans can absorb approximately 70%. In their opinion the application of an absorption factor of 2 contradicts the available data and would not be consistent with previous drafts of this RAC opinion. In their view, non-classified phthalates would be treated more severely than the classified phthalates as a result.

ECHA informed the Committee that the assessment of toxicokinetics in the draft ECHA report was based on the EU risk assessment reports for DINP and DIDP from 2003 (EU RARs), and that since no new studies had been performed. The McKee et al (2002) study was referenced in the EU RARs and in the draft opinion as Midwest Research Institute (1983). The conclusions of the EU RARs were thus considered to be still relevant. The RAC agreed to include a range of the absorption levels in the opinion (50-70%). The RAC concluded that a modification of the dose descriptor with a factor of two can be justified. It was also pointed out that the estimated absorption rate of 50% in adult rats might underestimate the actual absorption at low dose levels.

With regards to the selection of the starting point for the derivation of DNELs for DINP, the Rapporteur clarified that participants in the teleconference had agreed that a NOAEL of 15 mg/kg should be the starting point for the DNEL derivation considering the differences in methodology due to the lower number of sections per liver in the Aristech (1994) study. Statistical analysis by the US CHAP was supportive to this conclusion. The RAC acknowledged that the NAEL might be higher considering the dose spacing argument. Industry observers did not agree with the conclusion of the RAC, and referred amongst others to their own statistical analysis and to the conclusion of the pathology working group (PWG) that had concluded on a NOAEL of 88 mg/kg/day.

With regards to the derivation of DNELs for DIDP, the Rapporteur clarified that (next to the 90 day study in dogs (Hazleton 1968b) and the 90 day and 2 year studies in rats (BASF 1969 and Cho et al 2008)) the use of a second 90 day rat study by Hazleton (1968a) was not considered appropriate for DNEL calculation. The reason being that the

NOAEL in the Hazleton (1968) study was higher than in the other 90 days rat study by BASF (1969), and thus it is the BASF study that determines the overall NOAEL for a study of that duration in the rat.

The Cefic expert considered the argument presented by the RAC not sufficient for excluding the Hazleton 1968 rat study. The latter was conducted with a DIDP type that is produced commercially, whereas the BASF 1969 study was done with a DIDP type which has a different substance identity and is not REACH registered. The RAC did not consider this argument to be convincing as read-across between the two forms of DINP and between the two forms of DIDP has been general practice both by industry and by regulatory authorities.

Regarding the exposure assessment, members expressed support for 2 hours mouthing time as a reasonable worst case assumption.

The Cefic expert expressed the opinion that the correct mouthing time to be assumed for a reasonable worst case estimate for mouthing of toys and childcare articles with DINP or DIDP would be 18 min/day from the 95th percentile for "soft plastic items" by Greene (2002). ECHA replied that the data published by Greene had been considered and discussed at length in its replies to the comments from ECPI on the ECHA room document. A mouthing time of 2 hour had been selected for a reasonable worst case after consideration of all the available information in a weight of evidence approach, noting that for example Smith and Norris reported mouthing times for toys of nearly 4 hours per day.

The RAC concluded that 2 hours mouthing time would represent a reasonable worst case exposure. It was pointed out that the EU RARs for DINP and DIDP had used 3h/day, and that a case could be made for a higher estimate.

The Cefic expert did not agree that the exposure RCR on combined exposure from air, dust and food form a reasonable worst case but rather an extreme worst case scenario. For air, dust and food, in his opinion it was not a reasonable worst case exposure, since it is highly unlikely that an individual would ever be exposed to the 95th percentile for both substances for air, dust and food. The Cefic expert pointed out that this approach lacks justification and was not used by the RAC in their opinion on the classified low molecular weight (LMW) Phthalates (DEHP, DBP, BBP, and DIBP). He recommended that for a combined assessment for DINP and DIDP the typical exposures for the different sources should be used.

The RAC concluded that the reasonable worst case exposure estimates from toys and childcare articles alone, would result in RCRs exceeding 1 for all age groups for both DINP and DIDP (RCRs of 2.0 for 0-6 months, 1.6 for 6-12 months and 1.3 for 12-18 months respectively) based on DNELs of 0.075 mg/kg for both DINP and DIDP, which includes a modification of the dose descriptor of a factor 2.

Overall, the RAC concluded that a risk from mouthing of toys and childcare articles with DINP and DIDP cannot be excluded if the restriction were lifted.

After editing by the Rapporteur and the Secretariat, the Chairman presented the draft opinion and asked the Committee for their final comments. He presented all the replies to the questions listed in the mandate one by one.

The RAC adopted the opinion by consensus.

The Chairman informed the Committee that the Secretariat will make an editorial check of the opinion. The Rapporteur will ensure that the supporting document to the opinion (annex) is in line with the adopted RAC opinion. The Secretariat will distribute the revised annex to the opinion to the RAC members by 18 March 2013 and will launch a short RAC consultation on the annex (5 working days).

6.4 Appointment of (co-) rapporteurs for restriction dossiers

The Secretariat presented and the RAC took note of the pool of (co-)rapporteurs for the restriction dossier on cadmium and its compounds in plastics and paints (to be submitted

by ECHA on request of the Commission by 17 January 2014) as outlined in the room document RAC/24/2013/07 CONFIDENTIAL. The agreement on the appointment of (co-) rapporteurs will follow later on this year.

7. Authorisation

7.1 Capacity building

a) Trial exercise

i. DNEL setting for DEHP

ii. DNEL setting for DBP

The Secretariat provided an update on the trial exercise "reference DNELs and dose response curves". Following the commenting round on the draft document "reference DNELs derivation for DEHP", the Secretariat presented the revisions and replies to the RAC member's comments.

In the document on DEHP (RAC/24/2013/08), the selection of endpoints had been further discussed. It was stressed that the endpoint for which the substance was added to the Annex XIV is the only relevant one to be used when demonstrating that the risks arising from the use of the substance are adequately controlled. It should be noted however, that occasionally there can be more than one endpoint behind Annex XIV listing but not in the case of DEHP. The Secretariat clarified that an analysis of alternatives is required as part of the application, and thus also information on other endpoints may be important to allow comparison with the properties of the alternatives.

A similar document on DBP (RAC/24/2013/09) had been prepared by the Secretariat and was presented by a RAC member.

Some RAC members questioned the intraspecies assessment factor of five used for pregnant workers in the DNEL derivation. As pregnant women may be part of the potentially exposed group and as they are specifically to be protected on the basis of the endpoint reproductive toxicity, the same assessment factor as for the general public should be used, they argued.

Other RAC members considered an assessment factor of five justifiable also for pregnant workers, because the factor of 10 refers to the very young, very old and very ill individuals present in the general population, and they would not be part of the working population.

In general, RAC members were of the opinion that the participation of pregnant workers in the working population must be assumed; this needs to be addressed in the risk assessment under the authorisation regime.

The Cefic stakeholder observer (STO) stressed the importance to inform possible applicants for authorisation in a timely manner about the reference DNELs in order to set their applications on the right track using the most recent studies, selecting the relevant endpoints and choosing assessment factors according to ECHA's guidance.

The EEB Stakeholder stressed that discussions relevant to these phthalates were on-going as to whether as a consequence of their endocrine disrupting properties they could be considered to have no safe exposure level. The Chairman pointed out that the Committees' task is to concentrate on the assessments requested of it according to the current legislation, which in the case of the phthalates DEHP and DBP is the assessment of their reproductive properties in advance of applications for authorisation under REACH.

The RAC agreed to the Secretariat's proposal to revise the documents on the reference DNELs for DEHP (RAC/24/2013/08) and for DBP (RAC/24/2013/09) according to the discussions above. The DEHP document is to be additionally revised to be in line with the RAC conclusions reached on the absorption of DEHP in the opinion on the phthalates DINP/DIDP under agenda item 6.3.

RAC members requested a short consultation on the revised documents. In view of the short timelines for the upcoming last application dates for the substances in question an agreement is foreseen via written procedure on the revised and commented documents.

The RAC expressed once more appreciation for the work provided by the RAC members involved, in cooperation with the Secretariat and emphasised that these discussions will increase RAC's readiness for the upcoming authorisation process. RAC members expressed the need to further prepare for the authorisation process as a whole. It was highlighted that such an exercise would increase the RAC readiness of the authorisation process and would enable to estimate better the expected workload of RAC members in this process in the future.

b) Valuation of PBTs (joint RAC/SEAC session)

The Chairman reported that closing the gap between PBT hazard identification, risk assessment and impact assessment is a challenging task, with which the Committees may be faced in the near future – in the authorisation but also in the restriction process. For that reason the Secretariat had proposed the following session for the information of RAC and SEAC members.

The Chairman welcomed an invited expert to report on the results of their project entitled "A framework for valuing environmental impacts of PBT chemicals to inform decision-making on authorisation under REACH". The Chairman mentioned that the project had been funded by Luxembourg and had been initiated by a RAC member. He mentioned that this session should be seen as a thought starter, rather than a presentation of solutions.

The invited expert reported on ways to carry out monetary valuation of environmental impacts as a benchmark cost-benefit analysis (CBA) approach, non-monetary valuation of environmental impacts as a cost-effectiveness analysis (CEA) approach, and illustration of CEA on an example of HBCDD.

Following the presentation the Chairman opened the floor for discussions. One RAC member noted that at a policy level vPvB substances are treated equally with PBT substances. However, no toxicity or 'T' parameter is in place for vPvBs. Thus, using the proposed methodology, vPvB chemicals will receive lower scores. The member added that some of the data, which is needed for scoring, may not always be available. One RAC member noted that the 'T' criterion can also be assigned by the human health toxicity endpoints, such as acute toxicity, STOT SE or RE, CMR or endocrine disrupting properties.

The CEFIC stakeholder observer noted that a hazard-only based assessment does not reflect the true substance profile. He expressed his view that a monetisation factor could play a substantial role in substance identification. He also noted that there may be PBT substances available with a less hazardous profile. Although such gradation of severity of PBT consequences cannot be considered for the PBT identification, he expressed his view that it is extremely important that this is taken into consideration in the socio-economic analysis.

One Commission observer noted that the proposed methodology considers only hazard properties. He suggested introduction of other parameters, too (such as use, etc).

The RAC member, who commissioned the research on behalf of Luxembourg, mentioned that he appreciated the fruitful trans-disciplinary examination done by environmental economists and environmental chemists. He also noted that after two previous projects on impact characterisation, this one strives to achieve a consistent decision-making framework. The CBA benchmark model clarifies limitations of any pragmatic CEA model, he noted.

The Secretariat then introduced the work of the PBT expert group (EG). The PBT EG is coordinated by ECHA, and consists of approximately 15 experts, who are nominated by MSCAs, industry associations and NGOs. The PBT EG meets two to three times per year; in 2012 there were two meetings. The aim of the EG is to provide informal and non-binding scientific advice on questions related to the identification of PBT and vPvB properties of

chemicals. It was pointed out that if elements of PBT assessment and "PBT-hazard scoring" are used in documents discussed by the RAC, the PBT EG or a member could be consulted.

At the end of this session, a SEAC adviser reported on the continuation of their project "Economic Valuation of Environmental Impacts of Chemicals: SEA Methodology Development" commissioned by RIVM. The project started in May 2012, and it is expected to conclude in March 2013.

The Chairman thanked RAC and SEAC members for the lively discussion in this joint RAC-SEAC session. The aim of the session to initiate the thinking on the PBTs was met and welcomed by RAC and SEAC members. They expressed their interest to follow the developments in this field in the future.

8. RAC Manual of Conclusion and Recommendations

This agenda point was not discussed due to time constraints.

9. Guidance issues

a) Update on ECHA guidance activities

This agenda point was not discussed due to time constraints.

10. AOB

a) Commission's conclusions on the Review of REACH (joint RAC/SEAC session)

The Commission representative introduced the Commission's conclusions from the Review of REACH. The presentation summarised the context (objectives and legal obligations) of the Review, the scope and evaluation process, conclusions, recommendations as well as next steps. In general, the Commission had concluded that REACH functions well and delivers on all objectives that at present can be assessed. However, in the current framework, there is a need to reduce the impact on SMEs as well as to increase efficiency by all actors involved. Recommendations directly related to the RAC and SEAC were listed (e.g. the RAC and SEAC should improve their co-ordination; the Committees need to continue looking for more efficient ways of working and must be able to rely on strong support from the MSs, etc). It was also mentioned that a conference on the Review of REACH has been foreseen for March/April 2013.

Several RAC and SEAC members questioned the Commission's recommendation to improve the co-ordination between the RAC and SEAC, claiming that in their view this co-ordination has been functioning well. The Commission representative responded that the review had been carried out a year ago and indeed the co-operation of the two Committees has improved since then. The importance of maintaining the current co-ordination when the Committees start to process authorisation applications was also highlighted.

One participant asked how the Commission intends to decrease the impact of REACH on SMEs. The Commission observer replied that the first step has been revising the Fee Regulation, which has already been initiated. A stakeholder observer (CEFIC) noted that it is important to realize that the definition of SME is very strict under REACH and that due to this hardly any companies can be considered as SMEs. Reduction in fees does not improve the situation much.

Several members expressed concerns how the Committees would manage their workload in the future, when they start to process applications for authorisation. They explained that often the support of MSs to their nominated Committee members is very limited, although providing such support is an obligation of MSs according to REACH and members consider it very important.

The Commission representative confirmed that the views expressed at the meeting would be taken into account in further development of the follow-up actions of the Review of REACH.

b) New mandate to the RAC pursuant to Art. 77(3)(c) of the REACH

The Chairman informed the RAC about the new mandate from the Executive Director of ECHA requesting the RAC to draw up an opinion on whether **2-benzotriazol-2-yl)-4,6-di-tert-butylphenol** (UV-320) and **2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol** (UV-328) meet the criteria for repeated dose toxicity (STOT RE). The Annex XV dossiers for the substances were prepared by the German Competent Authority with a view to include UV-320 and UV-328 on the candidate list of Substances of Very High Concern (SVHC) by reason of their identification as PBT.

This is to allow the Member State Committee (MSC) to assess whether the proposed substances fulfil the criteria of Annex XIII of REACH for a Persistent, Bioaccumulative and Toxic (PBT) substance, recognising that UV-320 and UV-328 currently have no entry in Annex VI of the CLP Regulation which would cover repeated dose toxicity. The opinion of the RAC is requested at the latest at its 25th plenary meeting from 3 to 7 June 2013 and preferably before this date (by written procedure) in order to allow the MSC to meet their legal deadline for dealing with these substances.

The Secretariat sought volunteers as (co-)rapporteurs who have expertise in repeated dose toxicity to work on this task.

08 March 2013

Final

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
RAC 24, 05-08 March 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/24/2013**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC 24 minutes.
4b. Appointment of co-opted members **RAC** commented on the adoption of co-opted members, the required expertise and the proposed selection procedure for co-opting members expressing some reservations with the proposal by the secretariat. **RAC** agreed to re-discuss the adoption of co-opted members at a forthcoming plenary meeting(s).	**SECR** to redevelop the paper on co-opted members (RAC/24/2013/03) taking into account the RAC discussions. **SECR** to schedule the discussion of the redeveloped proposal at a forthcoming plenary meeting.
5. Harmonised classification and labelling (CLH)	
5.1 a Etridiazole	
RAC agreed to the classification and labelling for the hazard classes as indicated in bold in Table 2 below. Discussions on other hazard classes will be continued before or at RAC 25.	**Rapporteurs** to revise the draft opinion following the comments received and to provide it to the SECR. **SECR** to launch a second commenting round on the draft opinion until 5 April 2013. **Rapporteur** to revise the draft following the comments. **SECR** to distribute the revised draft opinion to RAC for possible adoption before or at RAC 25.
5.1 b Mandipropamid	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classifications as indicated in Table 1 below.	**Rapporteurs** to revise the opinion in accordance with the discussions in RAC and to provide it to the SECR. **SECR** to forward the adopted opinion and its annexes to COM and to publish it on the ECHA website.
5.1 c Fenoxaprop-p-ethyl	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classifications as indicated in Table 1 below.	**SECR** to make an editorial check of the opinion documents in consultation with the rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

5.1 d Isoxaflutole	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in Table 1 below.	**SECR** to make an editorial check of the opinion documents in consultation with the rapporteur if necessary. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1 e Tembotrione	
RAC discussed the draft opinion with a proposal for the harmonised classifications and agreed on classification for ENV endpoints as indicated in Table 2 below.	**Rapporteur** to revise the opinion in accordance with the discussions and the information provided by RAC on STOT RE (and full reports of already available study summaries) and to provide it to the SECR. **SECR** to launch the RAC consultation round on the revised opinion for STOT RE and Skin Sens. **Rapporteur** to revise the opinion on basis of the RAC comments and provide it to the SECR for the discussion at RAC 25.
5.1 f Potassium sorbate	
RAC adopted by consensus, the opinion with a proposal not to classify for Skin Irrit and to classify for Eye Irrit 2 as indicated in Table 1 below.	**SECR** to make an editorial check of the opinion documents in consultation with the rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1 g Nitric Acid	
RAC discussed the revised draft opinion and agreed on the classification subject to clarifications for Ox. Liq. 2 and the proposed SCLs (CLP and DSD), and for Acute inhalation toxicity, as indicated in Table 2 below.	**SECR** to clarify the issues and inform the rapporteur. **Rapporteur** to revise the draft opinion in accordance with the discussion in RAC. **SECR** to launch the written RAC consultation. **Rapporteur** to revise the draft opinion following the comments received and to provide it to the SECR. **SECR** to distribute the revised draft opinion to RAC for possible adoption before or at RAC 25.
5.1 h Flonicamid	
RAC discussed the draft opinion and agreed on all classifications except for carcinogenicity. The agreed hazard classes are indicated in Table 2 below.	**Rapporteur** to revise the draft opinion in accordance with the discussion in RAC. **SECR** to launch a RAC consultation. **Rapporteur** to revise the draft opinion following the comments received and to provide it to the SECR. **SECR** to distribute the revised draft opinion to RAC for possible adoption before

	or at RAC 25.
5.1 i Tricalcium diphosphide	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in Table 1 below.	**SECR** to make an editorial check of the opinion documents in consultation with the rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.1 j 8:2 Fluorotelomer alcohol (FTOH)	
RAC adopted by consensus, the opinion with a proposal not to classify for toxicity to reproduction as indicated in Table 1 below.	**SECR** to make an editorial check of the opinion documents in consultation with the rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.2 Requests under Article 77(3) (c) - CLH dossiers	
a. Gallium arsenide	
RAC discussed the key issues identified as crucial for the RAC decision and agreed on the harmonised classification for toxicity to reproduction in category 1B.	**Ad-hoc drafting group (incl. Rapporteurs)** to finalise the draft opinion based on the discussion and the agreement reached in the plenary meeting. **SECR** to launch the RAC editorial round with a view of reaching agreement on the final draft opinion. **SECR** to launch the public consultation on the draft opinion (in accordance with the mandate)
5.3 Appointment of RAC (co-)rapporteurs for CLH dossiers	
Call for expression of interest of (co-) rapporteur volunteerships for CLH dossiers listed in document **RAC/24/2013/04 CONFIDENTIAL**.	**SECR** to launch the written procedure for the agreement of appointment of (co-rapporteurs).
6. Restrictions	
6.2 Restriction Annex XV dossiers	
6. 2 a) Dichlorobenzene – 4th version of the 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 by consensus.	**Rapporteurs** to make final editorial changes to the justification of the opinion based on the discussions by Friday 8 March 2013. **Rapporteurs** to ensure that the supportive documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supportive documentation to SEAC. **SECR** to publish the adopted opinion and its supportive documentation on the ECHA website and CIRCABC IG.
6. 2 b) Nonyl phenol - outcome of conformity check	
RAC agreed that the dossier conforms to the Annex	**SECR** to compile the RAC and SEAC final

XV requirements and took note of the recommendations to the DS.	outcomes of the conformity check and upload this to CIRCABC. **SECR** to inform the DS on the outcome of the conformity check.
6. 2 c) Lead in consumer articles – outcome of conformity check	
RAC agreed that the dossier conforms to the Annex XV requirements and took note of the recommendations to the DS.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC. **SECR** to inform the DS on the outcome of the conformity check.
6.3 Requests under Article 77(3)(c) - restriction dossiers	
a) Non-classified phthalates (DINP and DIDP)	
RAC Rapporteur presented the 6th version of the draft opinion. **RAC** discussed the main changes made to the draft opinion after RAC 23 and the preceding WebEx meeting. **RAC** modified the draft opinion during the plenary meeting. **RAC** adopted the opinion by consensus.	**SECR** to make an editorial check of the opinion. **Rapporteur** to ensure that the supporting document to the opinion (annex) is in line with the adopted RAC opinion. **SECR** to distribute the revised Annex to the opinion to RAC by 18 March 2013. **SECR** to launch a short RAC consultation on the Annex (5 working days). **SECR** to publish the adopted opinion and its supportive documentation on the ECHA website and CIRCA IG.
6.4 Appointment of (co-)rapporteurs for restriction dossiers	
RAC took note of the pool for the appointment of (co-) rapporteurs for the substance on cadmium (room document ***RAC/24/2013/07 CONFIDENTIAL***).	**Members** to volunteer to be included into the pool of (co-)rapporteurs.
8. RAC Manual of Conclusion and Recommendations	
RAC/24/2013/10 This Agenda item was moved to future meetings.	
7. Authorisation	
Capacity building DNELs setting for DEHP/DBP	
RAC discussed the revisions made in the document draft reference DNELs for DEHP **RAC/24/2013/08** **RAC** discussed draft reference DNELs for DBP. **RAC/24/2013/09**	**SECR** to revise the documents based on the RAC discussions. **SECR** to launch a RAC consultation on the revised documents.
9. Guidance issues	
This Agenda item was moved to future meetings.	
Action points and main conclusions of RAC 24	
	SECR to upload the adopted action points to CIRCABC.

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

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

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	Mandipropamid	-	374726-62-2	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		Acute M = 1 Chronic M = 1	

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Mandipropamid	-	374726-62-2	N; R50-53	N R: 50/53 S: 60-61	N; R50-53: C ≥ 25% N; R51-53: 2,5% ≤ C <25% R52-53: 0,25% ≤ C < 2,5%	

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

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	ethyl (2R)-2-{4-[(6-chloro-1,3-benzoxazol-2-yl)oxy]phenoxy}propanoate	NYA	71283-80-2	Skin Sens. 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H317 H373 (kidneys) H400 H410	Wng GHS07 GHS08 GHS09	H317 H373 (kidneys) H410		Acute M=1 Chronic M=1	

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	ethyl (2R)-2-{4-[(6-chloro-1,3-benzoxazol-2-yl)oxy]phenoxy}propanoate	NYA	71283-80-2	Xn; R48/22 R43 N; R50/53	Xn; N R: 43-48/22-50/53 S: (2-)-24-37-46-60-61	N; R50-53: C ≥ 25% N; R51-53: 2,5% ≤ C <25% R52-53: 0,25% ≤ C < 2,5%	

Isoxaflutole

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

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
606-054-00-7	isoxaflutole (ISO); (5-Cyclopropyl-1,2-oxazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone	-	141112-29-0	Repr. 2 Aquatic Acute 1 Aquatic Chronic 1	H361d*** H400 H410	GHS08 GHS09 Wng	H361d*** H410		M = 10 M = 100	

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
606-054-00-7	isoxaflutole (ISO); (5-Cyclopropyl-1,2-oxazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone	-	141112-29-0	Repr. Cat. 3; R63 N; R50-53	Xn; N R: 50/53-63 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%	

Potassium sorbate

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

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
015-003-00-2	potassium (2E,4E)-hexa-2,4-dienoate	246-376-1	24634-61-5	~~Skin Irrit 2~~ Eye Irrit. 2	~~H315~~ H319	GHS07 Wng	~~H315~~ H319			

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
015-003-00-2	potassium (2E, 4E)-hexa-2,4-dienoate	246-376-1	24634-61-5	Xi; R 36~~/38~~	Xi R: 36~~/38~~		

*Text in the above table which has been struck through indicates the proposed removal of that part of the classification

Tricalcium diphosphide

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

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
015-003-00-2	calcium phosphide; tricalcium diphosphide	215-142-0	1305-99-3	Water-react. 1 Acute Tox. 2 Acute Tox. 3 Acute Tox. 1 Eye Dam. 1 Aquatic Acute 1	H260 H300 H311 H330 H318 H400	GHS02 GHS05 GHS06 GHS09 Dgr	H260 H300 H311 H330 H318 H400	EUH029 EUH032	M = 100	

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
015-003-00-2	calcium phosphide; tricalcium diphosphide	215-142-0	1305-99-3	F; R15/29 T^+; R26/28 Xn; R21 Xi; R38-41 R32 N; R50	F; T^+; Xi; N R: 15/29-21-26/28-32-38-41-50 S:(1/2)-3/9/14/49-22-26-30-36/37/39-43-45-60-61	N; R50: C ≥ 0,25%	

8:2 Flurotelomer alcohol (FTOH)
Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	8:2 fluorotelomer alcohol (3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecan-l-ol)	211-648-0	678-39-7	~~Repr. 1B~~	~~H360D~~	~~GSH08 Dgr~~	~~H360D~~			

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	8:2 fluorotelomer alcohol (3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecan-l-ol)	211-648-0	678-39-7	~~Repr. Cat 2; R61~~	~~T~~ ~~R: 61~~ ~~S: 53-45~~		

*Text in the above table which has been struck through indicates the proposed removal of that part of the classification

Table 2. Agreed new or revised hazard classes, category and hazard statement codes in Annex VI, CLP and DSD[5],

Etridiazole

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

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
613-133-00-X	etridiazole (ISO); 5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole	219-991-8	2593-15-9	Carc. 2 **Removal of (*) from Acute Tox. 4 *** **Removal of Acute Tox. 4 *** **Removal of Acute Tox. 3 *** **Adding of Skin Sens. 1B** ~~**Adding of STOT SE 3**~~	H351 **H302** **Removal of H312** **Removal of H331** **Adding of H317** ~~**Adding of H335**~~		**Removal of H312** **Removal of H331** **Adding of H317**		Adding of Acute M-factor 1 and Chronic M-factor 1	

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes

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

613-133-00-X	etridiazole (ISO); 5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole	219-991-8	2593-15-9	Carc. Cat. 3 **Removal of T; R23** **Removal of Xn; R21** **~~Adding of Xi; R37~~** **Adding of Xi; R43**	R40 **Removal of T** **Removal of R: 21-23** **Adding of R: ~~37-~~ 43**		

Tembotrione

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)		
	2-{2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl}cyclohexane-1,3-dione		335104-84-2	Skin Sens. 1 STOT RE 2 **Aquatic Acute 1** **Aquatic Chronic 1**	H317 H373 **H400** **H410**	GHS07 GHS08 GHS09 Wng	H410		**Acute M-factor 100** **Chronic M-factor 10**	

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	2-{2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl}cyclohexane-1,3-dione		335104-84-2	Xi; R43 Xn; R48/22 **N; R50-53**	Xi; Xn; **N** R: 42-48/22-**50/53** S:	**N; R50-53: C≥ 0,25 %** **N; R51-53: 0,025 % ≤C< 0,25 %** **R52-53: 0.0025 % ≤C< 0,025 %**	

Nitric acid

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

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
007-004-00-1	nitric acid ... %	231-714-2	7697-37-2	**Modify:** **Oxid. Liq. 2** **Add:** **Acute Tox. 1**	H272 **H330**	GHS03 **GHS06**	H272 **H330**	**EUH071**	**Modify:** Oxid. Liq. 2; H272: C ≥ 99% Ox. Liq. 3; H272: 99% > C ≥ 65 %	

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
007-004-00-1	nitric acid ... %	231-714-2	7697-37-2	**Add:** **T+; R26**	T+ R: 26 S: to be decided	**Modify:** O; R8: C ≥ 65 %	

Flonicamid

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

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code (s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	flonicamid; *(N*-(cyanomethyl)-4-(trifluoromethyl)pyridine-3-carboxamide)	N/A	158062-67-0	**Acute Tox. 4** (Carc. 2 or no classification)	**H302** (H351)	GHS07 Wng	H302			

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	flonicamid; *(N*-(cyanomethyl)-4-(trifluoromethyl)pyridine-3-carboxamide)	N/A	158062-67-0	**Xn; R22** Carc. Cat. 3; R40 or no classification	Xn R: 22(-40) S: to be decided		

Part III. List of Attendees of the RAC-24 meeting (5-8 March 2013)

RAC members	**ECHA staff**
BARANSKI Boguslaw	ATLASON Palmi
BARRON Thomasina	BARMAZ Stefania
BJORGE Christine	BOWMER Tim
BORGES Teresa	BROECKAERT Fabrice
BRANISTEANU Radu	CSAK Viktoria
CARVALHO João	De BRUIJN Jack
DUNAUSKIENE Lina	DVORAKOVA Dana
DUNGEY Stephen	ERICSSON Gunilla
GREIM Helmut	FUHRMANN Anna
GRUIZ Katalin	HELLSTEN Kati
HAKKERT Betty	HONKANEN Jani
JENSEN Frank	HUUSKONEN Hannele
KADIKIS Normunds	KIOKIAS Sotirios
KAPELARI Sonja	KLAUK Anja
KORATI Safia	KOKKOLA Leila
LEINONEN Riitta	KOSK-BIENKO Joanna
LUND Bert-Ove	LOGTMEIJER Christiaan
MULLOOLY Yvonne	LUDBORZS Arnis
PARIS Pietro	MAGGIORE Angelo
PASQUIER Elodie	MATTHES Jochen
PINA Benjamin	MERKOURAKIS Spyridon
POLAKOVICOVA Helena	MOSSINK Jos
PRONK Marja	NYGREN Jonas
RUCKI Marian	ORISPÄÄ Katja
RUPPRICH Norbert	RIVERO Debora
SCHLUETER Urs	RODRIGUEZ IGLESIAS Pilar
SCHULTE Agnes	ROGGEMAN Maarten
SMITH Andrew	SADAM Diana
SOERENSEN Peter	SOSNOWSKI Piotr
SPETSERIS Nikolaos	SPJUTH Linda
STOLZENBERG Hans-Christian	THUVANDER Ann
TADEO José Luis	VAINIO Matti
TSITSIMPIKOU Christina	Van HAELST Anniek
Van der HAGEN Marianne	ÖBERG Tomas

VIVIER Stéphanie		**Other observers**
		VARNAI Veda, Croatian observer
Invited experts		BILAU Maaike, Arcadis (an observer acting as an expert () to an observer representing Cefic for nitric acid)
PICHARD Annick (CLH Rapporteur, present on 5-6.3.2013)		DEKANT Wolfgang, University of Würzburg (an expert to an observer representing EuPC for non-classified phthalates)
		GELBKE Heinz-Peter, Cintox (an observer acting as an expert to an observer representing Eurometaux for Gallium Arsenide)
Advisers (to the RAC members)		MASANAO N, ISK Japan (an observer acting as an expert to an observer representing ECPA for flonicamid)
JANONYTE Agne (Dunauskiene) adviser for CLH Rapporteurs for nitric acid		SEMINO-BENINEL Giovanna, Bayer CropScience (an observer acting as an expert to an observer representing ECPA for fenoxaprop and tembotrione)
KORHONEN Hanna (Leinonen)		SEREX Tessa, DuPont (an observer acting as an expert to an observer representing Cefic for FTOH)
MAHIOUT Selma (Leinonen)		SHIPP Elizabeth, Bayer CropScience (an observer acting as an expert to an observer representing ECPA for isoxaflutole)
MC MICKAN Sinead (Mullooly)		SARGINSON Nigel, ExxonMobil (an observer acting as an invited expert to an observer representing CEFIC for non-classified phthalates)
NÚÑEZ Laura (Tadeo) adviser for CLH Rapporteurs for tembotrione		
PAPPONEN Hinni (Leinonen)		**Remote participants**
PECZKOWSKA Beata (Baranski) adviser for CLH Rapporteurs for flonicamid, nitric acid and tricalcium		**DSs:**
ROMOLI Debora (Paris)		GUNNARSDOTTIR Sjöfn (NL DS for etridiazole and isoxaflutole)
SMITH Helen (Smith)		MÜLLER Andre (NL DS for etridiazole and isoxaflutole)
		LARSEN Ann-Kristin (NO DS for FTOH)
SEAC restriction rapporteurs		CEDERBERG Inger (SE DS for nonyl phenol)
BOUSTRAS Georg (lead)		VASS Anne Marie (SE DS for lead)
FANKHAUSER Simone (nonyl phenol)		BERNAUER Ulrike (DE DS for nitric acid)

FIORE-TARDIEU Karine (nonyl phenol)		EPPLER Rosemarie (DE DS for nitric acid)
KIISKI Johanna (lead)		**Commission observers:**
		GARCIA-JOHN Enrique (Commission observer (ENTR) for restrictions)
<u>Commission observers</u>		GIRAL-ROEBLING Anne (Commission observer (ENTR) for restrictions and non-classified phthalates)
ROZWADOWSKI Jacek (DG ENTR)		LUVARA Giuseppina (Commission observer (ENTR) for restrictions and authorisations)
SCAZZOLA Roberto (DG ENTR)		STRECK Georg (Commission observer (ENTR) for authorisations)
LEFEVRE Remi (DG ENV)		**Advisers:**
		STARKE Sue-Martina (adviser to RAC member Hans-Christian Stolzenberg)
<u>Stakeholder observers</u>		
ROWE Rocky (ECPA)		**<u>Excuses</u>**
HENNES Christa (ECETOC)		GRUIZ Katalin (RAC member)
ANNYS Erwin (CEFIC)		di PROSPERO Paola (RAC member)
SANTOS Tatiana (EEB)		STASKO Jolanta (RAC member)
CLAES Walter (EuPC)		TROISI Gera (RAC member)
VEROUGSTRAETE Violaine (Eurometaux)		LOSERT Anne-Marie (RAC member)
		MORRIS Alick (SCOEL)
		MUNARI Tomaso EuCheMS)
		TAYLOR Katy (ECEAE)
		Del CASTILLO Francisco (Concawe)

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

SEAC Members
ALEXANDRE João
BENDL Jiri
BOUSTRAS Georgios
BRIGNON Jean-Marc
CSERGO Robert
DALTON Marie
DANTINNE Catheline
FANKHAUSER Simone
FEYAERTS Jean-Pierre
FIORE-TARDIEU Karine
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
GULBRANDSEN Magnus Utne
KIISKI Johanna
KNOFLACH Georg
LADOPOULOU Angela
LUTTIKHUIZEN Cees
RODRIGUEZ DE SANCHO Maria Jesus
SCHUCHTAR Endre
SIMON Franz Georg
SKARŽINSKAS Vitalius
THIELE Karen
THORS Åsa
TIRCHILA Liliana Luminita
VOIVONTAS Dimosthenis

ECHA staff
DUBOURG Richard
JACQUEMIN Katline
MOTTET Denis
PELTOLA-THIES Johanna
RODRIGUEZ IGLESIAS Pilar
SHUQOM Natasha

Advisors, Invited Experts, DSs (DS) & Observers
CASTELLI Stefano (Invited Expert, IT)
COGEN Simon (Advisor to J-P. Fayaerts)
D'AMICO Flaviano (Invited Expert, IT)
GABBERT Silke (Invited expert)
GOLOVACIOVA Llona (Advisor to V. Skarzinskas)
HENNIG Philipp (Advisor to K. Thiele)
KORHONEN Hanna (Advisor to J. Kiiski)
LESTANDER Dag (Nonylphenol DS representative)
PUES Jonathan (Advisor to C. Dantinne)
SCHOU Jorgen Peter (Advisor to L. Fock)
SLETTEN Thea Marcelia (Advisor to M.U.Gulbrandsen)
VASS Anne Marie (SE DS for lead)
VERHOEVEN Julia (Advisor to C. Luttikhuizen)

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

Representative of the European Commission
BENGYUZOV Manol (DG ENTR)
ZIELINSKI Janusz (DV ENV)

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-24 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-24 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-24 meeting

5 March 2013
RAC/A/24/2013

Final Agenda
24th meeting of the Committee for Risk Assessment

5-8 March 2013
ECHA Conference Centre (Annankatu 18, Helsinki)
5 March: starts at 9:00
8 March: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

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

RAC/24/2013/01
RAC/24/2013/02
For information

b) Appointment of co-opted members pursuant to REACH Art. 85.4 (CLOSED SESSION*)*

RAC/24/2013/03
CONFIDENTIAL
For discussion/agreement

Item 5 – Harmonised classification and labelling (CLH)

5.1 CLH dossiers

a) Etridiazole
b) Mandipropamid
c) Fenoxaprop-p-ethyl
d) Isoxaflutole
e) Tembotrione
f) Potassium sorbate
g) Nitric acid
h) Flonicamid
i) Tricalcium diphosphide
j) 8:2 Fluorotelomer alcohol (FTOH)

For discussion/adoption

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

a) Gallium arsenide

For adoption

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

RAC/24/2013/04
CONFIDENTIAL
For agreement

5.4 General and procedural CLH issues

a) State of play of CLH dossiers

RAC/24/2013/05 (Room document)
For information

b) Opinion development process *(partly CLOSED SESSION)*

RAC/24/2013/06
CONFIDENTIAL
For information/discussion

Item 6 – Restrictions

6.1 General restriction issues

a) Update on intended restriction dossiers

For information

6.2 Restriction Annex XV dossiers

a) Dichlorobenzene – 4th version of the draft opinion

For adoption

b) Nonyl phenol - outcome of conformity check

For agreement

c) Lead in consumer articles – outcome of conformity check

For agreement

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

- Non-classified phthalates (DINP and DIDP)

For adoption

6.4 Appointment of (co-)rapporteurs for restriction dossiers

RAC/24/2013/07 (Room document)
CONFIDENTIAL
For information

Item 7 – Authorisation

a) Capacity building
   - Trial exercise
     i. DNEL setting (DEHP)

RAC/24/2013/08
For agreement

ii. DNEL setting (DBP)

RAC/24/2013/09
For discussion/agreement

   - Valuation of PBTs

For information

Item 8 – RAC Manual of Conclusion and recommendations

RAC/24/2013/10
For information/agreement

Item 9 – Guidance issues

- Update on ECHA guidance activities

Item 10 – AOB

- Commission's conclusion on the review of REACH

Documents submitted to the members of the Committee for Risk Assessment for the RAC-24 meeting.

Number	**Title**
RAC/A/24/2013	Final Draft Agenda
RAC/24/2013/01	Report on RAC 23 action points and written procedures
RAC/24/2013/02	Report on other ECHA bodies
RAC/24/2013/03 (confidential)	Appointment of co-opted members
RAC/24/2013/04 (confidential)	Appointment of RAC (co-) rapporteurs for CLH dossiers
RAC/24/2013/05 (room document)	State of play of CLH dossiers
RAC/24/2013/06 (confidential)	Opinion development process
RAC/24/2013/07 (room document, confidential)	Appointment of RAC (co-) rapporteurs for restriction dossiers
RAC/24/2013/08	Authorisation, establishing reference DNELs for DEHP
RAC/24/2013/08 Annex	Response-to-comments table
RAC/24/2013/09	Authorisation – establishing reference DNELs for DBP
RAC/24/2013/10	RAC Manual of Conclusion and recommendation

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

Name of participant	**Potential conflict of interest in relation to**	**Reason**
RAC members		
Christine BJORGE	8:2 Fluorotelomer alcohol (FTOH)	His or her institution'sparticipation in the preparation of the dossiers submitted by the MSCA
Bert-Ove LUND	Lead in consumer articles Nonyl phenol	His or her institution's participation in the preparation of the dossiers submitted by the MSCA
Elodie PASQUIER	Mandipropamid Gallium Arsenide	His or her institution's participation in the preparation of the dossiers submitted by the MSCA
Hans-Christian STOLZENBERG	Potassium sorbate Nitric acid Tricalcium diphosphide	His or her institution's participation in the preparation of the dossiers submitted by the MSCA
Agnes SCHULTE	Nitric acid	His or her institution's participation in the preparation of the dossiers submitted by the MSCA
Marianne van der HAGEN	8:2 Fluorotelomer alcohol (FTOH)	His or her institution's participation in the preparation of the dossiers submitted by the MSCA
Invited expert		
Annick PICHARD	Gallium Arsenide	Carry forward from the last meeting (RAC-23). His or her institution's participation in the preparation of the dossiers submitted by the MSCA

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