MSC/M/34/2014
ADOPTED AT MSC-35

Minutes
of the 34th Meeting of the Member State Committee (MSC-34)
3-7 February 2014

I. Summary Record of the Proceedings

Item 1 - Welcome and Apologies

The Chair of the Committee, Ms Anna-Liisa Sundquist, opened the meeting and welcomed the participants to the 34th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

Item 2 - Adoption of the Agenda

The Agenda was adopted as modified at the meeting based on the draft agenda as provided for the meeting and SECR's suggestion for inclusion of three sub-items under AOB (final Agenda is attached to these minutes).

Item 3 - Declarations of conflicts of interest to the items on the Agenda

One member declared a potential conflict of interest in respect to the dossier evaluation case TPE 189/2013 (based on the annual declaration as published on the ECHA website) and was therefore considered not to be in a position to participate in the vote for this case. No conflicts of interests were declared by other members, experts or advisers with any other items on the agenda of MSC-34.

Item 4 - Administrative issues

- **Annual declarations for the membership**

The Committee was reminded to fill in, sign and submit to SECR the annual declaration of interests and of commitment forms during the meeting.

- **Satisfaction survey – oral report**

SECR provided an overview of the follow-up activities from the 2012 satisfaction survey confirming that all three action points had been performed - workshops on Areas of Concern and Substance Evaluation were held last year, links between the published ECHA recommendations and the respective MSC opinions were created on the ECHA website and information on the criteria and current practices of the open and closed sessions were made available on the ECHA website.

SECR thanked all the respondents of the 2013 satisfaction survey results. The survey results were being analysed by the SECR, so it could provide an oral report with the first assessment results. It was explained that responses were received from 24 out of 49 members and alternate members (response rate 49%) and 10 out of 18 stakeholder observers (response rate 56%). Overall, satisfaction of members was high; above 75% responded 'satisfied' or 'very satisfied'. The highest satisfaction rate was given to the chairing of the meeting (92%), preparation of the minutes and action points, and on the conference operators and audio-visual services. Additional comments were received and these will be further examined by the SECR after the meeting.

Stakeholder observers expressed medium satisfaction; more than 50% responded 'satisfied' or 'very satisfied'. The highest satisfaction rate was reached on conference operators and audio-visual services (100%) and the lowest of 44% was provided on preparation of the minutes and action points, and also on the secretarial support as regards the meeting documents.

The feedback was considered very useful and can help SECR to improve its work. The response rate was not very high, but this is probably due to the high frequency of the survey.

Following the meeting a written report with an action plan would be provided on MSC CIRCABC.

Item 5 – Adoption of the minutes of the MSC-33 meeting

SECR presented the revised version of the MSC-33 minutes informing MSC that written comments on the draft minutes were received in advance of the meeting. The minutes

were adopted with some changes made in the meeting. SECR would upload the minutes on MSC CIRCABC and ECHA website.

Item 6 - Substance evaluation decision-making

a. Written procedure report on seeking agreement on draft decisions on substance evaluation

SECR gave a report on the outcome of the written procedure (WP) for agreement seeking on four substance evaluation cases[1]. WP was launched on 10 January 2014. By the closing date 21 January 2014, responses to WP were received from 25 members with voting right and from the Norwegian member. Unanimous agreement was reached for three draft decisions. On the closing date 21 January 2014, the MSC Chair terminated the WP for one DD[2] on the basis of Article 20 (6) of the MSC Rules of Procedure, as one MSC member requested discussion at the MSC-34 meeting.

b. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA/ECHA reactions *(Session 1, open session except for case SEV-DE-009/2012)*

c. Seeking agreement on draft decisions when amendments were proposed by MS's/ECHA *(Session 2, closed)*

SEV-IT-021/2012 Hydroquinone (EC No. 204-617-8)

Session 1 (open)

Two representatives of the registrants participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

eMSCA expert from Italian CA (IT CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance performed by IT CA on the basis of the initial grounds for concern, i.e. relating to human health effects/CMR, Exposure/Wide dispersive use, consumer use, high aggregated tonnage, risk characterisation ratios close to 1 (human health). The members were guided through the information requirements and explained that additional concerns were identified during the process of the evaluation. These were toxicity for the respiratory tract (acute toxicity and sub-chronic), quality of the exposure assessment and DNEL derivation, effects on different environmental compartments, environmental exposure assessment and the risk characterization for all the identified professional uses, risk characterisation ratio close to 1 for the environment, and potential long term effects on aquatic compartment.

Fourteen PfAs were submitted by five MSCAs and ECHA.

Regarding the requirement for the mutagenicity testing eMSCA proposed to the Registrants to perform either a transgenic rodent somatic and germ cell gene mutation assay (TGR) or a comet assay in rats, oral route. Based on the available *in vitro* and *in vivo* study results and on the harmonised CLP classification as germ cell mutagen 2 – three PfAs agreed on the need to perform an *in vivo* study on germ cells. One PfA proposed to request only the TGR (in the target tissues as specified by the eMSCA) and suggested to provide two options for the route of administration in a TGR study, via oral (gavage) or by inhalation. Another PfA proposed to request only an *in vivo* comet assay in this case to detect a possible induction of gene mutations and/or clastogenic effects. In the absence of the test guideline this PfA proposed that the test design shall be agreed on by the eMSCA. A third PfA proposed the TGR or comet assay in the target organs (kidney, stomach, bone marrow, liver and germ cells) and to add as justification for these organs a reference to target organs for carcinogenesis, the site of contact and the systemic targets and to

[1] N-(1,4-dimethylpentyl)-N'-phenylbenzene-1,4-diamine (EC No 221-374-3), tris(2-ethylhexyl)-benzene-1,2,4-tricarboxylate (EC No 222-020-0), n-hexane (EC No 203-777-6), decan-1-ol (EC No 203-956-9)

[2] N-(1,4-dimethylpentyl)-N'-phenylbenzene-1,4-diamine (EC No 221-374-3)

include in the analysis slow and fast replicating tissues. Furthermore, this PfA suggested requesting the comet assay according to experimental protocols currently agreed by EFSA.

Regarding request for clarification of the initially indicated "CMR" concern one PfA requested clarification of this term i.e. whether the concern is C or M or R.

Regarding genotoxicity and carcinogenicity endpoints one PfA proposed to add a paragraph to justify route to route extrapolation.

Regarding the testing requirement for acute toxicity, rat, by inhalation, one PfA proposed to delete the request because there are no sufficient triggers for the study, and the reasoning for rejection of the read-across with resorcinol was considered unclear.

Regarding long-term toxicity testing on fish (OECD 210 (FELS)) and long-term toxicity testing on soil invertebrates and plants (invertebrates OECD 220 or OECD 232; plants OECD 208 or ISO 22030), the tiered approach presented was considered acceptable, however, one PfA proposed to introduce a paragraph in Section III explaining the rationale for the tiered testing based on results of the fish study and derived $PNEC_{water}$ and based on this information determination of the need for further testing on terrestrial organisms, since EPM method is not applicable but short term toxicity testing on soil micro-organism shall be performed irrespective of the results of the aquatic toxicity testing. Another PfA was submitted on the fish test, OECD 210 (FELS), proposing that this test is only required if the aquatic RCRs exceed one thus proposing to amend the justification and proposing that long-term aquatic testing may be required if risks are identified. Another PfA on this end point proposed that it may be more practical or appropriate to assess the degradant in any further ecotoxicity testing. Therefore it proposed that the registrant shall conduct a pre-test experiment to determine whether the FELS study should be conducted using a pre-oxidised test solution or the parent substance. Linked to this, another PfA proposes to include in DD a sentence requesting that the registrant shall include analysis of the known oxidised degradant p-benzoquinone in the test.

Other PfAs related to human exposure assessment proposed to include in Section II a request to perform transparent quantitative exposure assessments for all relevant exposures and to develop exposure scenarios and contributing scenarios accordingly; to further elaborate the conclusion on human risk characterisation in CSR; editorial comments and a general comment to include the Registrant's comments in the DD.

eMSCA responded to the PfAs and amended the DD provided for the meeting in accordance with the PfAs on the editorial suggestions, on specifying the protocol for the comet assay, on considering threshold in the *in vivo* genotoxicity testing, concerning route-to-route extrapolation, regarding tiered long-term toxicity testing on fish (FELS) and soil invertebrates and plants as well as use of EPM method and on human exposure assessment.

Registrants' comments on PfAs and discussion

The registrants provided written comments on the PfAs submitted and highlighted some of those comments in the discussion in the meeting.

Regarding genotoxicity the registrants agreed that the results in the databases on *in vivo* and *in vitro* are not consistent, however they listed a number of arguments not supporting TGR for testing mutagenicity, among other things problems in finding a CRO to offer conducting the TGR assay in transgenic rats. The Registrants considered that there are already many *in vivo* mutagenicity studies available on hydroquinone and they raised animal welfare concerns with testing. Furthermore they disagreed with the request to perform the test on five organs since only a couple of tissues are anticipated to be initially offered in the transgenic rat model (with an adequate control background reference database), once it will be commercially available in a GLP laboratory.

The registrants did not consider the proposal for inhalation route of exposure relevant as there is currently no data available by this route in standard rodent strains and very little experience in the CRO for the relevant tissues in the transgenic models. They explained that the concern on the respiratory tract was based on only one study which was not included in the original dossier as hydroquinone was one of the raw materials used on that

site and it was used in a process together with other substances. Furthermore, no exposure assessment to hydroquinone is available from that study, and the qualitative exposure assessment was based on a questionnaire which listed questions to determine the activity associated with or the presence near (same building) various production processes, some of which involved hydroquinone amongst other substances.

The registrants concluded that overall the lack of the rat model availability for TGR and acknowledgment of the current technical limitations should be carefully considered by the regulators in their decision making process and in setting the deadline for submission. If comet assay is requested the registrants suggested a study to start once the OECD test guideline is published.

Regarding long term toxicity test on fish, the registrants agreed with one PfA that there is the need to perform this study only if RCR is above 1 which is not the case in the dossier submitted. The study that eMSCA based the decision for FELS on was not considered reliable by the registrants. Considering the instability of the substance in water, the registrants agreed with the PfA proposing pre-test experiments to determine the suitable exposure conditions in the assay. Additionally, analysis of hydroquinone and p-benzoquinone in the test chambers should be performed during the study. If a long term toxicity study on fish has to be done, the registrants proposed to perform this study in a flow-through test. As these technical parameters can greatly influence the expression of the results of the long-term toxicity test on fish, the registrants asked for these elements to be provided in the final decision.

Regarding long-term toxicity on soil invertebrates and plants the registrants agreed with the PfA to apply the ITS for the determination on the need of long-term tests on terrestrial organisms. In a first step, the registrants will perform the long-term toxicity testing on fish, the soil micro-organisms toxicity testing and the refinement of the environmental exposure assessment. Only when the risk assessment demonstrates environmental RCR values greater than 1, the long-term toxicity testing on soil invertebrates and plants as requested by the evaluating MSCA will be performed and the risk assessment will be recalculated.

Regarding toxicity to soil micro-organisms the registrants suggested that the decision confirms that the equilibrium partitioning method is a good method based on their comments to the PfAs.

Furthermore the registrants highlighted that a response to their comments submitted to eMSCA was not received and considered it helpful if the decision making process can ensure that the registrant is informed on whether their comments have been considered or not. With reference to the uses listed in the introduction by eMSCA, the Registrants' representatives explained that photographic processing use has declined significantly together with consumer use. The classification of the substance was updated at the end of 2012 in their registration dossier and they consider it compliant. They added aquatic chronic 1 to be in line with the latest ATP of the CLP.

The discussion following the intervention by the representatives of the Registrants focused on whether to ask for TGR or comet assay or both. In their deliberations the Committee considered all the points raised by the registrants including the current lack of availability of a CRO able to perform a TGR in rats on all the five tissues listed, the current lack of a published OECD guidance on comet assay, and that the draft OECD guidance on comet assay considers that it is not applicable for/excludes specific assessment of germ cell mutagenicity. The Committee recognised that the comet assay can demonstrate that a substance is reaching the gonads after passing the gonadal barrier, and that when the somatic cells in the gonads are affected it could also be affecting the germ cells in the gonads. However, whether such results are sufficient to conclude on the classification of a substance as a mutagen category 1B is not within the remit of the MSC.

Regarding the acute inhalation toxicity study, the main concern related to the local effects of the substance. The discussion focused on whether this concern can be tackled through the sub-chronic toxicity study. In this context the risk of dust explosion when preparing

the atmosphere for the test was highlighted. Substance specific alerts for explosivity have not been identified in the dossier.

Regarding the FELS the eMSCA expert explained that the main degradants have the same acute toxicity as the parent hence considered it not relevant to distinguish between the parent and the degradant. Since the Registrants agree to perform FELS in a flow through test and the test guideline has the modification of a flow through test embedded in it, the eMSCA did not see the need for requesting an additional test using pre-oxidized test solution.

Session 2 (closed)

Based on the above considerations, MSC further amended the draft decision. MSC unanimously agreed to maintain the request for a transgenic rodent somatic and germ cell gene mutation assay (TGR) in rats treated via oral administration, in kidney, stomach, bone marrow, liver and germ cells or alternatively an *in vivo* alkaline comet assay performed in rats by oral administration, in stomach or duodenum, liver, kidney and gonadal cells; to delete the request for acute toxicity study in rats by inhalation; to maintain the request for sub-chronic toxicity study in rats by inhalation, however, subject to reliable and verifiable documentation of a ST3-rating regarding the explosivity of hydroquinone dust; to request transparent quantitative exposure assessment for all relevant exposures including development of respective exposure scenarios and to request justification of the route to route extrapolation from oral route to dermal/inhalation routes in consideration of the fact that the available carcinogenicity and genotoxicity studies are performed via oral route.

They also agreed that regarding long-term toxicity testing on fish (test method: OECD 210 (Fish Early-Life Stage Toxicity Test)) the OECD Guidance document on aquatic toxicity testing of difficult substances and mixtures is to be taken into account in consideration of the rapid degradation of hydroquinone into p-benzoquinone in aqueous solution.

Further clarifications in Section III, statement of reasons on the rationale for requesting the information specified above was added to the draft decision. Other testing requirements, including some amendments eMSCA had already implemented to the draft decision prior to the meeting, were not further discussed at the meeting. The MSC unanimously agreed on the decision, as further amended at the meeting.

SEV-IT-019/2012 Chloromethane (EC No. 200-817-4)

Session 1 (open)

Two representatives of the registrant working for a consortium on Chloromethane participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

eMSCA expert from IT CA presented the outcome of SEv of the above-mentioned substance performed by IT CA on the basis of the initial grounds for concern, i.e. relating to the classification, exposure and endocrine disruption. The members were guided through the information requirements and explained that additional concerns were identified during the process of the evaluation. These were environmental risk assessment and DMEL derivation.

Five PfAs were submitted by two MSCAs and ECHA.

Two general PfAs were submitted. One to explain in Section I why inhalation route is requested for developmental toxicity testing and another one to reflect the registrants' comments on developmental toxicity study and to justify in Section III why Section II was not amended based on the those comments. Furthermore, this PfA also requested inclusion of a motivation for the route of administration (inhalation) and to add an explanation in response to the registrants' comments on registration of transported isolated intermediates.

Regarding endocrine disruption (ED) one PfA noted that no information on such mechanism of toxicity was provided by the registrants, however, certain studies quoted indicate such effects. Thus this PfA requested to add in Section II a requirement for the

registrants to consider all available information and if needed perform confirmatory studies to evaluate the ED to make it possible to conclude whether the substance is or is not an ED.

Regarding personal protective equipment (PPE), a PfA proposed to add in Section II a request to provide sufficient and consistent information on the specifications of PPE especially those related to respiratory protection.

With regards to DNEL derivation in the risk assessment, a PfA proposed to request to the Registrant a DMEL derivation in accordance with REACH guidance R8 because of the genotoxic potential of the substance.

eMSCA responded to the PfAs and amended the DD provided for the meeting in accordance with all PfAs received except the PfA on ED effects.

Registrants' comments on PfAs and discussion

Written comments were received from registrants working together in a consortium on chloromethane and additionally comments were received from a Registrant on his own behalf.

The registrants that submitted comments together and were present at the meeting stated that the DD does not reflect on their comments and thus gives an impression that these have not been taken into consideration when revising the DD. Therefore the registrants resubmitted the comments originally submitted to the eMSCA including justifications why they do not agree with the developmental toxicity study in rabbit by inhalation as requested in DD. Their major point was that in view of the DNELs derived and the clear negative outcome in rats classification into category 2 based on the equivocal effects in the mice study is sufficiently conservative and cannot be better clarified by an additional rabbit study. Regarding the DNEL derivations they have asked a scientific expert to review whether the German OEL-value (MAK) for chloromethane can be considered equivalent to a DNEL within the REACH framework. The conclusion of this review was that the OEL may not be sufficiently conservative according to REACH regulation, but adequate DNELs can be derived from the data available. The consortium agreed to include the expert review in the next dossier update. The registrants referred to the ongoing work to establish a new OEL by SCOEL. Regarding the endocrine disruption effects, the registrants state that the consortium and the scientific experts they engaged for a review of the available information are of the opinion that endocrine disruption is not a relevant mode of action for the effects on sperm quality and fertility. The available data is sufficient to derive conservative DNELs for the effects on fertility as the relevant endpoint.

The other registrant submitted a written comment stating that because his registration in the joint submission is only as a transported isolated intermediate demonstrating strictly controlled conditions studies like on developmental toxicity and a chemical safety report including an exposure assessment are not required.

During the meeting the registrant's representatives highlighted the written comment regarding developmental toxicity testing. Regarding the risk assessment the representatives of the Registrant reconfirmed their intention to update the dossier with the DNELs proposed in their comments. This together with their proposed classification of the substance would lead to a higher level of risk management measures applied and thus ensure safe handling of the substance without further testing. They however objected to DMEL derivation based on the possible genotoxic mechanism in the induction of kidney, tumours in treated male mice only.

During the discussion it was pointed out by the Chair that since no PfA was submitted on the request for the test on developmental toxicity on rabbit by inhalation there was no need for it to be discussed by MSC. Regarding the PfA on DMEL derivation there was a consensus view that if genotoxicity for a substance classified as carcinogen cannot be excluded then a request for DMEL derivation is justified. The registrant's representatives explained that all *in vivo* genotoxicity testing is negative even under extreme conditions used in the tests (e.g. exposure concentration of 7000ppm for up to 9 days). Furthermore, they considered there are well elaborated mechanistic consideration for the species and

target organ specificity. When performing a weight of evidence analysis they conclude that it is unlikely that a direct genotoxic agent is leading to species, gender and organ specific carcinogenic response. In case there is a genotoxic effect one will not only observe tumours in male mouse kidneys, but also in female mice and both in male and female rats and other organs and tissues.

Session 2 (closed)

Based on the above considerations, and that the risk characterisation of chloromethane should take into account the possibility that a genotoxic mechanism is involved in the carcinogenicity of the substance MSC unanimously agreed to request justification for deviating in DMEL derivation and DNEL derivation from the requirements in the REACH guidance R8. Furthermore, MSC unanimously agreed to amend the decision and request sufficient and consistent information on the specification of personal protective equipment and the duration of use for all scenarios where the use of personal protective equipment is advised and to add some further clarifications in Section III, statement of reasons on the rationale for requesting the information specified above.

MSC unanimously agreed on this SEV DD as modified at the meeting.

SEV-DE-009/2012 Polyhaloalkene (EC No. 468-710-7)

Session 1 (closed)

Two representatives of the Registrants participated in the initial discussion. A closed session was held upon the Registrants' request.

eMSCA experts from German CA (DE CA) presented the outcome of SEV of the above-mentioned substance performed by DE CA on the basis of the initial grounds for concern, i.e. high aggregated tonnage, wide dispersive use, hazardous degradation products and high environmental exposure. During the evaluation an additional concern for mutagenicity had been identified. The members were guided through the information requirements and how the PfAs received and the Registrants' comments have been taken into account in the DD.

Six PfAs were submitted on the DD by two MSCAs and ECHA.

Regarding mutagenicity testing *in vivo* using transgenic rodent mutation assay (TGR, OECD 488) one PfA was proposing to give the option to the Registrant to perform either TGR, or comet assay, as both are suitable methods to investigate the mutagenicity concern in somatic cells. Furthermore, a specification was suggested of the species (for TGR testing - mice by inhalation or for comet assay - rats by inhalation) as well as tissues (lung, liver, bone marrow). Another PfA on the same issue supported the request for TGR only but requested to specify the somatic tissues to be sampled and proposed stomach, liver, intestine, bone marrow and testes to be sampled, as testes should be analysed in case a positive result is obtained in any of the somatic tissues.

One PfA proposed to re-phrase the statement of reasons in the DD for better expressing the mutagenicity/carcinogenicity concerns by using the conditional requirement for a carcinogenicity testing dependant on the results of the required TGR and of the ongoing repeated dose toxicity study in rabbits.

Concerning the requested detailed information on exposure scenarios and exposure estimations for the general population as regards hydrogen fluoride and carbonyl difluoride when generated as thermal degradation products, a PfA proposed to add to DD a clarification that hybrid vehicles are covered by the MAC (Mobile Air Conditioning) Directive.

Another PfA proposed to remove/amend the request for justification for not using a plausible auto-ignition temperature (AIT) in the risk assessment for the reasons that the conditions to determine the AIT in the laboratory test according to EU A.15 are not corresponding to the real conditions which occur during a car operation. Therefore the request was considered as not grounded for the MSCA that made this PfA.

A PfA also suggested the results of the eMSCA assessment of potential ED properties (which concluded that concern in this regard was low and no further data were needed at this point) to be mentioned in the summary conclusion document.

eMSCA has responded to the PfAs (RCOM) and amended the DD prior to the MSC meeting motivated by the two PfAs on mutagenicity testing. Further clarification has been made in the DD motivated by the PfAs concerning the testing strategy for carcinogenicity and on vehicle coverage by the MAC Directive. However, the eMSCA found no need to modify the DD based on the PfA regarding AIT and based on the PfA regarding ED indications.

Registrants' comments on PfAs and discussion
The Registrants provided written and oral comments on the DD and the PfAs received. In their comments concerning the *in vivo* mutagenicity study, the Registrants acknowledged the limitations of UDS that does not provide conclusive proof that the substance is not mutagenic in mammalian systems and accepted the TGR or comet assay as alternatives in somatic cells. They agreed that conducting a comet assay in rat using the EFSA protocol is appropriate to identify the *in vivo* mutagenicity and if somatic cell mutagenicity is identified in this testing then further assessment involving germ cells should be considered. The Registrants considered the two options of ECHA's PfA and recognised the difficulties in conducting TGR due to the lack of sufficient number of CROs able to conduct the study, lack of validation of the study via inhalation route, problems related to species (transgenic mice used for TGR and rat for other studies), shortage of transgenic animals, lack of historical data, the high costs of TGR compared with comet etc. The Registrants requested the timeline to be extended by 12 months in the event TGR is required due to unavailability of dedicated test facilities, although 24 months indicated in DD are sufficient in case of conducting a comet Assay. As regards the requested detailed information on exposure scenarios and exposure assessments for the general population regarding HF and COF2, the Registrants have found unnecessary the proposal to clarify that hybrid vehicles are covered under MAC Directive and further noted that hybrid vehicles are not covered by SAE CRP Risk Assessment but by risk assessment requirements for OEMs according to ISO 13043 and SAE J639, and risk of using hybrids or alternative drive vehicles can be considered less than risks considered in SAE CRP Risk Assessment. Concerning the carcinogenicity testing strategy proposed conditionally, the Registrants had the view that the requirement would not follow the proper legal procedure.

As regards the PfA on the justification for not using a plausible AIT, the Registrants agreed with the PfA to remove/amend this information requirement in support of 750^{o}C as the correct surface temperature for the substance/oil risk assessment. They noted that AIT is not an intrinsic property of a flammable substance, but rather depends on multiple factors including system volume, pressure, boundary conditions for heat transfer, and time of contact (induction time) between the hot environment and gas mixture. It was also noted that the laboratory based AIT test protocol is not representative of the rapid air movement associated with sudden engine compartment compression as would be experienced in a crash, and the experimental data and field experience indicate ignition of flammable hydrocarbon vapours by a hot surface in the open air that requires temperatures well above the laboratory-determined minimum ignition temperature of the material involved. Regarding PfA on ED indications the Registrants were of the view that there are no ED concerns arising from this substance.

Furthermore the Registrants considered that the DD information requirements on exposure from thermal degradation products (for which no PfAs have been received) go beyond the reasonably expected assessment under REACH and CoRAP as they address thermal decomposition and/or combustion products which do not occur under normally foreseeable conditions of use and do not concern the substance itself.

In the following discussion, different views were shared mainly on the appropriate *in vivo* somatic mutagenicity study to be requested considering the advantages and limitations of the TGR and comet assay for gathering information in this particular case in the light of the potential need for further testing in germ cells and on the AIT used by the Registrants in the risk assessment of polyhaloalkene. In this regard, the member from the MS who made the PfA shared a view that the temperature specified in DD as relevant in the

context of this risk assessment (AIT according to EU A.15 test method) was not appropriate because this temperature is not relevant in the context of an ignition in the engine compartment in real conditions; thus, it is considered as too conservative and leading to unrealistic results.

In response the eMSCA expert explained that, despite of the numerous discussions in different fora on the appropriate temperature to be used for the purpose of risk analysis, as the real conditions are not known, the eMSCA's approach followed in DD is to use the standardised temperature for such analyses according to the EU method A.15 and to further examine the worst-case scenario, e.g. in case of car accidents, unless the registrants can justify the use of another value.

The Registrants' representative expressed the view that not necessarily the worst-case scenario should be considered in this case but the most realistic situation.

Session 2 (closed)

As regards the *in vivo* mutagenicity testing, MSC concluded that both methods TGR (OECD 488) in mice via inhalation for 28 days and tissues (lung, liver, bone marrow) and comet Assay are suitable for gaining data on the substance's mutagenicity in somatic cells and decided to provide the Registrants with the opportunity to choose which one to perform while further specifying in section III, statement of reasons of DD, the conditions of the studies and the points to be considered by the Registrants when choosing the test. It was specified that if a TGR is the preferred test to be carried out, it shall be conducted in mice treated for 28 days via inhalation, and mutation frequency shall be assessed in lung, liver, and bone marrow. Germ cells from testes shall be sampled and stored; however, these testes cells only need to be analysed for mutation frequency, if positive test results are obtained for any of the somatic cells. If a comet assay is chosen, due to the absence of agreed TG, the test method according to the minimum requirements as outlined in the corresponding scientific opinion by EFSA (2012) should be followed. The comet assay shall be performed in rats via inhalation and DNA damage shall be assessed in lung, liver, and bone marrow.

Further, MSC noted that establishing and evaluating the TGR method via the inhalation route might indeed require additional time and therefore decided to grant an extension of the deadline for TGR testing (but not for the comet assay) to 36 months.

Regarding the DD request for information about the ignition risk of polyhaloalkene for the intended use in automobile air conditioning applications in case of accident, the member from the MS that had submitted the PfA explained that this MS considers as not scientifically justified to request the registrant to consider an AIT of 405°C as this temperature was determined in conditions that are not scientifically representative of car accident conditions and therefore this information request should be removed from the DD. Among other technical details, it was further explained that in the MS's opinion the experimental testing as carried out was based on representative test conditions, and that the case of an ignition temperature of 650°C relied on a specific measurement system not in direct contact with the hot surface (and thus underestimating the actual ignition temperature). Furthermore, the member noted that the temperature to be retained for the risk assessment for polyhaloalkene ignition in case of a car accident had implications on and interlinks with other information requests in the DD.

Some members expressed concerns if the request is within the scope of REACH substance evaluation. Besides, some concerns were expressed as regards the impact that this substance evaluation process may have on the on-going policy dispute under the existing specific EU legislation on mobile air conditioning systems. eMSCA's expert noted that the DD was neither policy-driven, nor had policy issues been raised in this substance evaluation that was done within the REACH regulatory framework. The expert further explained that the exposure scenarios covering the risks caused by the substance in a car crash are included in the registration dossiers following the earlier MSC agreement to the compliance check decision requesting such scenarios to be included in the registration dossiers for polyhaloalkene.

Following the above considerations, the MSC Chair launched the voting procedure based on the DD for polyhaloalkene as modified at the meeting. MSC did not reach unanimous

agreement on the DD provided for the vote. The Chair invited the disagreeing MSC member to provide written justification for the vote. Three MSC members made a statement to the minutes (Annex VI) as regards their position on AIT. ECHA will refer this DD to the Commission for further decision-making in accordance with Article 133(3) of the REACH Regulation.

SEV-DE-006/2012 N-1-naphthylaniline (EC No. 201-983-0)

Session 1 (open)

Two representatives of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

eMSCA expert from the German CA (DE CA) presented the outcome of SEv performed by the DE CA on the basis of the initial grounds for concern, i.e. relating to environment/suspected PBT and exposure/wide dispersive use. The members were guided through the information requirements and it was explained that additional concerns regarding the human health were identified during evaluation by the DE CA.

eMSCA expert explained that 10 PfAs to the DD were received by MSCAs and ECHA.

Regarding neurotoxicity study (90-day) one PfA was submitted proposing to remove reference as regards derivation of a long-term DNEL based on 28-day study, and another one related to the need for an update of the CSR based on that.

Two PfAs were submitted by an MSCA and ECHA which combined proposed to delete the request for an Extended one generation reproductive toxicity study (EOGRTS) and carcinogenicity, modify the deadline for submission of the data accordingly to 27 months, and include instead an explanation that further information requirements on those properties, may be necessary depending on the outcome of the neurotoxicity study and pre-natal developmental toxicity study.

Regarding higher tier exposure assessment for dermal and inhalation exposure two PfAs were received asking to include a text indicating that the use of local exhaust ventilation (LEV) modifier is advised against in ECHA guidance and that the use of such method further justifies the need for the higher tier exposure assessment.

One PfA suggested a new request regarding overall combined exposure estimate and overall risk characterisation ratios. In addition few PfAs more of an editorial nature had been submitted.

eMSCA had modified DD for the meeting based on PfAs and a version updated with procedural steps was provided to MSC for finding unanimous agreement.

Registrant's comments on PfAs of CAs and discussion

The registrant provided comments after receiving the PfAs. Regarding the requirements for EOGRTS and carcinogenicity study the registrant supported deletion of the requests. Regarding the deadline for submission of the information the registrant proposed to maintain the initial deadline, justifying the need due to lack of laboratory resources. Several others of the registrant's comments were outside the scope of the PfAs. Several of the Registrant's comments on PfAs became obsolete as the eMSCA had removed some information requests and amended DD in view of the PfAs.

At the meeting the representatives of the Registrant indicated that they agreed to all proposed changes, that the main issue regarding the information requirements stemmed from the rejection of the read across and they supported the PfAs that would allow to first examine results from the neurotoxicity and pre-natal development studies before deciding on the need for EOGRTS and carcinogenicity study. The registrant indicated a preference to have those tests removed from the decision at this stage. Although not covered in the written comments, the capacity problem in the laboratory linked to one of the representatives was indicated as the reason to allow more time for the conduct of the tests.

The registrant inquired about the cost-sharing provisions under substance evaluation since there is currently only one registrant, whereas there might be more registrants for the

same substance joining in the coming years. In responding SECR explained that cost sharing negotiations are not part of ECHA's scope of work but that the results from the studies requested may prove necessary to show safe use of the substance by all registrants.

Session 2 (closed)

Based on the above considerations, and the fact that PfAs had been largely reflected and accepted by eMSCA in the amended version of DD including the deletion of the requests for EOGRTS and carcinogenicity study, only limited discussion was needed which focused on the deadline to be set for the submission of the requested information. MSC concluded, also in line with previous similar situations, to shorten the deadline to 27 months with the reasons as explained in the PfA and in absence of any written proof of a contact with a laboratory. This was reflected also in the statement of reasons.

Following the above considerations, MSC unanimously agreed on this SEV DD as modified at the meeting.

SEV-UK-031/2012 1,1'-(ethane-1,2-diyl) bis[pentabromobenzene] (EC No. 284-366-9)

Session 1 (open)

Two representatives of the Registrants participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

eMSCA expert from UK CA presented the outcome of SEV of the above-mentioned substance performed by UK CA on the basis of the initial grounds for concern, i.e. PBT for environment. It was noted that EBP is an alternative for decaBDE (this latter substance is identified as SVHC, and nominated as a persistent organic pollutant (POP) under the Stockholm Convention on POPs). Due to suspicion of potential ED effects to the environment, eMSCA aims to examine the vitellogenin induction. The members were guided through the information requirements and explained how the PfAs received and the Registrants' comments have been taken into account in the DD.

Eight PfAs were submitted on the DD by two MSCAs and ECHA.

One PfA proposed a summary of the registrant's comments concerning the testing of the purest substance form and the eMSCA's response to these comments to be included in Section III of DD.

Regarding the bioaccumulation test in aquatic species (OECD TG 305), a PfA suggested an addition to be made for the registrant to consider combining the test with the essential elements of 21-day short-term screening fish assay for Oestrogenic and Androgenic Activity, and Aromatase Inhibition (OECD 230 with dietary exposure however) or as alternative the Registrant may carry out two separate studies, one according to OECD 305 and another one according to OECD 230.

As regards the soil and the sediment simulation testing (OECD TG 307 and OECD TG 308), it was proposed in a PfA to mention in the instructions for these simulation tests in Section II of the DD to perform the tests at 12°C, in order to obtain the most relevant results for the EU environment. Further, a PfA suggested an editorial modification to be made in Section III of DD for requesting the registrant to adapt the OECD 308 test method to include to the extent possible reliable measurements of the presence of dehalogenating microbial species and microporous black carbon to allow an evaluation of their possible impact on the test results and to provide additional context for the interpretation of the results.

Regarding the requested detailed exposure assessment (with sensitivity analysis) for the whole EBP life cycle, a PfA suggested adding further argumentation to section III.6 of the DD for bringing more clarity and justification to the Registrants on the information request made for a substance not classified as dangerous or not assessed as PBT/vPvB and the reference to the EBP transformation products from high temperature processes.

A final PfA proposed the inclusion of an Extended one-generation reproductive toxicity study (EOGRTS) in rats, oral route (OECD 443) including Cohorts 2A and 2B for

developmental neurotoxicity and Cohort 3 for developmental immunotoxicity but without F2. The reasoning given was that endocrine disruption was identified as a concern but was only addressed for the environment. The PfA provided some limited information indicating endocrine mediated action for EBP. It was noted that there was a potential data gap for the reproductive toxicity endpoint and a request for an EOGRTS could inform on this concern.

eMSCA has responded to the PfAs (RCOM) and amended the DD prior to the MSC meeting motivated by five PfAs. Further clarification has been provided in DD motivated by the PfA on combined OECD 305/230. However, eMSCA found no need to modify the DD based on PfAs regarding dehalogenating microbial species/microporous black carbon and regarding inclusion of an EOGRTS, and a separate OECD230 for ED concern. For the PfA suggesting inclusion of an EOGRTS, the eMSCA did not agree that the suspicion of ED effects in the environment was sufficiently strong to trigger further human health testing.

Registrants' comments on PfAs and discussion

The registrants provided written and oral comments on the amended DD and the PfAs received. In their comments the registrants clarified that they can only test a typical material from their production and respective radiolabeled samples. Based on a compositional analysis of EBP of the registrants addressed by this DD, they considered the difference in the purity of EBP as insignificant from a scientific perspective and therefore further differentiation in this regard of no scientific relevance. As regards the other PfAs, the registrants agreed that more detailed exposure assessment including the transformation products can be relevant in the context of the CSA and CSR under certain circumstances. However, they considered such assessment as related to the conditions relevant to identified uses and conditions of use in the registration dossier and are willing to gather first reliable evidence and reference for the formation of possible transformation products under the conditions of use covered by the CSA and CSR, and in particular during "high temperature processes". The Registrants considered it inappropriate, unjustified and premature to request in DD for specification of the chemistry of the transformation products when it is uncertain whether such will be formed. In this respect, the registrants asked for an additional 6 months to fulfil the requirements of the assessment of transformation products, i.e. a deadline for the dossier update of 36 months from the final decision in consideration that this assessment involves also investigations with Downstream Users. The Registrants did not agree with the PfAs on the need for temperature adjustment to 12^{o}C for the soil and the sediment simulation testing (OECD TG 307 and OECD TG 308) of EBP for the reasons outlined below and the additional reason that due the modifications for the soil study in the aerobic part as required by the DD, the addition of plants would not allow the temperature to be dropped to 12^{o}C as most of the plants would not grow at this temperature. Further, they agreed to the PfA to perform a standard OECD 305 dietary study and a separate study according to OECD 230, at two dose levels and including vitellogenin assessment, as they share the concern that adding additional elements to a study that is of high complexity may lead to results difficult to interpret and prefer to do two separate studies that are expected to lead to scientifically more reliable results. Regarding the PfA for strengthening the wording regarding measurement of de-halogenating microbial species and microporous black carbon the registrants did not oppose to the change provided that it is not considered as an information requirement. The registrants asked that should the additional measurements be made a formal information requirement, then they would be grateful of an indication of a relevant methodology for this request. However, with regard to the PfAs requesting an EOGRTS-study, the registrants are of the opinion that the available data do not indicate a concern that would trigger the conduct of an EOGRTS and also several other available studies do not support ED concern. However, if such a request is included in the DD, the Registrants requested an additional 18 months for the study performance and dossier update and thus a deadline of 52 months mentioned in the decision.

In the following discussion, eMSCA further clarified why the soil and sediment degradation testing should be carried out at 20^{o}C as this temperature is more suitable for maximising the formation of the degradation products. The members from the MSCAs who had submitted this PfA, as well as the PfA on microbial species accepted the response of the

eMSCA to their PfA and agreed that there is no need to amend DD in this regard. Further views were exchanged on the need to combine the fish bioaccumulation test (OECD 305) with OECD 230 and on the PfA to request for EOGRTS. The member from the MSCA who had made the PfA for EOGRTS reminded that there is no standard information requirement under REACH for endocrine disruption and the proposed EOGRTS would gain information on both reproductive toxicity and on potential ED effects of EBP. The registrants reminded MSC of the on-going developmental neurotoxicity study carried out due to other legislative framework requirements, mentioned that the test results are expected to be available in mid-2014, and indicated that they will subsequently update their registration dossiers accordingly.

With regard to the scope of the SEv when a data gap on a standard information requirement (normally addressed in compliance check) is found, SECR noted that the evaluating MS should consider to address this data gap under SEv where the main guiding principle should be whether the missing information is crucial for the safe use of the substance and for drawing the final SEv conclusions, in particular when an 'area of concern' is identified.

Session 2 (closed)

As regards the proposed combined bioaccumulation testing, MSC concluded that the best course of action would be to conduct this investigation in a single study combining bioaccumulation (the main purpose) with a screen for an oestrogenicity biomarker (vitellogenin). If the results of this study indicate that vitellogenin is induced by the substance, the eMSCA should consider further testing needs (which may require dietary exposure). Sampling and determination of vitellogenin shall follow the guidance for this parameter as described in OECD TG 229. Further details on the test specifications and the fish species to be tested were provided in Section III, statement of reasons of the decision.

Concerning the potential ED properties of EBP for mammalian species, including humans, and the potential reproductive toxicity data gap, the MSC decided to add further clarification in Sections I and III of the current DD highlighting that no conclusion is drawn for now regarding these points. It was noted that the dossier of the lead registrant contains an adaptation of the standard REACH information requirement 8.7.3 of Annex IX and X and hence that results of the corresponding test method referred to in Article 13 (3) are not available. Hence, an evaluation of this specific standard information requirement for Annexes IX and X may therefore still be warranted pursuant to title VI of REACH regulation (dossier or substance evaluation).

Following the above considerations, MSC unanimously agreed on this SEV DD as modified at the meeting. Two members made a statement to the minutes (Annex VI) with regard to this substance evaluation.

SEV-AT-001/2012 N-(1,4-dimethylpentyl)-N'-phenylbenzene-1,4-diamine (EC No. 221-374-3)

Session 2 (Closed session)

This SEV case, for which the substance evaluation had been prepared by the Austrian CA, was returned from the written procedure. None of the members disagreed with the SEv DD, as amended by the eMSCA to take into account PfAs received, however, as mentioned in item 6a above one member had requested a further editorial change to the decision. This change of the wording as regards the acceptance of the proposed justification of the read across was then briefly discussed in relation to an existing decision.

MSC unanimously agreed on this SEV DD after the editorial change was introduced to the Section III of DD itself.

d. Processing of draft decisions for substance evaluation - short update by the Secretariat

SECR presented a brief update on processing of draft decisions under substance evaluation. MSC was provided with statistical information of the evaluation state of play of the 36 substances included in CoRAP 2012 and of the 47 substances under evaluation in 2013. Further information was given with regard to the planned SEv activities in 2014 and

the expected MSC workload along the year. MSC was also informed of the envisaged SEv workshop preliminary scheduled for 26-28 May 2014.

In response to some questions raised, SECR further clarified the expected communication approaches for informing the public of the outcome of the substance evaluation process, including the cases where no decisions have been prepared or released in result of SEv. It is envisaged that the finalised conclusion documents or SEv reports as prepared by the eMSCAs will be made publicly available on ECHA's website.

e. Update on appeal process – preparation stage *(Closed session)*

SECR gave a presentation on the preparation process for handling of potential appeals on substance evaluation decisions and on the role of the evaluating MSCA in the preparation of the defence on decisions resulting from their substance evaluations. It was mentioned as well that SECR has an intention to establish a legal network with MSCAs' national experts with legal background involved in SEv for identifying some formal aspects and to exchange information of appeal cases.

Item 7 – Dossier evaluation

a. Written procedure report on seeking agreement on draft decisions on dossier evaluation

SECR gave a report on the outcome of the written procedure (WP) for agreement seeking on ten dossier evaluation cases (see Section V for more detailed identification of the cases). WP was launched on 10 January 2014 and closed on 21 January 2014. By the closing date, responses to WP were received from 24 members with voting right and from the Norwegian member. Unanimous agreement was reached on eight DD. For two DDs, MSC did not find unanimous agreement and these cases will be referred to the Commission to be dealt with in accordance with the procedure referred to in Article 133(3) of REACH Regulation.

b. Introduction to and preliminary discussion on draft decisions on testing proposals after MS-CA reactions *(Session 1, open session)*

c. Seeking agreement on draft decisions on testing proposals when amendments were proposed by MS's *(Session 2, closed)*

Hydrocarbons category

TPE 148/2013 Hydrocarbons,C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List No. 919-164-8)
TPE 149/2013 Decane (EC No. 204-686-4)
TPE 150/2013 Dodecane (EC No. 203-967-9)
TPE 151/2013 Undecane (EC No. 214-300-6)
TPE 152/2013 Tridecane (EC No. 211-093-4)
TPE 153/2013 Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, < 2% aromatics (List No. 920-107-4)
TPE 154/2013 Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics (List No. 927-676-8)
TPE 155/2013 Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 926-141-6)
TPE 156/2013 Hydrocarbons, C11-C13, isoalkanes, <2% aromatics (List No. 920-901)
TPE 157/2013 Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics (List No. 918-481-9)
TPE 158/2013 Hydrocarbons, C9-C12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List No. 919-446-0)
TPE 159/2013 Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List No. 927-344-2)
TPE 160/2013 Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics (List No. 919-857-5)

TPE 161/2013 Hydrocarbons,C11-C14, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List No. 925-653-7)
TPE 162/2013 Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 927-241-2)
TPE 163/2013 Hydrocarbons, C11-C12, isoalkanes, <2% aromatics (List No. 918-167-1)
TPE 164/2013 Hydrocarbons, C10-C12, isoalkanes, <2% aromatics (List No. 923-037-2)
TPE 165/2013 Hydrocarbons, C9-C11, cyclics, <2% aromatics(List No. 925-894-8)
TPE 166/2013 Hydrocarbons, C10-C13, isoalkanes, cyclics, < 2% aromatics (List No. 918-317-6)
TPE 167/2013 Hydrocarbons, C10-C13, n-alkanes, <2% aromatics (List No. 929-018-5)
TPE 168/2013 Hydrocarbons, C11-C12, isoalkanes, cyclics, <2% aromatics (List No. 931-121-5)
TPE 169/2013 Hydrocarbons, C11-C14, n-alkanes, <2% aromatics (List No. 924-803-9)
TPE 170/2013 Hydrocarbons, C13-C18, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 928-253-0)
TPE 171/2013 Icosane (EC No. 204-018-1)
TPE 172/2013 Hydrocarbons,C16-C20,n-alkanes, isoalkanes, cyclics, aromatics (2-30 %) (List No. 919-006-8)
TPE 173/2013 Hydrocarbons, C16-C20, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 919-029-3)
TPE 174/2013 Hydrocarbons, C13-C16, isoalkanes, cyclics, < 2% aromatics (List No. 918-973-3)
TPE 175/2013 Hydrocarbons, C14-C18, n-alkanes, isoalkanes, cyclics, aromatics (2-30%) (List No. 920-360-0)
TPE 176/2013 Hydrocarbons, C14-C18, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 927-632-8)
TPE 177/2013 Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics (List No. 920-114-2)
TPE 178/2013 Hydrocarbons, C11-C14, isoalkanes, cyclics, <2% aromatics (List No. 927-285-2)
TPE 179/2013 Hydrocarbons, C13-C15, n-alkanes, isoalkanes, cyclics, < 2% aromatics (List No. 917-488-4)
TPE 180/2013 Hydrocarbons, C9-C11, isoalkanes, cyclics, <2% aromatics (List No. 920-134-1)
TPE 181/2013 Hydrocarbons, C17-C19, n-alkanes, <2% aromatics (List No. 937-158-3)
TPE 182/2013 Tetradecane (EC No. 211-096-0)

Session 1 (open)

Three representatives of the Registrants participated in the initial discussion. In absence of specific confidentiality concerns in DDs, an open session was held.

Brief information on the category

The Registrants proposed a category approach for testing of hydrocarbons, which consists in total of 35 substances. The proposed category is based on the assumption on similar structural elements: the number of carbon atoms between C5 and C20; the presence of linear, branched and/or cyclic paraffins either as mono-constituents or as UVCBs in varying proportions, where UVCBs may also possess varying proportions of aromatic constituents, most of which are alkylated 1- and 2-ring aromatics (C8-C19); not containing benzene, toluene and/or aromatic constituents with 3 or more aromatic rings at more than trace levels (i.e. <1 ppm)).

Brief information on the read-across approach

The read-across hypothesis is based on the assumption that all substances within this category do not produce significant reproductive toxicity. Data already exists for linear, branched, cyclics and aromatics around carbon number C5–C9. The Registrants suggested performing a two-generation reproductive toxicity study, which is the only endpoint to be covered. Studies are proposed on three substances at the higher end of the carbon

number range. Assuming that the three new tests do not show adverse effects, interpolation is used for the carbon number range in the middle; otherwise, hypothesis will be revisited. The three tests will cover (a) the higher carbon number end for linear alkanes, (b) the higher carbon number end for branched and cyclic alkanes, and (c) the higher carbon number range for a high aromatic content and interactions between hydrocarbon classes. Confirmation of the hypothesis relies on the outcome of the proposed testing.

ECHA considers that the read-across approach still contains deficiencies and uncertainties that have to be addressed. Firstly, robust study summaries shall be included for all the studies that are used to support the hypothesis of absence of reproductive toxicity to allow an independent assessment of these studies. The selection of the test materials used should not lead to underestimation of the hazard. In addition, the final read-across based on the results of the proposed tests shall ensure that any remaining uncertainties have been taken into account for the entire category and the produced evidence will be assessed to decide whether further necessary information is required.

The substances within the category are proposed to be tested or read-across (RA) as follows:

	Substance	**Two-generation**
TPE 148	Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	RA
	…	
TPE 170	Hydrocarbons, C13-C18, n-alkanes, isoalkanes, cyclics, <2% aromatics	RA
TPE 171	Icosane	Test
TPE 172	Hydrocarbons, C16-C20, n-alkanes, isoalkanes, cyclics, aromatics (2-30 %)	Test
TPE 173	Hydrocarbons, C16-C20, n-alkanes, isoalkanes, cyclics, <2% aromatics	RA
	…	
TPE 176	Hydrocarbons, C14-C18, n-alkanes, isoalkanes, cyclics, <2% aromatics	RA
TPE 177	Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics	Test
TPE 178	Hydrocarbons, C11-C14, isoalkanes, cyclics, <2% aromatics	RA
	…	
TPE 182	Tetradecane	RA

Registrants' comments on PfAs of CAs and discussion

SECR explained that five PfAs to ECHA's DD were submitted by four MSCAs. The category approach as expressed in DDs based on the Registrants' proposal was not challenged by the PfAs.

One PfA agreed with the proposed read-across strategy but suggested that the Registrants should propose to test an additional one or two relevant hydrocarbon substances for the same endpoint as the others amongst the substances in the C9-C14 aliphatic range (2-25 % aromatics), i.e. mid carbon number range, by selecting substances for testing with the highest possible aromatics content. The weight of evidence approach for the middle carbon number range of the category would not be considered sufficient based on information obtained from repeated dose toxicity studies, one-generation reproduction toxicity and screening studies to cover the same information as produced by two-generation reproduction studies.

Four PfAs suggested requesting an EOGRTS for Annex X, 8.7.3 only instead of ECHA's proposal to give two options for the Registrant either to perform the two-generation reproductive toxicity test (EU B.35) or EOGRTS (OECD 443) with the second generation. One PfA suggested keeping the two options but excluding from the optional request for EOGRTS the extension of cohort 1B (production of F2 generation), whereas another one requested to specifically include reference to a 10-weeks premating period.

ECHA Secretariat has responded to the PfAs and is of the view that DDs do not need to be modified based on the PfAs.

The Registrants provided written comments and noted that the reproductive toxicity information requirements for the C9–C14 range of the proposed solvent category was covered by the rationale for read-across based on interpolation. The Registrants explained that supporting data in a weight of evidence approach was provided to show a lack of evidence for reproductive toxicity in substances in the C9–C14 carbon number range, and did not believe that there is a need to also include the robust summaries in the testing strategy document. The Registrants proposed to fulfil the standard information requirements via conducting the two-generation reproductive toxicity study (OECD 416).

The Representatives of the Registrant provided also oral comments and explained that they had no reason to believe that reproductive toxicity would be of concern, but in case of any effects from the testing more testing would be needed to resolve the issue.

A member of the MSC reiterated concerns of covering the carbon number mid-range of substances to be tested in the proposed category approach, in particular to address potential higher bioaccumulation in the mid-range as compared to the low and high carbon ranges. This uncertainty in the current testing plan was explicitly supported by another member, and needs to be addressed by the registrants. A member suggested to have first the proposed tests carried out and then to assess the results for further possible testing.

SECR noted the concerns on possible weaknesses of the proposal and that more information may be asked for in the follow-up process, in case these uncertainties are not adequately addressed by the registrants.

The Representatives of the Registrant agreed that results need to be carefully looked at if more testing would be needed.

Session 2 (closed)

Based on the above considerations, MSC agreed to the approach proposed by the Registrants and reflected in ECHA's DDs recognising the uncertainties still present in the approach and stating that although the hypothesis may be tested ECHA will consider acceptability of the read-across only when the information required by the decisions has been submitted to ECHA and ECHA has evaluated the information.

Even though the members agreed on the read across approach, MSC did not reach unanimous agreement on the DDs on these TPs for a two-generation reproductive toxicity study. The Chair invited the disagreeing MSC members to provide written justifications for their votes if the justification is different from the one provided for the previous similar cases (otherwise SECR would use the justification provided in previous similar cases). ECHA will refer these DDs to COM for further decision-making in accordance with Article 133 of REACH Regulation.

TPE 189/2013 4,4,13,13-tetraethoxy-3,14-dioxa-8,9-dithia-4,13-disilahexadecane (EC No. 260-350-7)

Session 1 (open)

Two representatives of the Registrant participated in the initial discussion. In the absence of specific confidentiality concerns in the DD, an open session was held.

Five PfAs to ECHA's DD were submitted by four MSCAs.

SECR explained that one PfA was provided on ECHA's DD for the pre-natal developmental toxicity study (OECD 414), explaining that the read-across is plausible and should be conditionally accepted even if the justification provided by the Registrant could be improved. The MSCA considers that the substance subject to the decision and the read-

across substance are structurally very similar, the only difference being the number of sulphur atoms in the chain connecting the identical silane ethers. In the view of MSCA the substances have very similar physico-chemical properties and they display similar toxicological profile. Therefore, MSCA proposes the test to be carried out with the read-across substance.

Four PfAs were submitted regarding the generation reproductive toxicity study, three MSCAs suggest requesting an extended one generation reproductive toxicity study (EOGRTS) for Annex X, 8.7.3 instead of ECHA's proposal to provide the registrant with a choice of two appropriate methods, either to perform the two-generation reproductive toxicity test (EU B.35) or EOGRTS (OECD 443) with the second generation. One MSCA suggests keeping the two choices but excluding from the optional request for EOGRTS the extension of cohort 1B (production of F2 generation). One PfA further considered that the read-across is plausible and should be conditionally accepted even if the justification provided by the Registrant could be improved, using the same reasoning as set out for the pre-natal developmental toxicity study above.

SECR split DD into part A and B where part A addressed the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity) and part B addressed the information requirement for prenatal developmental toxicity study. ECHA Secretariat modified due to splitting of the requirements the deadlines to be given to the Registrant to submit the required test results.

Registrant's comments on PfAs and discussion

The Registrant provided written comments on PfAs. In his comments, the Registrant agrees with the MSCA proposing to accept read-across. The Registrant explains that the registered substance and read-across substance are structurally very similar and that the read-across substance includes in its composition the registered substance. The Registrant is in agreement with the arguments presented by MSCA in support of the read-across approach.

The Representatives of the Registrant explained at the meeting that the registered substance and the read-across are the same compounds with different numbers of sulphur atoms in the chain, additionally the breakdown product is the same or similar for both substances. Therefore, according to the Registrant the substances fulfil the REACH Regulation Annex XI requirements. The Representatives of the Registrant agreed that the read-across justification in the technical dossier needs to be improved and that the Registrant is planning to update the dossier with this justification together with further information regarding the 28-day studies to show the substances are of similar toxicity. The Registrant informed the meeting that the updated dossier will include the available PNDT study on the read-across substance and the results of the PNDT study do not show substance-related developmental toxicity.

A MSC member stated that in his view the registered substance and the read-across follow the same metabolism pathway. Additionally, repeat dose toxicity studies show the same profile.

SECR explained that the read-across is not properly documented and that the issues were identified in the DD. Furthermore the Registrant neither addressed these satisfactorily, nor were PNDT results of the proposed source substance provided in an updated dossier upon receipt of the initial DD. Therefore the decision is to be taken on the basis of the information currently contained in the technical dossier.

The Registrant was reminded that in the event of no effects in the PNDT study on one species, a PNDT study on a second species would be required.

One MSC member noted that is the Registrant who has to build and properly justify the read-across; hence it is up to the Registrant to prepare a good read-across case.

Session 2 (closed)

MSC agreed unanimously on ECHA's split DD addressing the prenatal developmental toxicity study (part B) as modified during the meeting, based on the need to change the

deadline for submission of the data due to the splitting of the DD. Furthermore some modifications were made in the DD based on the registrant's comments on the PfAs.

MSC did not reach unanimous agreement on the DD addressing a two-generation reproductive toxicity study (part A). However, the relevant parts of this DD were also modified based on the agreement regarding the modifications and the deadline due to the splitting of the DD. The Chair invited the disagreeing MSC members to provide written justifications for their votes if the justification is different from the one provided in previous similar cases (otherwise SECR would use the justification provided in previous similar cases). ECHA will refer the DDs to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

TPE 183/2013 Heptanal (EC No. 203-898-4)

Session 1 (open)

No representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

Two PfAs to ECHA's DD were submitted by two MSCAs.

SECR explained that one PfA suggested that the sub-chronic toxicity study (90-day) in rats would be conducted via the inhalation route instead of the oral route. The other PfA to ECHA's DD suggested clarifying in Section II that testing for pre-natal developmental toxicity (PNDT) is required either on heptanal or on heptanoic acid (read-across substance), and proposed to modify Section III explaining that if the registrant fails to substantiate the read-across hypothesis (in the toxico-kinetic study they indicated to be carrying out), he shall carry out the pre-natal developmental toxicity study with the registered substance.

ECHA Secretariat amended the DD based on PfA related to the PNDT information requirement.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments explained that the toxico-kinetic study has been conducted confirming that read-across would be justified between heptanal and heptanoic acid. The registration dossier is to be yet updated with this information. The summary of the study report is attached to the comments. In the comments on the second PfA the Registrant agrees with ECHA's DD to perform the 90-day study by oral administration as it allows a comparison of the new toxicokinetic study via oral route and the 90-day study results.

A member of the MSC explained that on the basis of scientific arguments they would prefer the inhalation route and that there could also be potential for local effects. Other members raised that the local effects observed at site of contact were well below the exposure concentrations, and that costs of an inhalation study are higher than oral. The considerations also should be weighed into deciding on the most appropriate route of administration.

SECR explained that the substance is not volatile and its uses are controlled, therefore, the oral route can be considered the most appropriate route.

Session 2 (closed)

Based on the above considerations, MSC agreed not to amend the draft decision and found unanimous agreement on ECHA's draft decision as provided for the meeting.

TPE 184/2013 N-vinylformamide (EC No. 236-102-9)

Session 1 (open)

One representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

Six PfAs to ECHA's DD were submitted by four MSCAs.

SECR explained that one PfA on ECHA's DD was submitted regarding the developmental toxicity study (OECD 414). The MSCA proposes that oral route is the most relevant exposure route for the testing substance as the MSCA does not see sufficient arguments to perform the developmental toxicity study via the inhalation route as currently requested in DD, due to low vapour pressure of the liquid substance, available information on severity of local effects after inhalation exposure in the 90-day study, lack of kinetic studies enabling a statement on possible first-pass metabolism via oral route and lack of convincing arguments provided for conducting the developmental toxicity study via the inhalation route of administration.

Four PfAs were submitted regarding the generation reproductive toxicity study, three MSCAs suggest requesting an extended one generation reproductive toxicity study (EOGRTS) for Annex X, 8.7.3 instead of ECHA's proposal to provide the registrant with a choice of two appropriate methods, either to perform the two-generation reproductive toxicity test (EU B.35) or EOGRTS (OECD 443) with the second generation. One MSCA suggests keeping the two choices but excluding from the optional request for EOGRTS the extension of cohort 1B (production of F2 generation).

Concerning the route of administration for the 'generation' study, one MSCA proposed that oral route is the most relevant exposure route for testing of the registered substance, as was also suggested for pre-natal developmental toxicity study. This suggestion is in line with the view of another MSCA who proposed oral route, however it is in contrast with ECHA's DD which suggested inhalation route and two MSCAs who provided for in their PfAs that the most relevant route of administration is inhalation route.

One PfA was submitted where the MSCA proposed to test the purest possible grade of the registered substance (grade containing <0.3% formamide), as performing the proposed test with the commercial grade substance may not be able to detect a potential reproductive effect due to limited statistical power of the test in combination with the low concentration of the reproductive toxic impurity. The concentration of the impurity formamide in the grade of the substance requested to be tested is >= 0.3 to < 1%, which covers the commercial grade intended for testing and is above the (CLP) classification cut-off limit of 0.3 % formamide for Repr. 1B.

SECR has split DD into part A and B where part A addressed the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity) and part B addressed the information requirement for developmental toxicity study. Due to splitting of the requirements ECHA Secretariat modified the deadlines to be given to the Registrant to submit the required test results.

The Registrant provided written comments on PfAs. With his comments, the Registrant indicated he did not agree that the tests should be conducted via oral route and proposed to perform both studies via inhalation route considering that inhalation is the most appropriate route of administration having regard to the likely route of human exposure as only industrial uses apply for the registered substance. The Registrant requested deletion of reference to professional use of the substance in DD and he pointed out that the registration dossier was updated in this regard in April 2013. The Registrant has the view that relevant exposure concentrations for reproductive toxicity testing via vapour inhalation can be achieved as the substance does not cause severe local effects via inhalation, and that despite the low vapour pressure this is still technically feasible. Additionally, the Registrant suggested that inhalation provides the worst case for systemic exposure considering the rapid hydrolysis rates observed in an environmental hydrolysis rate study performed at low pH levels.

Furthermore the Registrant did not agree with the MSCA in relation to the material to be tested. The Registrant stated that the material to be tested must be appropriate to assess the properties of the registered substance. In their view the test material chosen must be adequate to support a robust risk assessment taking into account the composition of the registered substance as actually manufactured. Therefore, testing of the substance which represents the majority of the production (the grade containing impurity formamide >= 0.3 to < 1%) is considered to be appropriate to assess the hazardous properties of the

registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured.

The Registrant in his comments on the PfAs concerning the testing for reproductive toxicity supported that he should be provided with options to choose between OECD 443 and OECD 416 and disagreed with three MSCAs requesting to conduct the study in accordance with OECD 443. The Registrant agreed with the PfA that an OECD 443 study should be carried out without the second generation, but did not agree with the MSCAs requesting to include DIT and DIT cohorts.

The representative of the registrant at the meeting stated that in order to ensure a robust risk assessment, the tests should be performed using the composition of the registered substance as actually manufactured.

Several MSC members supported that normally substances on the market should be tested, and that in the requested tests systemic exposure has to be optimized to allow information generation with relevance for, and which does not underestimate, the hazard classification of the substance *inter alia*.

Session 2 (closed)

Based on the above considerations, MSC decided to split the DDs into part A and part B, where Part A address only the endpoint 'two generation' while part B addresses developmental toxicity. It was suggested that the "most appropriate route of administration" should be evaluated with the purpose to identify the route that is most appropriate for hazard identification, risk assessment, classification. It was agreed that exposure via the inhalation route will not result in systemic dose levels that are high enough to conclude on the potency to induce reproductive effects. Therefore, inhalation studies with the registered substance for reproductive toxicity, which may be technically feasible as claimed by the registrant, are expected to provide limited information on hazard identification, risk assessment and classification for reproductive toxicity. Whilst some hydrolysis may occur in the stomach the available information does not exclude the possibility that significant amounts of the registered substance itself will remain present in the gastro-intestinal tract and available for absorption. Consequently, the oral route was selected as the most appropriate route of administration for the reproductive toxicity studies having regard to the likely route of human exposure. No changes to the test material required were introduced.

MSC agreed unanimously on ECHA's split DD addressing the developmental toxicity study as modified during the meeting, based on the need to change the dead line for submission of the data due to the splitting of the DD. Further justification was included in the DD related to the route of administration.

MSC did not reach unanimous agreement on the DD addressing a two-generation reproductive toxicity study. However, the relevant part of this DD was also modified based on the agreement regarding the route of administration and the dead line due to the splitting of the DD. The Chair invited the disagreeing MSC members to provide written justifications for their votes if the justification is different from the one provided in previous similar cases (otherwise SECR would use the justification provided in previous similar cases). ECHA will refer the DDs to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

TPE 186/2013 N-(cyclohexylthio)phthalimide (EC No. 241-774-1)

Session 1 (closed)

No representative of the Registrant participated in the discussion.

Because of specific concerns regarding the withdrawing of the DD a closed session was held.

SECR explained that the case was withdrawn from decision making following a lead registrant's notification on a cease of manufacture.

Based on the above considerations, MSC agreed unanimously that the case should not be considered by the meeting.

d. General topics - Status report on on-going evaluation work

SECR gave detailed statistics and update on the status of dossier evaluation work. The Committee was also informed of the potential workload for the forthcoming MSC meetings. MSC took note of the report.

e. Update on appeal process *(Closed session)*

SECR provided MSC with feedback from the appeal cases on dossier evaluation decisions. As no information on the latest appeal cases had been published at the time of the meeting, a closed session was held.

Item 8 – Community Rolling Action Plan (CoRAP) update

a. Discussion on the MSC opinion on the draft Community Rolling Action Plan (CoRAP) update

The Rapporteur presented the draft opinion and its annex and explained the changes made since the December MSC-33 meeting. These changes include 1) updates of justification documents of substances already on the CoRAP as adopted in February 2013; 2) withdrawal of substances; 3) changes in years of evaluation and MS conducting the evaluation; 4) updated tonnage bands with those in ECHA dissemination website; 5) initial grounds of concern extended and 6) one entry separated in two separate entries. The Rapporteur and the working group proposed that for all the substances on the draft CoRAP update there are sufficient grounds to consider that the substance may constitute a risk for the environment and /or human health.

In the discussion the need to discuss in more detail at a later stage on how best to deal with substances placed on the CoRAP update that have been evaluated under the previous chemical legislation and which do have a Risk Assessment Report (RAR) available, was raised. It was also clarified that currently the term CMR is used whenever the hazard is either a C or M or R or any combination of the three hazards. It cannot be further differentiated anymore in this CoRAP update but it will be considered to provide more information in the 2015-2017 update.

b. Adoption of the MSC opinion

MSC adopted the opinion on the annual CoRAP update 2014-2016 and its annex by consensus, as amended during the meeting. It was concluded that the MSC opinion together with the final update to CoRAP will be published on the ECHA website in March 2014.

Furthermore, SECR gave some information on the practicalities following the adoption of the opinion and the publication of the annual CoRAP update, like signing of the contracts.

c. Development of the screening for future CoRAP substances – brief update on activities by ECHA

SECR updated the Committee on the new developments for screening of substances in ECHA. The main screening objective is to identify potential candidate substances for several of the processes under REACH and CLP based on agreed criteria (CoRAP, SVHC, CLH). The new developments came from the need to streamline the screening to be more efficient and to develop a common ECHA screening approach.

In the discussion that followed, the members asked for clarification on whether there are new procedures in place also if more than one MSCA books the same substance for evaluation. SECR explained that this would need to be agreed bilaterally amongst the interested MSCAs as per previous practice. SECR also advised the MSC members to inform their MSCA contact persons to be in touch with the coordination groups and expert groups that have been created for the SVHC 2020 roadmap. Another question was on how substances will be handled that are of interest to different processes at the same time. SECR explained that the selection of the relevant process depends on the identified concern and the information available for the substance. If further information is missing to clarify the identified concern, substance evaluation is the best way to follow. If sufficient

information exists to confirm the concern RMO can be prepared. The choice of the relevant process will be made by the MSCA during the manual screening. The selection of substances will be done as follow: first there will be an electronic mass screening of the ECHA databases based on IT-algorithms producing a first list of substances. This will be followed by the manual screening of a subset of these substances (short list) from the MSCAs who will have to document the outcome of their assessment in one of the templates given to them (e.g. SEv, CLH, RMO). More information on the manual screening will be given to the MSCAs together with the shortlist of substances.

Item 9 – Authorisation process

a. SVHC identification process and ECHA's recommendation of priority substances for Annex XIV – Short status report by the secretariat

SECR gave a brief report on the recently submitted five SVHC proposals in the 1st SVHC round for 2014 pointing out that due to substance identity considerations two of them might be considered in due time as one proposal. MSC was also informed of the timelines for this round.

Further, SECR reported on finalisation of the 5th ECHA's recommendation for prioritising substances for inclusion in Annex XIV and outlined the plans for the preparation of the 6th draft recommendation. It was specified that during the next recommendation development, the new Prioritisation approach is to be applied. All substances included in the Candidate List in June 2013 or before and which have not yet been recommended, will be assessed for their (comparative) priority (this will be around 100 substances). MSC will be provided with the list of substances subject to the examination for potential inclusion in the 6th draft recommendation via MSC CIRCABC after the meeting.

b. Applications for authorisation and decision making - role in the authorisation process and state of play

SECR gave a presentation (available in MSC CIRCABC) on the last stage of the authorisation process focusing on the role and the scope of applications for authorisation (AfA), the experience gained with the first applications and the other preparatory activities in this regard.

In the following discussion, SECR explained the progress made with regard to the downstream users' involvement in the authorisation process (incl. 'increasing awareness' campaigns organised by ECHA and IND and the support provided by ECHA's and national Helpdesks in this regard). There was a discussion on risk assessment of substances with combined exposure. SECR clarified that the ECHA's Risk Assessment Committee has addressed this in the Common approach of RAC and SEAC in opinion development on applications for authorisation[3]. Unless they are described in the application combined (aggregated) exposure and cumulative effects will be considered by COM who takes the decisions to grant or not to grant authorisations.

Item 10 – Report on MSC work 2013 and MSC work plan for 2014

SECR provided a report on the MSC work during 2013 and outlined the expected work plan for 2014 in relation to different REACH processes with MSC involvement. Some statistical information was presented and the key Committee's achievements were shortly addressed.

Item 11 – Any other business

- **Guidance consultation on update of Guidance IR&CSA – Chapter R.11, Part C, Chapter R.7b and Chapter R7.c (related to PBT/vPvB assessment)**

SECR informed MSC of the recently launched consultation of MSC on the above-mentioned guidance documents and encouraged the members to review them and submit any comments by 27 February 2014.

[3] http://echa.europa.eu/documents/10162/13555/common_approach_rac_seac_en.pdf

- **New IT platform tool testing**

SECR informed MSC of a planned new IT tool that could be as a potential alternative to the CIRCABC information exchange platform for increasing the security function in the Committees' work. In addition to CIRCABC, MSC Members (and supporting experts) will be granted access to the new tool for testing purpose in the following 3 months and will be requested to provide their feedback to the SECR on it, before SECR will come to a conclusion on the feasibility of its use.

- **Big 'thanks' from ECHA operational units to the MSC Chair**

The ECHA's Management of the operational units for Evaluation, Risk Management Identification and Legal Affairs expressed their gratitude to the MSC Chair Anna-Liisa Sundquist leaving the service after this meeting. They recognized her instrumental contributions to the REACH implementation, and the great work done with setting up of the Committee, her high professionalism, devotion to the work, and smooth running of the Evaluation and Authorisation processes throughout MSC.

Item 12 – Adoption of conclusions and action points

The conclusions and action points of the meeting were adopted at the meeting (see Annex IV).

SIGNED

Watze de Wolf
Chair of the Member State Committee
(from 1 March 2014 onwards)

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ANDRIJEWSKI, Michal (PL)
ATTIAS, Leonello (IT)
BASTIJANCIC-KOKIC, Biserka (HR)
BELVEZE, Corinne (FR)
BIWER, Arno (LU)
COCKSHOTT, Amanda (UK)
COSGRAVE, Majella (IE)
HUMAR-JURIC, Tatjana (SI)
DEIM, Szilvia (HU)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
GAIDUKOVS, Sergejs (LV)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina(CZ)
LUNDBERGH, Ivar (SE)
KYPRIANODOU-LEONTIDOU, Tasoula (CY)
LULEVA, Parvoleta (BG)
MARTÍN, Esther (ES)
MIHALCEA UDREA Mariana (RO)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
WIJMENGA, Jan (NL)
Representatives of the Commission
GARCÍA-JOHN Enrique (DG ENTR)
KOBE, Andrej (DG ENV)
Observers
ANNYS, Erwin (CEFIC)
DEL CASTILLO, Francisco (CONCAWE)
BUONSANTE, Vito (ClientEarth)
DROHMANN, Dieter (ORO)
STODDART, Gilly (PETA)
WAETERSCHOOT, Hugo (EUROMETAUX)

ECHA staff
AJAO, Charmaine
BELL, David
BERNASCONI, Giovanni
BIGI, Elena
BONNOMET, Vincent
BROERE, William
CARLON, Claudio
CARTLIDGE, George
DE COEN, Wim
DE WOLF, Watze
DREVE, Simina
FEEHAN, Margaret
HUUSKONEN, Hannele
JOHANSSON, Matti
KARHU, Elina
KARJALAINEN, Antti
KARKOLA, Sampo
KOJO, Anneli
KORJUS, Pia
KOULOUMPOS, Vasileios
LE CURIEUX, Frank
MAZZZEGA SBOVATA, Silvia
MELZER, Kai
MONTERO RAMIREZ, Manuel
NAUR, Liina
NYGREEN, Beryl
O'FARRELL, Norah
PELLIZZATO, Francesca
RÖCKE, Timo
RÖNTY, Kaisu
SOBANSKA, Marta
SUNDQUIST, Anna-Liisa
VAHTERISTO, Liisa
VAINIO, Matti
VASILEVA, Katya
WALKER, Lee
ZANDER, Joakim

Proxies

ATTIAS, Leonello (IT) also acting as proxy of CAMILLERI, Tristan (MT)
KOUTSODIMOU, Aglaia (EL) also acting as proxy of KYPRIANIDOU-LEONTIDOU, Tasoula (CY) on Monday

Experts and advisers to MSC members

BAUMBUSCH, Angelika (NO) (adviser to REIERSON, Linda)
BOUWMANN, Tialda (NL) (adviser to WIJMENGA, Jan)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
CATONE, Tiziana (IT) (expert to PISTOLESE, Pietro)
DRAGUSANU, Mihaela (RO) (expert to MIHALCEA UDREA, Mariana)
GÓMEZ CONTRERAS, Jeannette (NL) (expert to WIJMENGA, Jan)
GOURLAY FRANCE, Catherine (FR) (expert to BELVEZE, Corinne)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
INDANS, Ian (UK) (expert to COCKSHOTT, Amanda)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)

MALKIEWICZ, Katarzyna (SE) (expert to LUNDBRGH, Ivar)
SEBESTYÉN, István (HU) (expert to DEIM, Szilvia)
SCHWÄGLER, Mark (DE) (expert to FINDNEGG, Helene)
PARIS, Pietro (adviser to ATTIAS, Leonello)
TRAAS, Theo (NL) (adviser to WIJMENGA, Jan)
VILNISKE, Lina (LT) (expert to DUNAUSKIENE, Lina)
WAGENER, Alex (LU) (expert to BIWER, Arno)
ZELJEZIC, Davor (HR) (expert to BASTIJANCIC-KOKIC, Biserka)

MSCA Experts for SEV cases
AQUILINA, Gabriele (IT)
DOYLE, Ian (UK)
ESPOSITO, Dania (IT)
HERZLER, Matthias (DE)

By WEBEX-phone connection:
During agenda items 1-7 from Italy: Maria Teresa Russo, Debora Romoli, Silvia Alivernini and Lucia Citro.
During agenda item 6: Steve Dungey (UK), Friederike Neisel (DE), Kai Holtappels (DE) and Alberto Mantovani (IT).
During agenda items 8 and 9 from the European Commission: Mariana Fernandes de Barros, Georg Streck, Giuseppina Luvarà, Jacek Rozwadowski, Valentina Brtato, Anna Borras Herrero and Temenuzhka Popova

Case owners:
Representatives of the Registrants were attending under agenda item 6b for SEV-IT-021/2012, SEV-IT-019/2012, SEV-DE-009/2012, SEV-DE-006/2012, SEV-UK-031/2012; under agenda item 7b for Hydrocarbons category TPE-148/2013-TPE-182/2013, TPE-189/2013 and TPE-184/2013.

Apologies:
CAMILLERI, Tristan (MT)
DRUGEON, Sylvie (FR)
PISTOLESE, Pietro (IT)

III. Final Agenda

ECHA/MSC-34/2014/A/34

Agenda

34th meeting of the Member State Committee

3-7 February 2014
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

3 February: **starts at 10:00**
7 February: **ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/034/2014
For adoption

Item 3 – Declarations of conflicts of interest to items on the Agenda

Item 4 – Administrative issues

- Feedback from 2013 Satisfaction Survey
- Renewal of the annual MSC membership declarations

For information

Item 5 – Adoption of minutes of the MSC-33

- Adoption of draft minutes of MSC-33

MSC/M/33/2013
For adoption

Item 6 – Substance evaluation decision-making

Closed session for 6c&e
Indicative time plan for 6b is Day 1&2

a. Written procedure report on seeking agreement on draft decisions on substance evaluation

ECHA/MSC-34/2014/001
For information

f. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA/ECHA reactions *(Session 1, tentatively open session except for case SEV-DE-009/2012)*

ECHA/MSC-34/2014/002

- **SEV-IT-021/2012** Hydroquinone (EC No. 204-617-8)
  ECHA/MSC-34/2014/007-008
- **SEV-IT-019/2012** Chloromethane (EC No. 200-817-4)
  ECHA/MSC-34/2014/009-010
- **SEV-DE-009/2012** Polyhaloalkene (EC No. 468-710-7)
  Tentatively closed session
  ECHA/MSC-34/2014/005-006
- **SEV-DE-006/2012** N-1-naphthylaniline (EC No. 201-983-0)
  ECHA/MSC-34/2014/003-004
- **SEV-UK-031/2012** 1,1'-(ethane-1,2-diyl) bis[pentabromobenzene] (EC No. 284-366-9)
  ECHA/MSC-34/2014/011-012

For information and discussion

g. Seeking agreement on draft decisions when amendments were proposed by MS's/ECHA *(Session 2, closed)*

As listed above, and one case returned from written procedure:

SEV-AT-001/20121 N-(1,4-dimethylpentyl)-N'-phenylbenzene-1,4-diamine (EC No. 221-374-3)[4]

For agreement

h. Processing of draft decisions for substance evaluation - short update by the Secretariat

For information

i. Update on appeal process – preparation stage *(Closed session)*

For information

Item 7 – Dossier evaluation

Closed session for 7c&e

Indicative time plan for item 7b is Day 2 pm & Day 3

a. Written procedure report on seeking agreement on draft decisions on dossier evaluation ECHA/MSC-34/2014/013

For information

b. Introduction to and preliminary discussion on draft decisions on testing proposals after MS-CA reactions *(Session 1, tentatively open session)*

ECHA/MSC-34/2014/014

Testing proposals

Hydrocarbons category

TPE 148/2013 Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List No. 919-164-8)
ECHA/MSC-34/2014/015-016

TPE 149/2013 Decane (EC No. 204-686-4)
ECHA/MSC-34/2014/017-018

TPE 150/2013 Dodecane (EC No. 203-967-9)

[4] Documents are available for members in substance specific folder in MSC CIRCABC.

ECHA/MSC-34/2014/019-020

TPE 151/2013 Undecane (EC No. 214-300-6)

ECHA/MSC-34/2014/021-022

TPE 152/2013 Tridecane (EC No. 211-093-4)

ECHA/MSC-34/2014/023-024

TPE 153/2013 Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, < 2% aromatics (List No. 920-107-4)

ECHA/MSC-34/2014/025-026

TPE 154/2013 Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics (List No. 927-676-8)

ECHA/MSC-34/2014/027-028

TPE 155/2013 Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 926-141-6)

ECHA/MSC-34/2014/029-030

TPE 156/2013 Hydrocarbons, C11-C13, isoalkanes, <2% aromatics (List No. 920-901)

ECHA/MSC-34/2014/031-032

TPE 157/2013 Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics (List No. 918-481-9)

ECHA/MSC-34/2014/033-034

TPE 158/2013 Hydrocarbons, C9-C12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List No. 919-446-0)

ECHA/MSC-34/2014/035-036

TPE 159/2013 Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List No. 927-344-2)

ECHA/MSC-34/2014/037-038

TPE 160/2013 Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics (List No. 919-857-5)

ECHA/MSC-34/2014/039-040

TPE 161/2013 Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List No. 925-653-7)

ECHA/MSC-34/2014/041-042

TPE 162/2013 Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 927-241-2)

ECHA/MSC-34/2014/043-044

TPE 163/2013 Hydrocarbons, C11-C12, isoalkanes, <2% aromatics (List No. 918-167-1)

ECHA/MSC-34/2014/045-046

TPE 164/2013 Hydrocarbons, C10-C12, isoalkanes, <2% aromatics (List No. 923-037-2)

ECHA/MSC-34/2014/047-048

TPE 165/2013 Hydrocarbons, C9-C11, cyclics, <2% aromatics (List No. 925-894-8)

ECHA/MSC-34/2014/049-050

TPE 166/2013 Hydrocarbons, C10-C13, isoalkanes, cyclics, < 2% aromatics (List No. 918-317-6)

ECHA/MSC-34/2014/051-052

TPE 167/2013 Hydrocarbons, C10-C13, n-alkanes, <2% aromatics (List No. 929-018-5

ECHA/MSC-34/2014/053-054

TPE 168/2013 Hydrocarbons, C11-C12, isoalkanes, cyclics, <2% aromatics (List No. 931-121-5)

ECHA/MSC-34/2014/055-056

TPE 169/2013 Hydrocarbons, C11-C14, n-alkanes, <2% aromatics (List No. 924-803-9)

ECHA/MSC-34/2014/057-058

TPE 170/2013 Hydrocarbons, C13-C18, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 928-253-0)

ECHA/MSC-34/2014/059-060

TPE 171/2013 Icosane (EC No. 204-018-1)

ECHA/MSC-34/2014/061-062

TPE 172/2013 Hydrocarbons, C16-C20, n-alkanes, isoalkanes, cyclics, aromatics (2-30 %) (List No. 919-006-8)

ECHA/MSC-34/2014/063-064

TPE 173/2013 Hydrocarbons, C16-C20, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 919-029-3)

ECHA/MSC-34/2014/065-066

TPE 174/2013 Hydrocarbons, C13-C16, isoalkanes, cyclics, < 2% aromatics (List No. 918-973-3)

ECHA/MSC-34/2014/067-068

TPE 175/2013 Hydrocarbons, C14-C18, n-alkanes, isoalkanes, cyclics, aromatics (2-30 %) (List No. 920-360-0)

ECHA/MSC-34/2014/069-070

TPE 176/2013 Hydrocarbons, C14-C18, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 927-632-8)

ECHA/MSC-34/2014/071-072

TPE 177/2013 Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics (List No. 920-114-2)

ECHA/MSC-34/2014/073-074

TPE 178/2013 Hydrocarbons, C11-C14, isoalkanes, cyclics, <2% aromatics (List No. 927-285-2)

ECHA/MSC-34/2014/075-076

TPE 179/2013 Hydrocarbons, C13-C15, n-alkanes, isoalkanes, cyclics, < 2% aromatics (List No. 917-488-4)

ECHA/MSC-34/2014/077-078

TPE 180/2013 Hydrocarbons, C9-C11, isoalkanes, cyclics, <2% aromatics (List No. 920-134-1)

ECHA/MSC-34/2014/079-080

TPE 181/2013 Hydrocarbons, C17-C19, n-alkanes, <2% aromatics (List No. 937-158-3)

ECHA/MSC-34/2014/081-082

TPE 182/2013 Tetradecane (EC No. 211-096-0)

ECHA/MSC-34/2014/083-084

Other TPEs

TPE 189/2013 4,4,13,13-tetraethoxy-3,14-dioxa-8,9-dithia-4,13-disilahexadecane (EC No. 260-350-7)

ECHA/MSC-34/2014/091A&B-092

TPE 183/2013 Heptanal (EC No. 203-898-4)

ECHA/MSC-34/2014/085-086

TPE 184/2013 N-vinylformamide (EC No. 236-102-9)

ECHA/MSC-34/2014/087A&B-088

TPE 186/2013 N-(cyclohexylthio)phthalimide (EC No. 241-774-1)

ECHA/MSC-34/2014/089-090

For information and discussion

c. Seeking agreement on draft decisions on testing proposals when amendments were proposed by MS's *(Session 2, closed)*

As listed above under **7b**

For agreement

d. General topics

Status report on on-going evaluation work

For information

e. Update on appeal process *(Closed session)*

For information

Item 8 – Community Rolling Action Plan (CoRAP) update

d. Discussion on the MSC opinion on the draft Community Rolling Action Plan (CoRAP) update

e. Adoption of the MSC opinion

ECHA/MSC-34/2014/093
For discussion and adoption

f. Development of the screening for future CoRAP substances – brief update on activities by ECHA

For information

Item 9 – Authorisation process

b. SVHC identification process and ECHA's recommendation of priority substances for Annex XIV – Short status report by the secretariat

ECHA/MSC-34/2014/097
For information

c. Applications for authorisation and decision making - role in the authorisation process and state of play

For information

Item 10 – Report on MSC work 2013; MSC work plan for 2014

ECHA/MSC-34/2014/096
For information

Item 11 – Any other business

- Update on Guidance IR&CSA – Chapter R.11 (related to PBT/vPvB assessment)
- New IT platform tool testing
- Big 'thanks' from ECHA operational units to the MSC Chair

For information

Item 12 – Adoption of conclusions and action points

- Table with conclusions and action points from MSC-34

For adoption

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-34, 3-7 February 2014
(adopted at MSC-34)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 - Administrative issues **a. Satisfaction survey**	
MSC took note of the oral report given by the Secretariat.	**MSC-S** to upload the report from the 2013 Satisfaction Survey on MSC CIRCABC once available.
Item 5 – Adoption of minutes of the MSC-33	
	MSC-S to upload final version of the minutes on MSC CIRCABC and ECHA website by 11 February 2014.
Item 6 - Substance evaluation decision-making **b. Written procedure report on seeking agreement on draft decisions on substance evaluation**	
MSC took note of the report.	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions agreed in written procedure, as indicated in document ECHA/MSC-34/2014/001.
Item 6 - Substance evaluation decision-making **b. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CAs/ECHA reactions *(Session 1, tentatively open session except for case SEV-DE-009/2012)*** **c. Seeking agreement on draft decisions when amendments were proposed by MS-CAs/ECHA *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting (where appropriate): **SEV-IT-021/2012** Hydroquinone (EC No. 204-617-8) **SEV-IT-019/2012** Chloromethane (EC No. 200-817-4) **SEV-DE-006/2012** N-1-naphthylaniline (EC No. 201-983-0) **SEV-UK-031/2012** 1,1'-(ethane-1,2-diyl) bis[pentabromobenzene] (EC No. 284-366-9) **SEV-AT-001/20121** N-(1,4-dimethylpentyl)-N'-phenylbenzene-1,4-diamine (EC No. 221-374-3) MSC could not reach unanimous agreement on the following draft decision regarding the following substance evaluation draft decision: **SEV-DE-009/2012** Polyhaloalkene (EC No. 468-710-7)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions/cover letters of the agreed cases. **MSC-S** to provide COM for further decision making with the relevant documents (DD provided for the vote, RCOM, minutes, outcome of the vote, justification for the position at the vote).
Item 7 – Dossier evaluation **a. Written procedure report on seeking agreement on draft decisions on dossier evaluation**	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
MSC took note of the report.	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions agreed in written procedure, as indicated in document ECHA/MSC-34/2014/013_Rev. **MSC-S** to provide COM for further decision making with documents (DD, RCOM, outcome of the vote, justifications for NO votes) of cases on which MSC did not reach agreement, as indicated in document ECHA/MSC-34/2014/013_Rev.
Item 7 – Dossier evaluation **b. Introduction to and preliminary discussion on draft decisions on testing proposals after MS-CA reactions *(Session 1, tentatively open session)*** **c. Seeking agreement on draft decisions on testing proposals when amendments were proposed by MS's *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting where appropriate: **Testing proposals** **TPE 183/2013** Heptanal (EC No. 203-898-4) **TPE 184B/2013** N-vinylformamide (EC No. 236-102-9) **TPE 189B/2013** 4,4,13,13-tetraethoxy-3,14-dioxa-8,9-dithia-4,13-disilahexadecane (EC No. 260-350-7)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions/cover letters of the agreed cases.
MSC could not reach unanimous agreement on the following draft decisions regarding examination of the testing proposals for a two-generation reproduction toxicity study (Annex X, 8.7.3) (including Part A of split decisions): **Testing proposals** **Hydrocarbons category** **TPE 148/2013** Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List No. 919-164-8) **TPE 149/2013** Decane (EC No. 204-686-4) **TPE 150/2013** Dodecane (EC No. 203-967-9) **TPE 151/2013** Undecane (EC No. 214-300-6) **TPE 152/2013** Tridecane (EC No. 211-093-4) **TPE 153/2013** Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, < 2% aromatics (List No. 920-107-4) **TPE 154/2013** Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics (List No. 927-676-8) **TPE 155/2013** Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 926-141-6) **TPE 156/2013** Hydrocarbons, C11-C13, isoalkanes, <2% aromatics (List No. 920-901) **TPE 157/2013** Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics (List No. 918-481-9) **TPE 158/2013** Hydrocarbons, C9-C12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List No. 919-446-0) **TPE 159/2013** Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List No. 927-	**MSC-S** to provide COM for further decision making with the relevant documents (DD on generation testing, RCOM, minutes, outcome of the vote, justification for the position at the vote).

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
344-2) **TPE 160/2013** Hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics (List No. 919-857-5) **TPE 161/2013** Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) (List No. 925-653-7) **TPE 162/2013** Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 927-241-2) **TPE 163/2013** Hydrocarbons, C11-C12, isoalkanes, <2% aromatics (List No. 918-167-1) **TPE 164/2013** Hydrocarbons, C10-C12, isoalkanes, <2% aromatics (List No. 923-037-2) **TPE 165/2013** Hydrocarbons, C9-C11, cyclics, <2% aromatics (List No. 925-894-8) **TPE 166/2013** Hydrocarbons, C10-C13, isoalkanes, cyclics, < 2% aromatics (List No. 918-317-6) **TPE 167/2013** Hydrocarbons, C10-C13, n-alkanes, <2% aromatics (List No. 929-018-5 **TPE 168/2013** Hydrocarbons, C11-C12, isoalkanes, cyclics, <2% aromatics (List No. 931-121-5) **TPE 169/2013** Hydrocarbons, C11-C14, n-alkanes, <2% aromatics (List No. 924-803-9) **TPE 170/2013** Hydrocarbons, C13-C18, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 928-253-0) **TPE 171/2013** Icosane (EC No. 204-018-1) **TPE 172/2013** Hydrocarbons, C16-C20, n-alkanes, isoalkanes, cyclics, aromatics (2-30 %) (List No. 919-006-8) **TPE 173/2013** Hydrocarbons, C16-C20, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 919-029-3) **TPE 174/2013** Hydrocarbons, C13-C16, isoalkanes, cyclics, < 2% aromatics (List No. 918-973-3) **TPE 175/2013** Hydrocarbons, C14-C18, n-alkanes, isoalkanes, cyclics, aromatics (2-30 %) (List No. 920-360-0) **TPE 176/2013** Hydrocarbons, C14-C18, n-alkanes, isoalkanes, cyclics, <2% aromatics (List No. 927-632-8) **TPE 177/2013** Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics (List No. 920-114-2) **TPE 178/2013** Hydrocarbons, C11-C14, isoalkanes, cyclics, <2% aromatics (List No. 927-285-2) **TPE 179/2013** Hydrocarbons, C13-C15, n-alkanes, isoalkanes, cyclics, < 2% aromatics (List No. 917-488-4) **TPE 180/2013** Hydrocarbons, C9-C11, isoalkanes, cyclics, <2% aromatics (List No. 920-134-1) **TPE 181/2013** Hydrocarbons, C17-C19, n-alkanes, <2% aromatics (List No. 937-158-3) **TPE 182/2013** Tetradecane (EC No. 211-096-0) **Other TPEs** **TPE 184A/2013** N-vinylformamide (EC No. 236-102-9) **TPE 189A/2013** 4,4,13,13-tetraethoxy-3,14-dioxa-8,9-dithia-4,13-disilahexadecane (EC No. 260-350-7) The Chair informed MSC that ECHA had received a letter from the Lead Registrant on his cease of manufacture regrading TPE 186/2013, N-(cyclohexylthio)phthalimide, EC No. 241-774-1. Therefore, the case is withdrawn from the decision making process of MSC.	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 8 – Community Rolling Action Plan (CoRAP) update **c. Adoption of the MSC opinion**	
MSC adopted by consensus the draft opinion and its Annex on the draft CoRAP update 2014-2016 as modified in the meeting.	**SECR** to upload the MSC CoRAP opinion including its Annex on MSC CIRCABC after the meeting **SECR** to publish the opinion on the ECHA website together with the annual CoRAP update on 19 March 2014[5].
Item 9 – Authorisation process **d. SVHC identification process and ECHA's recommendation of priority substances for Annex XIV –** Short status report by the secretariat	
MSC took note of the plan for the next recommendation and the way how substances for assessment for this round are selected.	**SECR** to upload to the MSC CIRCABC after the meeting the list of substances envisaged for the assessment for possible prioritisation in the 6th ECHA draft recommendation. **SECR** to present the prioritisation results of the selected substances for 1st discussion in MSC meeting in April.
Item 10 – Report on MSC work 2013 and MSC work plan for 2014	
MSC took note of the report and the 2014 work plan presented by the MSC-S.	**MSC-S** to upload on MSC CIRCABC and on ECHA website the tentative MSC meeting dates for 2015 after the meeting.
Item 11 AOB **a. Updated Guidance on information requirements and chemical safety assessment – Chapter R.11: PBT and vPvB Assessment**	
MSC took note of the announcement for the launched MSC Guidance consultation.	**Members** to review the revised guidance document and to submit comments (if any) by 27 February 2014. **MSC-S** to compile and send the comments received to the Guidance Unit for their further uptake.
Item 11b New IT platform testing	
	MSC-S to organise the testing of the new IT tool by granting access to members and providing instruction in this regard. **Members** to provide feedback on the new IT tool testing in the following three months.
Item 12 – Adoption of conclusions and action points	
MSC adopted the conclusions and action points of MSC-34.	**MSC-S** to upload the conclusions and action points on MSC IRCABC by 10 February 2014.

[5] Post meeting information: Publication date for updated CoRAP is not yet confirmed and might be later than announced.

V. Dossier evaluation cases addressed for MSC agreement seeking in WP:

Cases unanimously agreed by MSC in WP:

MSC ID number	Substance name used in draft decision	EC number
CCH 164B/2013	Humic acids, potassium salts	271-030-1
CCH 165B/2013	Humic acids, sodium salts	268-608-0
CCH 167/2013	Synthetic fibres, alk. earth silicate; AES wool; Alkaline earth silicate	610-130-5
CCH 170/2013	Manganese alumina pink corundum	269-061-0
CCH 171/2013	Reaction mass of Fumes, silica and diiron trioxide	909-981-8
CCH 173/2013	Chromium iron oxide	235-790-8
CCH 182/2013	2-ethylhexyl diphenyl phosphate	214-987-2
CCH 185/2013	Tris(methylphenyl) phosphate	215-548-8

Cases to be referred to COM:

MSC ID number	Substance name used in draft decision	EC number
CCH 164A/2013	Humic acids, potassium salts	271-030-1
CCH 165A/2013	Humic acids, sodium salts	268-608-0

VI. Statements of MSC members made with regard to the MSC agreement seeking on ECHA's draft decisions resulting from the substance evaluation process

- **Regarding SEV-IT-021/2012 Hydroquinone**

Statement by the Netherlands and Denmark on the vote:

For the Netherlands and Denmark it is clear that in a case where a substance is already classified as Mutagen 2, we would under normal conditions ask for a Transgenic Rodent Assay, in line with our PfA.

However, in this specific case, where the TGR has to be preferably performed in rat, we note that there may be an issue with the availability of this study and consequently with the ability to ask for this.

So, in this specific case, where our preference is still TGR, we could accept leaving the choice to the registrant.

If the registrant chooses to perform a comet assay, it might lead to an additional request for a TGR test targeting germ cells in the future, if the outcome of the comet does not lead to enough information for the Risk Assessment Committee to conclude on the classification MUTA category 1B.

With this remark NL and DK can vote in favour.

- **Regarding SEV-DE-009/2012 Polyhaloalkene**

Statement by Denmark, Lithuania and the Netherlands on the vote:

This decision contains requests for more information on several issues of concern, which we support, even though we are currently unsure whether it is needed to include the particular request to provide more justification regarding the already provided information in the registration dossier on the auto-ignition temperature.

- **Regarding SEV-UK-031/2012 1,1´-(Ethane-1,2-diyl)bis-(pentabormobenzene) (or decabromodiphenyl ethane, EBP)**

Statement by Denmark and the Netherlands on the vote:

A concern for endocrine disruptive properties of the substance has been recognized in this decision. A request for new animal testing addressing concern for endocrine disruptive properties of the substance in fish has therefore been included.

It was noted in a proposal for amendment of the draft decision that the REACH standard information requirement concerning reproductive toxicity information according to REACH Annex X 8.7.3. is currently not available. In our view, the waiver provided in the registration dossier for not providing this information is not justified, but this was unfortunately not explicitly stated in the proposal for amendment. Such information would also provide essential information about endocrine disruptive properties of the substance in mammalian species in addition to the now requested information to be provided on endocrine disruptive properties of the substance in fish.

We vote however yes to this decision due to procedural reasons.

This also means that the required testing on formation of degradation products with PBT properties and of the bioaccumulative and endocrine disruptive properties of the substance in fish will not be postponed.

Performance of a targeted compliance check of the registration dossier of this substance regarding the current lack of REACH standard information requirements according to Annex X 8.7.3 or a later request for an EOGRTS in the context of the current substance evaluation could both provide an essential part of the required minimum information about reproductive toxicity and well as providing essential information concerning the endocrine disruptive properties in mammalian species (including humans).