MSC/M/32/2013
ADOPTED AT MSC-33

Minutes
of the 32nd Meeting of the Member State Committee (MSC-32)
4-8 November 2013

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 32nd 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 by SECR and a member'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

No potential conflicts of interests were declared by any members, experts or advisers with any item on the agenda of MSC-32.

Item 4 - Administrative issues

The MSC Chair informed the Committee of the upcoming MSCA Directors' planning meeting that is to be held in ECHA on 20th November, pointing out that also the item related to the functioning of the ECHA's Committees will be on the agenda.

Members with expiring term of office were also advised to remind their respective Competent Authorities to respond to the on-going membership renewal procedure well in advance to avoid any disruptions in the Committee's functioning.

Due to the shorter deadlines in the next meeting invitation, SECR requested the members to consider in advance the experts to be proposed for MSC-33.

Item 5 – Adoption of the minutes of the MSC-31 meeting

SECR presented the revised version of the MSC-31 minutes informing MSC that written comments on the draft minutes were received by two MSC members and two Commission observers prior to the MSC-32 meeting. One MSC member provided its comments at the MSC-32 meeting. The representatives of the Registrants for five dossier evaluation cases who had participated in MSC-31 have also been consulted for the respective parts of the draft minutes. Four provided comments which were included in the minutes. In conclusion, the minutes were adopted with few slight changes carried out at 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 two substance evaluation cases[1]. WP was launched on 10 October 2013 and closed on 21 October 2013. By the closing date, responses to WP were received from 25 members with voting rights and from the Norwegian member. Unanimous agreement was reached on the draft decision (DD) for 'A mixture of: cistetrahydro-2-isobutyl-4-methylpyran-4-ol; transtetrahydro-2-isobutyl-4-methylpyran-4-ol (EC No. 405-040-6)'. For DD on N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine (EC No. 221-375-9), WP was terminated by

[1] A mixture of: cistetrahydro-2-isobutyl-4-methylpyran-4-ol; transtetrahydro-2-isobutyl-4-methylpyran-4-ol (EC No. 405-040-6), evaluated by Spanish CA and N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine (EC No. 221-375-9), evaluated by Belgium CA

the MSC Chair on the basis of Article 20.6 of the MSC Rules of Procedure as one MSC member requested discussion at the MSC-32 meeting.

b. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA reactions *(Session 1, open session except for SEV-FR-015-2/2012 closed)*

c. Seeking agreement on draft decisions on testing proposals when amendments were proposed by MS-CAs/ECHA *(Session 2, closed)*

SEV-DE-005/2012 4,4'-isopropylidenediphenol (Bisphenol A, BPA) (EC No. 201-245-8)

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

The MSC Chair pointed out that in relation to this substance evaluation, a representative of an industry consortium approached by e-mail all MSC members during the agreement seeking session in contrary of the established ECHA rules for interactions of ECHA bodies with the concerned stakeholders. The Chair reminded the Committee of the *General principles and guidance for Committee members of the European Chemicals Agency* which has been released by the decision of the ECHA Executive Director (http://echa.europa.eu/documents/10162/13559/ed_decision_08_2013_en.pdf). As a consequence of attempts to influence the view of the individual members MSC decision making would be at risk because the same basis for decision making would not be available for all. REACH has established ways of communication via public or other consultations of registrants/affected companies ensuring a possibility to contribute. It would be important to maintain impartiality and credibility of the Committee's decision making and refrain from communicating with stakeholders on dossiers that are currently on-going with the Committee, as stated in the ECHA document.

MSC was also reminded of the difference between substance evaluation (SEV) and the dossier evaluation (DEV) processes clarifying that information requests under SEV can go beyond the standard information requirements of REACH in order to conclude on the (initial concerns or the ones identified during the substance evaluation) for the substance. It was explained that SEV follows DEV provisions by *mutatis mutandis* as the main procedural difference is that the substance evaluation resulting in a DD is carried out by an evaluating Member State Competent Authority (eMSCA).

eMSCA's experts from German CAs presented the SEV outcome for BPA done on the basis of the initial grounds for concern relating to suspected endocrine disruption towards the ecosystem, exposure/wide dispersive use, consumer use and high aggregated tonnage. An additional concern was identified during SEV process regarding the consumer use of articles. eMSCA's expert explained the information requests to clarify the concerns, i.e. for the skin absorption study *in vitro* including investigation of metabolism of BPA and for further information on emission pathways to the environment. Proposals for amendment (PfAs) were received from other MSCAs and ECHA (mostly editorial) on DD as follows: Two PfAs were asking for further clarification how the skin absorption test (*in vitro)* should be conducted. One PfA challenged the need for a new skin absorption study. One PfA proposed to add a paragraph explaining that eMSCA has not concluded evaluation of endocrine disruption for human health and may consider it in a later stage after finalisation of several on-going studies and the need for further testing may depend on the results from these studies. One PfA was provided to add a reminder to the Registrants that they are expected to update the registration dossiers when new information on the on-going studies is made available. Another PfA proposes to add a request to the registrants to take into account any new publicly available information which may include the currently on-going biomonitoring study in cashiers (carried out by ANSES/France) and tellers handling thermal paper containing BPA and/or BPS (carried out in US) and possibly information based on other studies. One PfA indicated no agreement with the outcome of the substance evaluation on dermal absorption and considered that based on available studies the risk can be identified with enough confidence to carry on with risk management measures. According to this PfA the risk of BPA used by consumers and workers in thermal paper can be demonstrated. One PfA proposed to add further responses to the Registrants'

comments on the DD and PfAs. eMSCA's expert explained that DD was amended in order to accommodate most of the PfAs received. Further explanation was included in Section III responding to the concerns raised by the Registrants in their comments on the DD and PfAs. However, eMSCA did not amend the DD based on PfA suggesting to delete the request for skin absorption study and did not amend in all respects the part concerning thermal paper. The amended DD had been provided to MSC for finding unanimous agreement.

eMSCA's expert mentioned that common understanding will most likely be possible on the need for further information on skin absorption without challenging the intention to restrict the use of BPA in thermal paper.

Registrant's comments on PfAs of CAs and discussion

The Registrants provided written comments mainly challenging the legality and proportionality of the DD itself. Only minor part of the comments referred to the PfAs which are in the scope of the MSC discussion. Regarding the skin absorption study the Registrants considered relevant the investigation of dermal metabolism in the *in vitro* study and requested again for extension of the deadline to submit the test results. It was noted that to the extent that the Registrants do not manufacture or import thermal paper, information on the amounts of imported paper and releases from it cannot be gathered by them. The registrants indicated in the comments that they did not understand the request to recalculate the tonnages for production of BPA and its use in production of polymers. The registrants have found inacceptable the PfA from a MSCA proposing a statement to be added to DD that eMSCA has not concluded evaluation of endocrine disruption for human health and may consider it in a later stage since several on-going studies will be finalised in the near future and the need for further testing may depend on the results from these studies.

The representatives of the Registrants gave short overview of the Registrants' concerns at the meeting. The Registrants noted that they had not been given access to the draft Evaluation Report, its Annexes and underlying documents and the amended DD, thereby restricting their ability to assess the DD and to comment upon it. As regards the reported tonnages in the registration dossiers, the Registrants explained that they held the declared amounts to be correct; however, some third parties' imports are possible without Registrants' knowledge that leads to difficulties in the evaluation. Some further remarks were made as regards the scope and reasoning of DD requirements to be kept clear, justified and reasonable, in particular as the Registrants considered exposure from articles and polymers excluded from the scope of REACH registration requirements for BPA. Regarding the requested environmental exposure assessments, in the Registrants' view, the DD should provide the option to generate cumulative scenarios for uses with e.g. comparable conditions of use or with negligible residual BPA contents to avoid excessive building of new exposure scenarios. A request was made for re-consideration of the deadlines for submission of data in DD as well as for further clarity on the approach to be followed for data collection/information gathering. The representatives of the registrants were interested to know by which means the requested environmental exposure data are to be provided and whether laboratory analyses or modelling data are sufficient or whether monitoring data are required.

The Chair reminded that MSC discussion should focus on PfAs to the DD made by MSCAs and ECHA and not on the scope of DD as such.

eMSCA's expert responded to the issues raised by the Registrants' representatives by clarifying that the distribution of the tonnages in industrial manufacturing of BPA and its use in production of polycarbonate as indicated in the registration dossiers is unclear in eMSCA's view and discrepancy in the tonnages is seen comparing with the declared total amount. eMSCA expert announced to clarify the tonnage discrepancy bilaterally with the Registrants. As regards the information request on polymers, it was specified that the residual BPA content in the provided exposure scenario has been found unclear and although the residual BPA content in polymers may be low, due to the high production tonnage of polymers, the relevant pathways need to be clarified and considered. eMSCA's expert pointed out to some late modifications made in the amended DD concerning the

import of thermal paper and polymers. It was highlighted that the information requests with the legal basis are clearly expressed in the decision and data can be produced in accordance with the relevant guidance documents which would allow both using modelling and monitoring data for assessment of exposure/emissions.

With regard to polymers in the scope of REACH Regulation, SECR noted that despite of the general exemption for registration of polymers under REACH, monomers (as starting materials of polymers) are not excluded from the registration process and are therefore in the scope of substance evaluation. REACH does cover the whole life cycle of the monomers, also when included in polymers. It was also noted that the SEV requests can go beyond the standard information requirements of the Regulation and further information not included in the registration dossiers can be requested. As regards to the data gathering, it was explained that the Registrants are left to decide on their own the way to derive the necessary information and clarify the discrepancy identified by eMSCA.

MSC acknowledged that exposure from imports of articles and polymers by 3rd parties does not fall within the scope of the registrants' REACH registration of BPA and thus should not fall within the scope of the DD.

The representative of the Registrants also noted the potential difficulties in fulfilling the requirements of dermal absorption test guideline within the specified timeline, due to need for further clarification of additional parameters specified in DD (such as BPA metabolic pathways), difficulties in checking the metabolic activation in the tissues and in finding a GLP laboratory for performing these studies. The representatives of the Registrants repeated the request for prolongation of the dead line for submission of data that could guarantee higher quality study results.

The eMSCA's expert expressed readiness to discuss the deadline and possibly extend it, although it still held that the deadline in the revised decision was sufficient.

Session 2 (closed)

The expert from the MSCA who was not in agreement to request the skin absorption study presented the rationale for their PfAs on BPA and the MSC member from this MSCA specified the outcome of the bilateral discussions with eMSCA to come to an agreement regarding how to clarify and strengthen the request for the skin absorption study. In result, the scope of the DD was further clarified. In details, clarification was introduced in Section I referring to evaluation of risks for consumers (excluding assessment for endocrine disrupting properties at this point of time) and justification that robust information is needed on dermal absorption to allow final conclusion on certain risks for consumers (uses of larger PVC articles and toys). Furthermore it was clarified that risks for workers handling thermal paper was not evaluated. Further justification was provided in Section III of DD explaining the need for the skin absorption study taking into account the available information and the uncertainty related to critical risk characterisation ratios for specific consumer uses (uses of larger PVC articles and toys).

This view was supported by several MSC members. Some small modifications were made in DD based on PfAs and the registrants' comments. The justification for request of further information on emissions from BPA production/use/production of polymers and articles/releases from polymers/articles covering the whole life cycle was slightly reformulated by explaining that further information may be requested under substance evaluation either on intrinsic properties and/or on exposures. It was added that in the present case at this stage no further information is required on hazards for the ecosystem as the eMSCA has sufficient information in this respect.

Following the Registrants' request and eMSCA's proposal for extension of the deadline for updating the registration dossiers with the information requested in this DD, MSC agreed to prolong the deadline from 18 to 24 months.

Based on the above considerations, MSC unanimously agreed on the SEV DD for BPA as modified at the meeting.

SEV-DK-011/2012 Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol (EC No. 700-960-7)[2]

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

eMSCA's expert from Danish CA presented the outcome of SEV of the above-mentioned substance performed by DK CA on the basis of the initial grounds for concern, i.e. relating to potential PBT properties, potential endocrine disrupting properties, wide dispersive use and high tonnage. The members were introduced with the information requests included in DD regarding bioaccumulation test in fish (OECD305, dietary test) with additional measurements of VtG induction and combined sub-chronic toxicity study (90-day) (EUB26/OECD408) and extended one generation reproductive toxicity study (EOGRTS) (OECD443) including DNT and DIT cohorts. No PfAs were introduced on the bioaccumulation test in fish and therefore this was not discussed by MSC. One PfA was provided and accepted by eMSCA regarding the need to change the name and identifiers in DD of the substance based on the outcome of the substance identity compliance check. However, no amendments were made in DD as regards the PfA suggesting not to request for a combined 90-day repeated dose toxicity (RDT) study and EOGRTS but to conduct the studies separately to ensure robust results. Furthermore, according to the PfA 10-week pre-mating exposure period for P animals and extension of the Cohort 1B to mate the F1 animals to produce F2 generation were proposed to be included in the EOGRTS study design, as well as substance-specific reasoning for including the DNT and DIT cohorts to be provided in DD. Additional reasoning (e.g. for inclusion of DNT/DIT cohorts) had been added by eMSCA to the amended draft decision provided for the meeting but no changes were made with regard to the test design. The eMSCA's expert explained that the registrants supported the combined study and did not see outstanding problems in running the combined study. Some members supported this line. It was also noted that special attention should be paid to the interaction between the on-going testing proposal examination for conducting a pre-natal developmental toxicity (PNDT) study and the current SEV process. The PNDT study might be useful as the range-finder study for the combined RDT/EOGRTS study and so ideally would be conducted first.

Registrant's comments on PfAs and discussion

The Registrant in his written comments on a PfA regarding the combined 90-day and EOGRT study supported the proposal of the eMSCA for merging the two studies and confirmed their position at the meeting. They indicated that some further adjustments could be made in the study design, like e.g. the inclusion of a recovery group; however, for the dose-range finding purpose, the representatives of the Registrant underlined that the PNDT study should be carried out before the combined 90-day and EOGRT study is launched.

SECR informed MSC of the procedural status of DD for TPE noting that the delay in handling of the TP was due to the recently completed compliance check on substance identity and currently the DD is targeted for the MSC meeting in June 2014. Further, the rationale for the PfAs was presented and SECR suggested that substance-specific triggers should be explained in Section III of the decision for DNT/DIT cohorts and substance specific reasons for omitting F2 generation instead of the general justification provided for the study design. SECR view was supported by some members. However, some other members noted that according to the OECD 443 guideline, substance specific reasons for omitting the DNT/DIT cohorts are needed, whereas the F2 generation is not needed by default but may be triggered if this can be justified. One member noted that some of the substance's constituents are potentially bioaccumulative and it is therefore expected that considerable time may be needed to reach a steady stage during the pre-mating exposure period for the P generation. Therefore 10 weeks pre-mating period may be warranted.

Session 2 (closed)

MSC concluded that the combined 90-day RDT study and EOGRTS with DNT/DIT cohorts and without the second generation (F2) could be requested. However, some changes were

[2] Substance name used for listing on the CoRAP was Phenol, methylstyrenated (EC No 270-966-81).

agreed to be made in section III. It is stated that a dose-range finder study should be conducted first because no such data are available. The same study may be useful before conducting the prenatal developmental toxicity study if the decision on that testing proposal comes later than starting the combined 90 day/EOGRTS requested in the present decision. The premating period was set to 10 weeks due to an assumption that reaching steady stage with this substance would take long time. It was agreed that in this case when referring to OECD 443, the DNT/DIT cohorts can be considered to be included as default (unless justified to be omitted) and the test to be performed without the second generation (F2) unless F2 is triggered. However, substance specific justifications were included for requests of the DNT and the DIT cohorts. Although F2 was not requested in the present case information for omitting F2 is provided in DD with a brief reference to publications in scientific literature based on retrospective analysis regarding the general lack of need for F2. It was emphasised that application of EOGRTS (OECD443) for this case is case specific and cannot be used as a precedent for other cases.
Following the above considerations, MSC unanimously agreed on this SEV DD as modified at the meeting.

SEV-FR-015-1/2012 Carbon tetrachloride (EC No. 200-262-8)

SEV-FR-015-3/2012 Carbon tetrachloride (EC No. 200-262-8)

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

eMSCA's expert from the French CA presented the outcome of substance evaluation of the above-mentioned substance performed by FR CA on the basis of the initial grounds for concern, i.e. relating to human health/CMR, exposure for workers and high aggregated tonnage. The members were introduced with the information requests included in DD for FR-015-1/2012 to request a two-generation reproductive toxicity study. eMSCA's expert explained that four PfAs to DD were submitted. One was suggesting to reject the proposed two-generation reproductive toxicity study based on available information from repeated dose toxicity studies and a non-guideline study using weight of evidence. According to the PfA the studies used as indications for testicular toxicity and effect on the oestrus cycle should not be taken into account because the studies were conducted via intraperitoneal route. According to PfA there is lack of concern for reproductive toxicity. Two other PfAs were suggesting to request an extended one generation reproductive toxicity study (EOGRTS) without F2 and with DIT/DNT cohorts. Two PfAs were suggesting to specify the most relevant route of administration for the "generation" study (oral or inhalation route) which was missing in the DD.

eMSCA had modified DD for the meeting based on PfAs and suggested also modifications based on registrant's comments on PfAs. However, the request for the two-generation study was maintained in the DD and route of administration was intended for discussion. The eMSCA's expert further explained the rationale of the eMSCA for requesting two-generation reproductive toxicity study.

Registrant's comments on PfAs and discussion

The Registrant in his written comments on the PfAs supported the view that no further 'generation' test would be needed and provided further translated evidence from study reports in support of that, the reports that had been requested before but not provided. The representatives of the Registrant at the meeting did not agree with the request for the two-generation study nor EOGRTS justifying that there is already sufficient evidence to characterise the reproductive toxicity potential of the substance based on weight of evidence approach. They indicated that the absence of effects on reproductive organs in repeat-dose toxicity study, as indicated in the additional data that was brought forward. Furthermore information on reproductive toxicity from a non-guideline study supports the conclusion that there would be no concern for the reproductive toxicity. This information together with the view that restrictive controls are already in place are reasons for that further testing is unjustified. Use of the substance mainly as an intermediate was also brought forward as an argument for not asking further studies when there is already a lot of data available, and the new results would not have impact on how the substance is handled. The Registrant and one MSC expert expressed concern regarding the introduction

by the eMSCA of new data into the substance evaluation process at such a late stage, a week prior to the MSC meeting. Due to the very late introduction of the data that does not allow the Registrant had not had sufficient time to assess the information and its relevance to the discussion.

The eMSCA expert responded that in eMSCA's view that due to deviations from standard protocols and some parameters lacking from the assessments it was not possible to conclude either based on the new data from the registrants that there is no concern for reproductive toxicity. It was also noted that the new literature search from 2013 indicated concern over some abnormal findings in sperm parameters in studies using gavage administration. However, the eMSCA expert acknowledged that the statements in DD had been carefully reviewed taking into account the Registrant's contributions. It was also noted that even if restrictive control is already in place, there is still exposure as shown by the existing monitoring data.

In the following discussion, different views were shared mainly whether the two-generation study or EOGRTS (test method: OECD 443) should be requested and whether under EOGRTS the second generation should be asked, or whether test would be needed at all. In that context it was noted that consideration should be paid in particular on the fertility concern identified by eMSCA. A stakeholder observer expressed concerns regarding the animal use in this test.

DD related to SEV-FR-015-3/2012 was introduced briefly and it was explained that it was an additional data request not addressed to all registrants. The members were introduced with the information requests, and eMSCA expert explained that two PfAs to DD were submitted by MSCAs. eMSCA agreed with those suggestions and modified the DD accordingly for the meeting.

Session 2 (closed)

Based on the discussions in Session 1 it was concluded that the fertility concern has still to be addressed and that EOGRTS could be used for that purpose. The study would potentially give a possibility to derive a more protective DNEL even without the second generation. As regards the route of exposure, both oral and inhalation were considered as relevant, however, inhalation was deemed more valid route taking into account the high vapour pressure of the substance.

DD was modified taking into account the registrant's comments and the discussion at the meeting. In conclusion, MSC supported EOGRTS. As the request is for OECD 443 protocol the DIT/DNT cohorts will be required as default, however, DD indicates that the registrant may consider waiving these cohorts based on scientific justification. It was emphasised that application of EOGRTS (OECD443) for this case is case specific, based on the latest data provided by the registrant and cannot be used as a precedent for other cases.

Following the above considerations, MSC unanimously agreed on this SEV DD (SEV-FR-015-1/2012) as modified at the meeting. As regards DD SEV-FR-015-3/2012, MSC unanimously agreed on DD without further modifications at the meeting.

SEV-FR-015-2/2012 Carbon tetrachloride (EC No. 200-262-8)

Session 2 (closed)

No representative of the Registrant participated in the initial discussion. Because of concerns indicated for confidential business information in DD, a closed session was held.

This DD was not addressed to all registrants.

Two PfAs were submitted, one relating to aggregated exposure and the other suggesting to clarify the scope of the request.

eMSCA had modified DD for the meeting based on both PfAs.

MSC unanimously agreed on this SEV DD after some editorial modifications at the meeting.

SEV-UK-030/2012 Imidazole (EC No. 206-019-2)

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.

eMSCA's expert from the 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. relating human health/CMR, wide dispersive uses and high tonnage. In the course of evaluation additional concerns regarding environmental hazards were identified. The PfAs were reflected upon as well as responses to them. To clarify the concerns the DD indicated that further detailed information on worker exposure/risk management measures for all scenarios, *in vitro* mouse lymphoma study (OECD 476) and robust study summaries for the existing short-term aquatic tests would be requested as well as information required providing documentation on strictly controlled conditions.

Two PfAs addressed the need to reformulate the request for training for use of personal protective equipment. Another PfA proposed that an adequate exposure assessment addressing each relevant route of human exposure shall be performed (inhalation, oral, dermal) and combined through all sources of exposure. One PfA proposed to soften the wording in Section III regarding feasibility of read-across approach for *in vitro* mouse lymphoma study. It was also proposed to consider splitting the DD depending on the information requests relevant for different registrants. Another PfA proposed to add to the DD request for a two-generation study which is missing in the registration dossiers.

eMSCA's expert explained that DD has been amended based on the PfAs but no change was introduced regarding the information gap for the generation study although the data gap has been recognised. eMSCA considered that the developmental toxicity is confirmed by the available information and a proposal for harmonised classification (Repr 1B) has been submitted in this regard (this classification has been agreed by RAC and recommended for addition to Annex VI of the CLP regulation). Based on conclusion on developmental toxicity eMSCA considers it very important that the exposure assessment is carried out and any necessary risk management measures put in place to ensure safe use of the substance. According to UK requesting a generation study would require extending by 1-2 years the deadline for collecting the exposure information. eMSCA considered that addressing of fertility concerns can be done in a later stage.

Registrant's comments on PfAs and discussion

The Registrant provided written comments on the PfAs of MSCAs and ECHA. As regards the PfA from a MSCA regarding the two-generation study the Registrant submitted additional information on volumes for different uses of the substance and explained that exposures to imidazole would be well controlled at a work place. As there are no consumer uses of imidazole, only minor indirect exposure for consumers could be expected. As the substance is classified as Repr 1B for developmental toxicity (self-classification at the moment, but RAC opinion for harmonised classification Repr 1B is available) and the exposure to the substance should therefore be minimised, strict workplace safety precautions and regulatory measures are already in place. Regarding the PfA concerning *in vitro* mouse lymphoma study, the Registrants stated that they accept the request for the study.

The representative of the Registrant at the meeting confirmed that CSR in the registration dossier will be further updated with the requested information on exposure scenarios and exposure modelling data. As regards the proposed two-generation testing, he repeated the arguments provided in the written comments by stating that it probably should be of low priority, due to the classification of the substance for its developmental toxicity, RMMs already in place, well-controlled exposure for workers, lack of additional indications for fertility effects in reproductive organs in the 90-day RDT study, as well as taking into account the uses of the substance. The registrant agreed with the eMSCA's suggestion to consider using an additional safety factor for management of the potential risk for fertility as proposed by eMSCA.

SECR further confirmed that the transported isolated intermediates, although less information than for other substances is required for their registration, are in the scope of

the substance evaluation. Therefore further information going beyond the standard information requirements for transported isolated intermediates can be requested.

Some members did not agree with the suggested approach of not requesting testing to fill the current data gap regarding Annex X 8.7.3.and using of an assessment factor of 2 (without scientific justification) in risk assessment as a surrogate for uncertainty regarding lack of information on fertility and peri- & post-natal reproductive toxicity. It was pointed out that a 'generation' study would produce information in addition to fertility also on peri- and postnatal effects. It was emphasised by some members that there is a close structural relationship and similarity of imidazole with other chemicals (e.g. other imidazoles like prochloraz and conazoles) classified for both developmental and fertility toxicity. eMSCA's expert noted that the indicated assessment factor of 2 is not fixed and the assessor may change it when the conclusion of this concern should be drawn.

The representative of the Registrants did not accept the arguments regarding structural similarity of imidazole with conazoles. He explained that azole class of substances comprise of very different N-heterocyclic substances with different toxicological properties. He informed MSC about recent study results of some structurally closely related imidazole derivatives not indicating any fertility concern and pointing to a possibility to consider a read-across/weight of evidence approach for imidazole. The expert of eMSCA clarified the issue of similarity/difference of molecules by showing structural formulas of related substances.

An integrated testing strategy (ITS) was suggested as a possibility to be considered in DD if clearly stated that the peri- & postnatal reproductive toxicity and fertility endpoints should be evaluated at a later stage if relevant at that time. It was underlined that as SEV should deliver robust data in order to remove the concern from the substance, if a read-across is further chosen, proper QSAR analyses of similar chemicals and well-built justification should be prepared and included in an update of the registration dossier.

Some concerns were expressed by one member with regard to the multifunctional effects seen for anti-androgenicity, as well as to the residual concerns for endocrine disruption.

The registrant's representative disagreed with the views expressed on possible anti-androgenic/endocrine disruptive effects of imidazole solely based on its chemical structure and pointed out that following the recent tests of imidazole derivatives, no specific indications for endocrine disruption have been seen in any of the tests, but only developmental toxic effects have been identified.

MSC supported the ITS inclusion in DD as a reasonable approach to consecutively address the mutagenicity (together with exposure concerns) first, later followed by the other concerns for fertility and peri- and post-natal effects. It was left to the eMSCA who has to review the information gathered under this decision once provided and to conclude on the concerns from this substance.

Session 2 (closed)

Following the MSC conclusions made above, DD was further amended by adding an information requirement for the registrants to submit via an update of their dossiers documentation and justification giving information on the structurally related substances that the concerned registrants believe would be applicable in an appropriate weight of evidence assessment of the reproduction effects of imidazole. The eMSCA will examine the provided information and conclude whether it is sufficient or whether further information to clarify any remaining concern on fertility endpoints would be needed. It was specified by SECR that different deadlines could have been set up if necessary.

MSC unanimously agreed on the SEV DD for imidazole as modified at the meeting. The member from France abstained from the vote.

SEV-BE-003/2012 N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine (EC No.221-375-9)

Session 2 (closed)

MSC Chair explained that agreement on DD for this substance was sought in WP which was terminated on request of one MSC member suggesting MSC discussion on the

temperature specified in DD at which the soil simulation test should be performed. The member who had requested the discussion asked whether specific reasons imply for specifying the temperature (of 12°C) for the requested soil simulation test, as no clear guidance on this parameter has been indicated. This DD would create a precedent that should be followed for consistency also in the other decisions where this test is proposed.

The eMSCA's expert from the Belgium CA who performed the SEV explained that eMSCA considers 12°C as a more representative temperature for EU in the soil simulation test than 20°C mentioned by the registrants. This temperature of 12 °C is considered as typical for the soil compartment in the average EU-environment (cfr. Table R.16-9 of the Guidance on IR & CSA), it is used in EUSES and the guidance as well as the test guideline is giving a possibility to use another temperature than 20°C. It is recommended that the test is carried out at a temperature corresponding to real conditions to avoid a need to apply temperature correction to the test results. eMSCA concluded that the request for performing the study at 12°C remained unchanged.

The members supported the eMSCA's proposal and requested SECR to follow this approach when soil simulation testing is proposed under evaluation processes, by specifying as test temperature 12°C for soil simulation testing. It was mentioned but not further discussed that for simulation testing in fresh water also 12°C should be followed and 9°C for simulation testing in marine water.

MSC found unanimous agreement on ECHA's DD as provided for the meeting with a small editorial modification made at the meeting.

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 four dossier evaluation cases (see Section V for more detailed identification of the cases). WP was launched on 15 October 2013 and closed on 25 October 2013. By the closing date, responses to WP were received from 25 members with voting rights and from the Norwegian member. Unanimous agreement was reached on one DD. For one DD on testing proposals involving the standard information requirement for Annex X, 8.7.3 unanimous agreement was not reached by MSC. Thus, this DD is to be referred to COM for further decision-making under Article 133 (3) of REACH. For two DDs, WP was terminated by the MSC Chair on the basis of Article 20.6 of the MSC Rules of Procedure as at least one MSC member requested meeting discussion at the MSC-32 meeting.

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

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

CCH 116/2013 2-methylbut-2-ene (EC No. 208-156-3)

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.

SECR explained that two PfAs to ECHA's DD were submitted. One of them agrees with the sub-chronic toxicity study (90-day) in rats, inhalation route, but suggest requesting additional clinical pathology, functional tests and histopathology as the substance is suspected to induce neurotoxicity. The second one does not agree with the sub-chronic toxicity study (90-d) in rats, inhalation route because the exposure should already be stringently controlled and further testing will not lead to any further refinement of the risk assessment and thus have no impact on the risk management measures already in place. The view of the MS making the PfA is that the 90-day test is unnecessary (legal basis comes from REACH Article 25(1)). SECR did not modify the DD for the meeting based on the PfAs but proposed discussion based on the registrant's comments.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs disagreed to supplement the test with additional parameters (clinical pathology, functional tests and histopathology) because no effects were noted in an OECD 422 screening study up to 7000 ppm and therefore exposure in a 90-day study would not exceed 7000 ppm and the substance is not expected to be neurotoxic under foreseeable study conditions. On the other hand, the Registrant agrees that the proposed study will have no impact upon risk management therefore the 90-day study should not be required. Also the Registrant believes that the test should be deemed unnecessary on basis of animal welfare considerations.

The representative of the Registrant stated that the required test is not needed as the substance is imported in reacted form as a polymer and the registration has been done based on monomer. This means that there is no exposure to the unreacted monomer. Additionally the substance is also used as a transported isolated intermediate under strictly controlled conditions. The test should not be required based on Article 25(1).

One member representing the MS making the PfA indicated that even if it was requested to perform the test with additional neurotoxicity parameters, they currently agree with the explanation of SECR and therefore, requesting for additional parameters might not be proportionate.

Session 2 (closed)

Based on the above considerations, MSC agreed unanimously on ECHA's DD addressing the sub-chronic toxicity study (90-day) in rats (inhalation route of administration) as amended during the meeting. Amendments were made to for Section III reflecting that the study is a standard information requirement and risk management measures alone cannot be considered to fulfil the adaptation possibilities listed in Annex IX, 8.6.2., Column 2 or the specific rules of adaptation of Annex XI, Section 1. Moreover, the Registrant did not propose an exposure-based adaptation according to Annex XI, Section 3 of the REACH Regulation. The member from UK abstained from the vote.

CCH 117/2013 Terpineol (EC No. 232-268-1)

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.

SECR explained that one PfA to ECHA's DD was submitted. The PfA agrees with the request for sub-chronic toxicity study (90-day) in rats but proposes to change the route of administration from inhalation to oral as there were indications of systemic toxicity in oral study (OECD 422). Although the substance is a skin and eye irritant, there is no evidence from an acute inhalation toxicity study for respiratory tract irritation, and in the view of the MS making the PfA there is not an established association between skin and/or eye irritation and respiratory tract irritation. Conducting the study by the oral route will maximise systemic toxicity. SECR did not modify the DD for the meeting based on the PfA but proposed discussion based on the registrant's comments.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs agreed with the PfA regarding the route of exposure for the sub-chronic toxicity study (90-day) in rats. In Registrant's opinion, the study should be conducted by the oral route as there was evidence of systemic toxicity following the repeated oral dosing in the OECD 422 screening study and therefore, in order to further investigate the previously observed effects, the same route of exposure should be tested. The Registrant in his comments provided information on systemic toxicity after repeated oral dosing, which was not available when the PfAs from member states were submitted.

One member stated that there is only one inhalation study available in the technical dossier with high concentrations and only minimal signs of effects and no information on

necrosis, also the member stated that the repeated dose toxicity test shows effects in liver and kidney, therefore there is a concern for the systemic toxicity. If the test is to be performed via inhalation effects may not be seen as if the test is performed via oral.

One member highlighted that there is no correlation between skin and eyes irritation. However, it was pointed out that it is important to take into account that the substance is used in spray applications and in applications likely to give rise to aerosol formation (e.g., metal-working fluids).

One member indicated support to SECR views in this case to ask the test via inhalation route, because it is the most relevant route of exposure taking into account the uses of the substance. Furthermore, the substance belongs to a group of substances with a strong odour. Testing via inhalation route should not be able to detect local effects on the respiratory tract as well as systemic effects. This was supported by some members.

Calculations performed by ECHA demonstrated that inhalation exposure would lead to sufficiently high doses to ensure an adequate investigation of the systemic effects seen in the studies of shorter duration.

Session 2 (closed)

Based on the above considerations, MSC agreed unanimously on ECHA's DD addressing the sub-chronic toxicity study (90-day) in rats, inhalation route of administration as amended during the meeting for Section III explaining to the registrant why the Registrant's agreement to the PfA requesting to use oral route was not taken up in the decision reflecting that there is a major concern for systemic toxicity together with effects on male fertility. Additionally, the substance is used in spray applications at concentrations up to 25% so inhalation administration is considered the most appropriate route for the sub-chronic toxicity study (90-day).

HOPA Alkenes

TPE 090/2013 Nonene (EC No. 248-339-5)

TPE 091/2013 Hex-1-ene (EC No. 209-753-1)

TPE 092/2013 Oct-1-ene (EC No. 203-893-7)

TPE 093/2013 Hydrocarbons, C12-30, olefin-rich, ethylene polymn. by-product (EC No. 272-762-4)

TPE 094/2013 Octadec-1-ene (EC No. 204-012-9)

TPE 095/2013 Octadecene (EC No. 248-205-6)

TPE 096/2013 Tetradec-1-ene (EC No. 214-306-9)

TPE 097/2013 Alkenes, C8-10, C9-rich (EC No. 271-212-0)

TPE 098/2013 Hexadecene (EC No. 248-131-4)

TPE 099/2013 Tetradec-1-ene (EC No.214-306-9)

TPE 100/2013 Dodec-1-ene (EC No. 203-968-4)

TPE 101/2013 Alkenes, C10-14 (EC No. 288-213-7)

TPE 102/2013 Alkenes, C11-12 (List No. 931-515-7)

TPE 103/2013 Alkenes, C13-14 (List No. 931-071-4)

TPE 104/2013 Alkenes, C15-18 (EC No. 297-797-2)

TPE 105/2013 Alkenes, C16-18 (List No. 900-050-1)

TPE 106/2013 Alkenes, C20-24 α- (EC No. 300-202-1)

TPE 107/2013 Alkenes, C21-32 linear and branched (List No. 931-505-2)

TPE 108/2013 Alkenes, C24-28 α- (EC No. 300-203-7)

TPE 109/2013 Alkenes, C6-8 (List No. 931-293-1)

TPE 110/2013 C26-28 (even numbered) α-alkenes (List No. 934-268-3)

TPE 111/2013 Dec-1-ene (EC No. 212-819-2)

TPE 112/2013 Decene (EC No. 246-870-7)

TPE 113/2013 C20-C22 (even numbered, linear and branched) and C24 (branched) alkenes (List No. 700-497-0)

TPE 114/2013 Hexadec-1-ene (EC No. 211-105-8)

TPE 115/2013 Hexadec-1-ene (EC No. 211-105-8)

TPE 116/2013 Octadec-1-ene (EC No. 204-012-9)

Session 1 (open)

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

Brief information on the read-across approach

SECR gave a general presentation in order to explain the Registrants' proposed category approach for testing of higher olefin substances which consists in total of 27 substances. The Registrants submitted a proposal for a testing plan based on use of a read-across hypothesis. The proposed category hypothesis is based on the following assumptions: similar structural elements (alpha olefin, internal olefin (di, tri, tetra substituted), vinylidene olefin, number of carbon atoms (including even/odd), extent of branching), constant low toxicity across the substances within the proposed category, trend of bioavailability with increasing molecular weight from "high" to "low" and a cut-off at a carbon chain length (to be determined) to "virtually no absorption". Confirmation of the hypothesis relies on the outcome of the presented testing plan going beyond but including the testing proposals addressing Annex IX and X requirements. The Registrants propose to perform the following tests: Sub-chronic repeated dose toxicity study (90-day RDT) (OECD 408) on five source substances, Pre-natal developmental toxicity (PNDT)(OECD 414) on five source substances and two-generation reproductive toxicity study (OECD 416) on five source substances (with alternative source substances in three cases). This means to conduct five tests per endpoint on the proposed source substances or the specified alternates.

The substances within the category proposed to be tested/read-across are as follows:

	Substance	90-d	PNDT	two-generation
TPE090	Nonene	test	test	test
TPE091	Hex-1-ene	available	test	test
TPE092	Oct-1-ene	test	RA	RA
TPE095	Octadecene (CAS No.27070-58-2)	test	test	test[1]
TPE098	Hexadecene	RA	RA	test[1]
TPE093	Alkenes, C19-23	test	test	test[2]
TPE097	Alkenes, C8-10, C9 rich	RA	RA	test[2]
TPE094	Octadec-1-ene (CAS No. 112-88-9)	test	test	test[3]
TPE096	Tetradec-1-ene UVCB	RA	RA	test[3]
TPE099	1-Tetradecene MC	RA	RA	RA
…	…	…	…	…
TPE110	Alkenes, C26-28, alpha	RA	RA	RA

[1), 2), 3)] pairs of alternative substances for testing for the 2-generation study

The substances in the category were divided to sub-categories representing the position of the olefin group and molecular structures present at their highest concentration. These subgroups comprised of *High alpha olefin; High vinylidene; High di-substituted and high tri-substituted, High di-substituted and high tetra-substituted, Even/Odd carbon number; High tri-substituted, Odd carbon number.* The substances belonging to these sub-groups may be UVCBs.

Registrant's comments on PfAs of CAs and discussion

SECR explained that one PfA to ECHA's DD was submitted regarding the selection of the source substance for read-across for the 90d RDT endpoint, three PfAs were submitted on the selection of the substance for the testing of all three endpoints, four PfAs were submitted on the selection of the test method regarding reproduction toxicity and several PfAs were related to editorial issues.

Regarding the PfA related to the substance to be tested, the member had the view that testing with oct-1-ene, as proposed by the Registrants, for the 90-day RDT, is scientifically unjustified. It was considered that hex-1-ene should be used for repeated dose toxicity as a source substance for read-across because it is with the highest alpha olefin elements, is regarded as potentially having the most toxic properties and a 90 day study is already available for hex-1-ene. Therefore the Registrants failed to justify the need for a sub-chronic toxicity study for oct-1-ene.

Concerning the selection of test material, it was suggested testing with tetradec-1-ene UVCB to cover the high vinylidene category for all three endpoints. Similarly, it was proposed hexadec-1-ene to be tested for all endpoints to cover the high di- and tri-substituted category. The suggested approach was based on the screening information which according to the Registrants is used for selecting of substances for testing (gut-sac in vitro absorption models, screening study for reproduction toxicity, OECD 422). According to NL-CA absorption models show zero absorption for octadec-1-ene (substance proposed to be tested) whereas hexadec-1-ene (0.2% absorption) and tetradec-1-ene UVCB (0.2-0.7%) seem to be more relevant from biological point of view as a test substance and the alternative substance indicated by the Registrants for testing, i.e. tetradec-1-ene, showed effects in OECD 422 and should be considered as a source substance. Following the same approach, it is suggested testing with alkenes C8-10, C9-rich (with information on high absorption) instead of the Registrants' selection for alkenes, C19-23. However, to cover the whole group in the proposed group approach testing with an alkene >C20 is desired and therefore both substances, alkenes, C8-10, C9 rich and alkenes, C19-23, should be tested for 90 day RDT, PNDT and reproduction toxicity in a tiered way. Furthermore it is indicated that the alternative substances selected by the Registrants for reproduction toxicity are not logical as the effects of the alternative substances would question the results of the initially tested substances.

Regarding testing for reproduction toxicity, three PfAs 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 PfA suggests keeping the two choices but excluding from the optional request for EOGRTS the extension of cohort 1B (production of F2 generation).

The Registrants provided written comments addressing the PfAs regarding testing for reproduction toxicity and confirmed their intention to conduct two-generation reproductive toxicity study (OECD 416) instead of EOGRTS (OECD 443). The Registrants provided comments to the PfAs related to the high alpha olefin group and testing of oct-1-ene for 90 day RDT. They are of the view that the study is needed at the lower end of the molecular weight range of the category in order to cover the greatest potential for biological effects.

The Registrants also commented on the PfA related to the 'high vinylidene' and 'high di- and tri-substituted' groups and testing of octadec-1-ene and alkenes, C19-23. The Registrants explained that the information used for selection of substances was based on studies that were still currently underway but are important to support the overall strategy. The Registrants acknowledge the issue of a definition for low/no absorption and agree that this term and its consequence is not detailed in the testing strategy. This subject will be addressed as a result of the radiolabelled in vivo absorption work. This work is also designed to give greater confidence for the use of the data from lower carbon number substances to read across to higher olefins with a carbon number >C23.

The Representatives of the Registrants explained that the objective of the testing program is to provide data to resolve any uncertainty with the category hypothesis and also to demonstrate the low toxicity of the substances in the category. The Representatives of the Registrants indicated that the absorption studies will provide useful information on the need for the high tier testing. The Representatives of the Registrants believe that the 15 tests proposed together with all the background information already available and the studies already underway will give a good profile of the hazard of the substances and the category as such.

A member of the MSC indicated that the testing proposals were under discussion and that in the future the read-across should be evaluated on the basis of the testing plan out-come. Therefore, the plausibility and/or acceptability of the read-across was not being decided now. The member expressed the view that the read-across discussion should be done under the compliance check process.

A member asked the Representatives of the Registrants if there was a trend in relation to the degree of branching within the defined category. In the same question, the member asked the Representatives of the Registrants to what extent they were sure about the hypothesis and how well the hazards (of the category) were covered, as well as whether the Registrants have considered for example the effect of branching on the properties of the category substances.

The representatives of the Registrants replied to the member that currently there were 23 studies on-going in order to get information for defining the chemical space of the category. With the proposed approach it was expected that it would be possible to establish if the hypothesis will be valid or not. The representatives of the Registrants stated that they have taken into account the branching and also the position of the double bonds. Based on published information available it was assumed that with increasing branching the absorption and reactivity of the substance decreases. They also indicated that because of sterical hindrance caused by branching or the internal position of the double bond the alpha olefin group was the most reactive part of the molecules and the category approach has been built based on the presence of the olefin group at different positions of the molecule to prove this trend.

A member asked why the 90-day study was proposed to be carried out with a substance having alpha olefin group in the molecule and not with any other substances available.

The representatives of the Registrants replied to the member that they wanted to generate data for this type of substances with high concentration of alpha olefin groups as well as for other structural elements as for example another selected substance had a high concentration of vinylidene content. As the substances are UVCB substances they may contain several structural elements and selection of substances for testing has been made taking into account the chemical structures present in the sub-group and trying to identify a best representative for testing.

Regarding the absorption, a member indicated that the substance selected (high vinylindene and high di- tri- substituted groups) for the absorption test did not show any absorption so far and therefore it might be more appropriate to test another substance which showed some absorption instead of the selected one.

The Representatives of the Registrants replied that the substance had been selected based on the structural elements. Concerning the low absorption, he pointed out that the *in vivo* validation studies of the in vitro model and also combined repeated dose and reproduction toxicity screening studies were still on-going and that absorption alone could not – at the moment –be used as a basis for the selection of a test material.

Session 2 (closed)

Based on the above considerations, MSC agreed to the approach proposed by the Registrants and reflected in the ECHA's DD 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 decision has been submitted to ECHA and ECHA has evaluated the information. MSC decided to split the DDs into part A and part B, where Part A address only the endpoint "two-generation" while part B address Sub-chronic repeated dose toxicity and Pre-natal developmental toxicity.

MSC agreed unanimously on ECHA's split DDs addressing the 90-day study and PNDT 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. Furthermore regarding the substances proposed to be tested a change was introduced in Section III of the DD adding a reference to the screening information the Registrants indicated to be used as the basis for selecting the substances, i.e. that the absorption of individual substances, as well as their toxicological

properties, are currently identified as key parameters in the selection of substances to be tested.

MSC did not reach unanimous agreement on the DDs on TPs for a two-generation reproductive toxicity study. However, the relevant parts of these DDs were also modified based on the agreement regarding selection of the substances for testing and change of 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 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.

Petroleum substances

TPE 117/2013 Condensates (petroleum), vacuum tower (EC No. 265-049-4)
TPE 118/2013 Gas oils (petroleum), light vacuum (EC No. 265-059-9)

TPE 119/2013 Distillates (petroleum), light hydrocracked (EC No. 265-078-2)

TPE 120/2013 Gas oils (petroleum), hydrodesulfurized light vacuum (EC No. 265-190-1)
TPE 121/2013 Fuels, diesel (EC No. 269-822-7)

TPE 122/2013 Fuel oil, no. 2 (EC No. 270-671-4)

TPE 123/2013 Fuel oil, no. 4 (EC No. 270-673-5)

TPE 124/2013 Fuels, diesel, no. 2 (EC No. 270-676-1)
TPE 125/2013 Gas oils (petroleum), hydrotreated light vacuum (EC No. 295-407-5)

TPE 127/2013 Residues (petroleum), vacuum (EC No. 265-057-8)

TPE 128/2013 Residues (petroleum), thermal cracked vacuum (EC No. 295-518-9)

TPE 129/2013 Asphalt (EC No. 232-490-9)

TPE 130/2013 Asphalt, oxidized (EC No. 265-196-4)
TPE 131/2013 Distillates (petroleum), heavy straight-run (EC No. 272-817-2)

TPE 132/2013 Distillates (petroleum), full-range straight-run middle (EC No. 272-341-5)

TPE 133/2013 Distillates (petroleum), straight-run middle (EC No. 265-044-7)

TPE 134/2013 Gas oils (petroleum), straight-run (EC No. 265-043-1)

TPE 135/2013 Extracts (petroleum), deasphalted vacuum residue solvent (EC No. 295-332-8)

TPE 136/2013 Extracts (petroleum), residual oil solvent (EC No. 265-110-5)

TPE 137/2013 Distillates (petroleum), hydrodesulfurized middle (EC No. 265-183-3)
TPE 138/2013 Gas oils (petroleum), hydrodesulfurized (EC No. 265-182-8)
TPE 139/2013 Distillates (petroleum), hydrotreated middle (EC No. 265-148-2)

Session 1 (open)

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

Brief information on the read-across approach

SECR gave a general presentation in order to explain the Registrants' proposed category and read-across approach for testing of 24 petroleum substances. Using information on manufacturing processes, boiling point and carbon number ranges, the Registrants have divided the substances into five sub-categories: Vacuum Gas Oils, Other Gas Oils, Residual Aromatic Extracts, Bitumen, and Straight-Run Gas Oils. The registrants proposed to perform a two-generation reproductive toxicity study (OECD 416); or a two-generation reproductive toxicity study (OECD 416) and pre-natal developmental toxicity study (OECD 414) per sub-category and, separately not part of any of the sub-categories, to test asphalt oxidised (TPE 130) for both endpoints.

SECR explained that the Registrants define the category by the refining processes and physico-chemical properties. The read-across justification provided by the Registrants is based on:

- insight in the compositions of the substances;
- the assumption that the alkanes (aliphatic hydrocarbons; linear, branched and cyclic) do not significantly contribute to the overall reproductive toxicity of the substances compared to the aromatic substances;
- the relative scarcity of other elements than carbon and hydrogen;
- the published correlation between reproductive (and developmental) toxicity and the concentration of 4-7 ring poly-cyclic aromatic hydrocarbons (PAHs); and
- the testing of a worst-case in terms of the concentration of 4-7 ring PAHs (concentration of 16 US/EPA PAHs for bitumen and residual aromatic extracts).

The substances within the proposed category were proposed to be tested/read-across as follows:

TPE No	Substance	2-generation	PNDT
Vacuum gas oils			
TPE117	Condensates (petroleum), vacuum tower	RA	
TPE118	Gas oils (petroleum), light vacuum	test	
TPE119	Distillates (petroleum), light hydrocracked	RA	
TPE120	Gas oils (petroleum), hydrodesulfurized light vacuum	RA	
TPE121	Fuels, diesel	RA	
TPE122	Fuel oil, no 2	RA	
TPE123	Fuel oil, no 4	RA	
TPE124	Fuels, diesel, no 2	RA	
TPE125	Gas oils (petroleum), hydrotreated light vacuum	RA	
Bitumen			
TPE126	Residues (petroleum), vacuum distn. residue hydrogenation	Terminated (cease of mfc)	
TPE127	Residues (petroleum), vacuum	RA	RA
TPE128	Residues (petroleum), thermal cracked vacuum	test	test
TPE129	Asphalt	RA	RA
Not a category member:			
TPE130	Asphalt, oxidised	test	test
Straight run gas oils			
TPE131	Distillates (petroleum), heavy straight run	test	
TPE132	Distillates (petroleum), full-range straight-run middle	RA	
TPE133	Distillates (petroleum), straight-run middle	RA	
TPE134	Gas oils (petroleum), straight-run	RA	
Residual aromatic extracts			
TPE135	Extracts (petroleum), deasphalted vacuum residue solvent	test	
TPE136	Extracts (petroleum), residual oil solvent	RA	
Other gas oils			
TPE137	Distillates (petroleum), hydrodesulfurized middle	test	
TPE138	Gas oils (petroleum), hydrodesulfurized	RA	
TPE139	Distillates (petroleum), hydrotreated middle (EC No 265-148-2)	RA	
TPE140	Distillates (petroleum), sweetened middle	Terminated (cease of mfc)	

Registrant's comments on PfAs of CAs and discussion

SECR explained that one PfA on ECHA's DD regarded the Registrants' proposed grouping of substances and read-across approach was received. In the PfA the MSCA agreed with ECHA assessment that the Registrants have failed to scientifically justify the proposed category. However, the PfA considered that a one-to-one read-across by testing an analogue substance is not fully justified and that the read-across hypothesis based on the PAHs is not plausible.

Four PfAs were submitted on the selection of the testing method for the testing of reproduction toxicity. Regarding TPE 126 to 130 a PfA challenged the inhalation route of administration and proposed that the test should be conducted via the oral route.

The Registrants had provided written comments addressing PfAs relating to the test method for reproduction toxicity and confirmed their intention to conduct two-generation reproductive toxicity study (OECD 416) instead of extended one-generation reproduction toxicity study (OECD 443) as suggested by the PfAs. The Registrants commented the PfAs regarding the read-across by further explaining that the read-across approach is based on hazard profile of the substances, which is supported by available toxicology data.

The Representatives of the Registrants explained at the meeting that the substances have similar composition and contain similar molecular structures therefore all substances in the proposed categories are similar. The representative of the Registrants stated that it is not possible to establish a trend within the categories because they are made up of similar substances. They believe that the substances proposed for testing represent the worst case for each sub-category; the proposed test substances were selected based on their concentration in four to seven ring PAHs. The representatives of the Registrants recognised that the chemical composition of the substance is difficult to fit with the category definition of the REACH Regulation; this is the reason why the category is based on the refining process of the crude oils, physico-chemical properties of the substance and worst case approach based on the most hazardous constituents of the substances. The representative of the Registrants noted that the category has been established following the REACH Guidance for petroleum substances. They explained that the Registrants are currently working in order to improve the information on the chemical composition of the substances.

A MSC member noted that these types of substances are difficult to be characterised and that characterisation involves complex analytical methods and the substances are complex UVCBs. The MSC member was of the opinion that the Registrants have not characterised the substances in full details, therefore, this has impacted the evaluation, especially because it will be difficult to define what has been tested in the end. He concluded that the outcome of something that is not well defined is difficult to use and especially when the Registrants want to read across between different substances.

A MSC member stated that in his view the Registrants have failed to justify the category and the category is not scientifically justified. The member also highlighted that the substance identity is a problem because is not clear, the sample varies a lot and there is no information available on the composition of the substance.

A MSC member noticed that it is difficult to establish the border between developmental toxicity effects and the concentration of PAHs in the substance. Furthermore, the member explained that the information provided by the Registrants (justification documents) indicated developmental toxicity effects but not reproductive toxicity effects. The member concluded that that for certain substances of the category it is documented that both effects, developmental and reproductive have been identified.

The Representative of the Registrants explained that there are two substances for which the effects are posed by the PAHs. But he explained that the category/sub-categories are based on the presence of poly-cyclic compounds. He also explained that even if the names of the substances do not include information on the whole composition of the substance, the registrants are aware of the composition of the substances because they have to provide well defined substances for certain uses (e.g. fuel for certain purposes) for their customers.

The Representatives of the Registrants explained that they have carried out developmental toxicity tests with the light substances (without PAHs) and they have not seen adverse effects, as well they have tested substances containing high amounts of PAHs and they have seen effects, so, this is the reason why they have selected substances having PAHs and they are the candidates to be tested.

In relation to the last explanation of the Representatives of the Registrants, a member of the MSC indicated, that this explanation is not in any document in the technical dossier.

The Representative of the Registrants stated that the information provided for the TPs is generic.

A StO observer asked for clarification how the worst case has been identified pointing out on the difficulty to find the worst case for these types of substances and on the uncertainty in the identification of the worst case and applying a read-across.

The Representatives of the Registrants admitted that it is difficult to identify the worst case for these types of substances and this is the reason why they have set up a hypothesis that should be confirmed with the testing plan.

In relation to the route of administration for the generation study, a MSC member raised the concern because if inhalation route of administration is selected for bitumen and asphalt oxidised based on testing of tank fume condensates the results of the test may not be applicable for classification of the substance itself because the test has been conducted on fumes from the substance and not on the substance itself.

The Representatives of the Registrants explained that it is difficult to collect the samples and this is the reason why the inhalation route of administration has been selected and also because they have experience when carrying out the test via inhalation as this has been done in the past.

Session 2 (closed)

MSC agreed to further precise the requirements in Section III of the DDs for exact information on the composition of the substance to be tested and the target substance for one-to-one read-across to ensure that the hazard of the substances would not be underestimated.

Based on the above considerations, MSC agreed with ECHA not to accept the category approach, but to accept the testing plan proposed as plausible based on the one-to-one read-across. Further, MSC agreed to the approach proposed by the Registrants and reflected in the ECHA's DD 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 decision has been submitted to ECHA and ECHA has evaluated the information.

MSC agreed to split the DDs where both PNDT and two-generation study are proposed, TPE-127A/2013 and TPE-127B/2013, TPE-128A/2013 and TPE-128B/2013, TPE-129A/2013 and TPE-129B/2013, TPE-130A/2013 and TPE-130B/2013, respectively, where Part A addresses the information requirement for generation reproductive toxicity and Part B addresses the information requirement for pre-natal developmental toxicity study. The deadlines for submission of the data were modified due to the splitting of the DDs.

DDs are not split as the only study being requested in the DDs is the two-generation study, for the following cases: TPE-117/2013, TPE-118/2013, TPE-119/2013, TPE-120/2013, TPE-121/2013, TPE-122/2013, TPE-123/2013, TPE-124/2013, TPE-125/2013, TPE-131/2013, TPE-132/2013, TPE-133/2013, TPE-134/2013, TPE-135/2013, TPE-136/2013, TPE-137/2013, TPE-138/2013 and TPE-139/2013.

The information requirements regarding the composition of the substance to be tested and the target substance for one-to-one read-across were added also to the DDs to be submitted to the Commission. The inhalation route of administration was agreed for bitumen and asphalt oxidised.

MSC agreed unanimously on ECHA's split DDs and non-split DDs addressing the PNDT as modified during the meeting.

MSC did not reach unanimous agreement on the split DDs and non-split DD on TP 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 those 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.

CCH 098/2013 2,4-di-tert-butylphenol (EC No. 202-532-0)

Session 2 (closed)

SECR explained that agreement on DD was sought in WP with termination of the written procedure by the Chair of MSC on request of one MSC member suggesting MSC discussion on whether relevant environmental temperature should be mentioned and defined in the draft decision in relation to the simulation degradation testing.

The issue was further explained and clarified by SECR by stating that it would be possible to specify the temperature for future cases, following the agreement on the BE-SEV case 003/2012 where it was agreed that 12°C is the most appropriate and relevant temperature for the EU region. However, for the present case the temperature cannot be specified because the registrant had no chance to comment such specification.

Based on the above conclusion, MSC found unanimous agreement on ECHA's DD.

CCH 099/2013 2,4-di-tert-butylphenol (EC No. 202-532-0)

Session 2 (closed)

SECR explained that agreement on DD was sought in WP with termination of the written procedure by the Chair of MSC on request of one MSC member suggesting MSC discussion on whether relevant environmental temperature should be mentioned and defined in the draft decision in relation to the simulation degradation testing.

The issue was further explained and clarified by SECR by stating that it would be possible to specify the temperature for future cases, following the agreement on the BE-SEV case 003/2012 where it was agreed that 12°C is the most appropriate and relevant temperature for the EU region. However, for the present case the temperature cannot be specified because the registrant had no chance to comment such specification.

Based on the above conclusion, MSC found unanimous agreement on ECHA's DD.

d. Update on appeal cases *(Partly closed session)*

SECR provided MSC with feedback from the appeal cases on dossier evaluation decisions.

e. General topics

1) **Testing strategies under dossier evaluation *(Closed session)***

SECR discussed with MSC a strategic approach to testing strategies.

2) **Status report on on-going evaluation work**

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

At the request of a member, ECHA clarified its approach for CCH of SEv substances for 2015 and beyond stating that ECHA plans to perform CCH for all substances listed on the CoRAP when timing allows.

Item 8 – Community Rolling Action Plan (CoRAP) update

- **Introduction of the draft CoRAP update by ECHA and first exchange of views on the draft CoRAP**

SECR in its presentation informed the meeting participants that the final draft CoRAP containing 125 substances (56 substances planned for 2014, 49 for 2015 and currently 20 for 2016) was submitted to MSC and MSs. It was also explained that evaluation is postponed for 11 substances listed in the current CoRAP. The public draft CoRAP version was published on the ECHA website on 4 November 2013, also indicating at this early stage the MS contact details and the status of the substance (new entry or already currently listed in CoRAP). Justification documents were provided to the meeting participants and those will also be published in March 2014 together with the final CoRAP annual update.

SECR indicated that justification for selection of the substance for the draft CoRAP, together with a preliminary overview on the initial concern, is provided in the justification documents. However, the identified concern is to be considered as indicative and not exhaustive or conclusive. Furthermore it was explained that some of the substances listed in the draft CoRAP were grouped together due to the structural similarities. The full presentation was made available to MSC members and stakeholders on MSC CIRCABC.

During the discussion some members asked some clarifying questions. Some members commented that it was not clear what the purpose of identifying structurally similar substances was, an exercise that was carried out for this update round for the first time. SECR explained that it is a pure and rough chemical similarity check indicating to the MSs to consider further whether it would make sense to evaluate some substances together taking also other aspects than pure chemical similarity into account in further considerations. Input from expert groups for finding candidates for CoRAP as well as the screening exercise for purposes of different REACH processes and the aim to avoid overlaps were welcomed. One MSC member expressed the view that the screening exercise for purposes of different REACH processes has not been through CARACAL validation. This MSC member also requested that Member States should be informed about the ongoing consultation of expert groups and that MS Competent Authorities should be consulted on the screening criteria. A StO observer showed appreciation for publishing the draft at this early stage. Another StO observer expressed an interest to contribute to the screening and selection of substances for evaluation. SECR concluded that further exchange of ideas on use and possibilities from the similarity check in terms of substance evaluation could be explored in one of the future workshops. In addition, several MSC members took the view that there was a need for further discussion on the implications (including financial implications) of considering several similar substances under the same CoRAP entry.

The rapporteur of the working group (WG) for the MSC opinion on the second CoRAP update invited MSC members to provide the rapporteur and SECR with any contributions or questions on the substances included on the draft CoRAP update. He then informed that the first draft MSC opinion is to be made available by end of November for the first discussion at MSC.

Item 9 – SVHC identification

- **Update on the comments received in the public consultation on SVHC proposals**

SECR provided brief statistical information of the comments received during the public consultation (58 in total) on the seven substances proposed for SVHC identification. Presumably due to the fact that all SVHC candidates have harmonised CMR classification, the comments received support the SVHC proposals or provide additional information of uses, exposure and alternatives that will be considered at the later stage when the substances are to be prioritised for inclusion in Annex XIV of REACH Regulation.

Item 10 – Prioritisation of Candidate List substances for inclusion in Annex XIV

a. **Update of the Priority Setting Approach for recommending substances for inclusion in Annex XIV**

SECR presented the updated Prioritisation Approach Paper for inclusion of substances from the Candidate List in Annex XIV. MSC was reminded that the main principles applied when updating the approach had been agreed at the MSC-31 meeting and the preceding Preparatory meeting. Further, the expert views exchanged at MSC-31 have also been considered for document provided for the meeting. Members' views were sought on the scoring for endocrine disruptors and whether the proposed updated approach is acceptable, as presented.

MSC members expressed their satisfaction with the SECR's proposal in general and considered the revised approach to be an improvement to the present practice. It was emphasised that verbal expression of the priority setting conclusion is important and has always to be expressed in parallel with using scores. However, some issues were raised, such as: general concern regarding the selection of substances for which authorisation is not considered as the best RMO. In particular, one MSC member stated that, in the case of a substance where the RMO concludes inclusion in Annex XIV is not the best regulatory risk management measure, the considered substance should not be prioritised nor even taken into account for the prioritisation exercise. The same member had the view that if it ECHA considers in the paper that all substances on the Candidate List need to be considered for prioritisation, in her view that this should be clarified in the paper, for the sake of transparency and consistency in the context of the roadmap 2020 finalisation. Further development of the use descriptor system for more realistic scoring of WDU could be considered.

Two of the ASO observers stated that the updated prioritisation system should be transparent while keeping the approach simple and logic. The broader use of verbal descriptions when explaining scoring given in the priority assessment of a substance was encouraged. It was highlighted that the industry incentives to make sufficient information available for this process and to improve the quality of the registration dossiers have not yet been well accommodated in the updated prioritisation approach paper where only the worst-case situations are currently considered.

The prioritisation approach was further discussed for each of the three criteria of Article 58(3). It was stated that the scoring result is as uncertain (although a number is given) as the conclusion expressed verbally. The approach to give equal weight for each of criterion was supported. Regarding intrinsic properties the balance of the scoring between different intrinsic properties was considered and giving highest scores for PBT/vPvB substances is in line with the legal emphasis. It was reflected how the different hazards and their combinations should be scored and whether some combinations should get higher score than others as well as whether endocrine disruptors identified under Article 57 (f) should get a higher score than other substances identified under Article 57 (f). Some members expressed a view that endocrine disruptors should get a higher score because they considered that there is no specific legislation covering these substances. On the other hand several members did not find arguments to treat endocrine disruptors differently from other Article 57 (f) substances. Therefore, views on possible scores for endocrine disrupting substances varied from low (*i.e.* as CMRs) to high (i.e. as high as PBTs) with also quite a number opting for a medium score.

Regarding volumes criterion it was suggested that a logarithmic score or scoring with intervals of 2 could also be considered as alternative to the present proposal.

Regarding the criterion for wide dispersive use it was emphasised that it could be made clearer in the document that possibilities for using the use descriptor system should be kept open and should be used whenever it would be possible.

It was also suggested that retrospective analyses should be conducted on the basis of the present proposal and compare the results with the outcome of application of the present priority setting approach.

A remark was made by SECR that RMOA is a voluntary approach agreed to be used to support the work preceding the SVHC identification of a substance and there is no process

or requirement to reach agreement on the conclusions of RMOA. It was stressed that it would not be possible to consider RMOA conclusions or possible comments on them at the prioritisation stage of the authorisation process as such issues are not part of the prioritisation criteria. SECR also agreed that the relation between verbal description and numbers in scoring is important and the verbal argumentation could be used to explain the reasons for substance being prioritised or not prioritised.

SECR responded to some of the questions raised pointing out that further development of the approach will be considered when further updates are made in the registration dossiers and an improved database would allow a more sophisticated approach to be used in particular taking into account the information on use descriptor system (PROCs and ERCs).

SECR agreed to consider the proposals made when revising the current draft paper.

Regarding number of scores for endocrine disruptors SECR emphasised that the criterion deals with intrinsic properties and therefore the extension of the discussion to other areas, such as whether and with what effect other legislation may apply, should be avoided. It was proposed to score SVHCs identified under Article 57 (f) based on the conclusion of equivalent level of concern to the specific intrinsic property (57 (a), 57 (b), 57 (c), 57 (d), 57 (e)) the substance was identified on. The MSC Chair thanked the Committee for the good suggestions made at the meeting and invited MSC to send the remaining comments in writing by 15 November 2013 for further SECR consideration when preparing the revised version for the MSC endorsement at its December meeting.

b. Progress report after closure of the public consultation on ECHA's Draft 5th Recommendation, Draft RCOMs and Draft Annex XIV entries for prioritised substances

SECR gave a presentation (available in MSC CIRCABC) providing an overview of the main comments received in the public consultation on the draft 5th ECHA's Recommendation and the SECR's responses to them. Regarding priority scoring, it was reminded that priority assessment in a comparative task and that the same methodology needs to be applied for all assessed substances. As regards the Article 58 (2) legal interpretation, it was underlined that use of SVHC could be exempted only when other EU legislation is in place for controlling the risks in the equivalent way to the REACH Regulation. The Chair suggested that the responses prepared by SECR will be discussed in the context of the draft opinion under the next agenda item.

c. Preparations for the opinion on ECHA's Draft 5th recommendation of priority substances to be included in Annex XIV

- Report by the rapporteur and discussion of the first draft opinion, exchange of views on comments received

The rapporteur presented the first draft opinion on the draft 5th recommendation as provided to the meeting. The main issues as indicated by the rapporteur were discussed. While going through the comments and the different substances in the draft opinion MSC provided further feedback for rapporteur's consideration in finalisation of the draft opinion.

As regards Al- and Zr-RCFs, views were exchanged on potential problems for duty holders and enforcement authorities with the potential ambiguity of the substance identity for the entries of RCFs on the candidate list. That could lead to difficulties to distinguish the fibres from those which are similar but not covered by the entries on the candidate list. Furthermore questions were asked whether the forms RCFs are placed on the market are articles (blankets, robes, etc.) or whether they are substances the uses of which would require authorisation. The score for volumes of these substances was questioned as only the volumes of the fibres used as substances and incorporated into articles should be counted for the volumes and would require authorisation. It was suggested that the volumes of RCFs used as articles should not be considered for the volume scoring. SECR explained the volume score is derived based on the registered volume for RCFs – uses in the scope of authorisation include uses of the substance (for e.g. insulation) as such / in

mixtures, as well as its incorporation into articles. Furthermore it was clarified that under REACH the whole life cycle of the substance must be considered and e.g. releases from articles need to be covered in the authorisation applications - although the use of the article itself would not need any authorisation. Regarding the substance definition, as explained in the SECR's presentation given (*rf. Response to comment 2272 on p.61 of RCOM ECHA/MSC-33/2013/024 (PART 1))* under the previous sub-item 11.b, SECR further clarified that in their view, fibres containing below 10 % of e.g. chromium oxide but above 10 % of the defined main constituents still fall under RCF entries in the Candidate List. Although the occurrence of other fibres with same hazard of those in the CL cannot be excluded, there is currently no indication of initiation of an SVHC process, while manufacture/import of any such fibres requires registration. SECR further explained that when it comes to the interpretation of what is an article and what is a substance the responsibility lies with the registrants. It can be noted that RCFs are not manufactured with the aim of achieving specific shape but to fulfil certain properties (isolation, inertness etc.). It was concluded that MSC will reflect the comments and considerations in the opinion.

With regards to DMF, it was proposed a holistic approach to be taken regarding the appropriate risk management measures for all polar aprotic solvents, as currently one of the substances (NMP) is dealt with under the restriction process and two others (DMAC and DMF) are considered under the authorisation process. Further, the wide dispersive use of DMF was considered over-scored due to the controlled industrial uses. It was suggested that MSC should include in the draft opinion a remark on the need for consistency in the regulatory approach towards the polar aprotic solvents proposing the continuation of the discussion on this issue in REACH Committee at the Commission level. SECR explained that wide dispersive use has been estimated based on the best available information and following the prioritisation approach. According to the registration data and other information there are several processes with potential for exposure in several uses with very high tonnage each, like textile coating, fibre production, formulation of mixtures; and/or occurring at very many sites (e.g. handling of acetylene cylinders and potentially other uses). Members who expressed doubts on the prioritisation of DMF at this stage were requested to provide to the rapporteur their argumentation for further up-take in the opinion development for this substance.

Regarding ADCA, several members supported the view of the MSC member who have re-calculated the prioritisation scores for this substance and proposed lowering of the score for ADCA and its de-prioritisation. Concerns were shared by some on the chosen regulatory route, as restriction seems to them a better RMO. Some members commented also on the lack of new exposure information for workers indicating risk, well-controlled exposure at work place, as well as on the effectiveness of the occupational exposure limits (OEL) set by the UK which seem to have prevented new cases of occupational asthma. SECR reminded that the prioritisation process is based on use/process information and does not involve exposure or risk assessments; thus, the conclusions on the ADCA wide dispersive use have been made on the basis of best available information (mainly from registration dossiers, but as well as from other sources such as the public consultations) which indicates that there are several open or semi-open processes which have potential for exposure. Therefore, written justification was requested from the members who do not support the prioritisation of ADCA for further consideration in the MSC opinion development.

No specific issues for discussion have been raised with regard to the prioritisation of 4-tert-octylphenol, ethoxylates.

A member reminded that in their view the task of MSC in this process is to assess whether ECHA has correctly applied the prioritisation approach and other rules in preparation of the draft recommendation for Annex XIV. If members disagree with ECHA they should provide justification for their different view using the same approach as ECHA (jointly accepted criteria and priority setting approach).

It was also noted that when other issues not relevant for the ECHA's prioritisation assessment and recommendation preparation are identified, they could be included under a separate heading in the opinion template for the relevant substances. This would allow

expressing other concerns which are not in the scope of the assessment of whether the draft ECHA's recommendation prepared is in accordance with the prioritisation criteria. Such issues are not for MSC discussion but for information and further consideration of the Commission in the decision-making process.

In conclusion, the MSC Chair encouraged the members to send their comments/justified views (when the prioritisation of a substance proposed is not supported) on the draft opinion by 14 November 2013 for further consideration by the rapporteur and the WG members when revising the MSC opinion on the 5th draft recommendation. The revised draft opinion will be provided for MSC adoption at MSC-33 in December.

Item 11 – Any other business

Several suggestions were made by members for this agenda item.

- **Interaction with stakeholders and case owners on cases with on-going MSC decision making (closed session)**

Following a member's request, discussion took place about requests by the stakeholders to meet with the members on issues for which MSC agreement seeking is on-going, in particular concerning the prioritisation of substances for inclusion in the authorisation list. The stakeholders have been very active regarding the present round of the recommendation raising the issue how to ensure the impartiality in the MSC decision making.

MSC was reminded that following the ECHA guidance and general principles for avoidance the conflicts of interest and the perception for external influence in the ECHA Committees' work, members should refrain from communicating with the concerned parties during the MSC decision-making process for ensuring the independency and impartiality of the Committee's decisions. Recognising the sensitivity of the issue from members' perspective when most of them are civil servants of MSCAs, some practical suggestions were considered and recommendations were provided in this regard.

- **Role and involvement of eMSCAs in the appeal process if a SEV decision prepared by this CA is appealed (closed session)**

Following the request for clarification from an expert from eMSCA, a discussion took place in MSC on the role and the expected involvement of the eMSCAs when an ECHA's decision resulting from the substance evaluation performed by this MSCA is appealed. SECR gave some practical recommendations to the eMSCAs in this regard.

- **Communication between evaluating MSCA and Registrants under the Substance Evaluation process**

The MSC member suggesting this item further specified that there is a need for discussion on how the responses to the PfAs and to registrants' comments on the PfAs under the SEV decision-making process are communicated to the concerned registrants, as there is no legal clarity on the issue in REACH Regulation.

In this regards, MSC was informed of the draft Paper developed by a CARACAL working group for discussion in the next CARACAL meeting on the Interaction between the evaluating MSCA and the registrants under the SEV process.

- **Addressees of an ECHA's decision in the case of SEv – how to consider "new registrants"**

In response to a request of an MSC member's adviser, SECR further clarified that the addressee of the final decision released under SEV will be the same pool of registrants to whom the first DD was addressed in the beginning of the decision-making process, but not

to any new registrants of the substance who made their registrations during the decision-making stage. Such new registrants will be approached in the next SEV stages.

- **MSCAs' involvement in the approach of dealing with complex read-across TPE cases**

A MSC member raised the concern in relation to the involvement of the MSC when dealing with complex read-across cases under the testing proposal evaluation. The member stated that the MSCAs should get involved at the beginning for the process and not only at the late stage when the DDs are referred to CA consultation as the cases normally are complex and the time that the MSC has for dealing with the cases is too short.

SECR explained that there has been some experience in the past where WEBEX conferences have been organised between ECHA and the MSCAs and this possibility can be developed further and for example when dealing with complex cases, it is possible to arrange WEBEX between scientific experts of ECHA and the MSCAs.

The MSC member agreed with this approach and stated that this type of process will have a positive impact in the decision making process and will streamline the whole process.

Item 13– Adoption of conclusions and action points

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

SIGNED

Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ANDRIJEWSKI; Michal (PL)
BASTIJANCIC-KOKIC, Biserka (HR)
BIWER, Arno (LU)
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
GAIDUKOVS, Sergejs (LV)
HUMAR-JURIC, Tatjana (SI)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina(CZ)
LULEVA, Parvoleta (BG)
MARTIN, Esther (ES)
MIHALCEA UDREA Mariana (RO)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI)
TRAAS, Theo (NL)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
Representatives of the Commission
GARCIA-JOHN, Enrique (DG ENTR)
KOBE, Andrej (DG ENV)
Observers
ANNYS, Erwin (CEFIC)
DE KNECHT, Joop (OECD)
DEL CASTILLO, Francisco (CONCAWE)
HÖK, Frida (ChemSec)
LIGTHART, Jerker (ChemSec)
MUSU, Tony (ETUC)
STAIRS, Kevin (Greenpeace)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
ANDERSSON, Niklas
BALLESTER, Juan
BELL, David
BIGI, Elena
BONNOMET, Vincent
BORNATOWICZ, Norbert
BROERE, William
CALEY, Jane
CARLON, Claudio
DE COEN, Wim
DELOFF-BIALEKT, Anna
DE RAAT, Karel
DE WOLF, Watze
DOMINGUEZ ESTEVEZ, Manuel
FEEHAN, Margaret
GARALEVICIENE, Dalia
HAUTAMÄKI, Anne
JACQUET, Cyril
JOHANSSON, Matti
KARJALAINEN Anne-Mari
KARHU, Elina
KORJUS, Pia
KOULOUMPOS, Vasileios
MELZER, Kai
MONTERO RAMIREZ, Manuel
MÜLLER, Birgit
NAUR, Liina
NYLUND, Lars
PELLIZZATO, Francesca
RODRIGUEZ IGLESIAS, Pilar
RUOSS, Jürgen
RÖCKE, Timo
RÖNTY, Kaisu
SIMON, Rubert
SOBANSKA, Marta
SUNDQUIST, Anna-Liisa
WALKER, Lee
VAHTERISTO, Liisa
VASILEVA, Katya
WOLLENBERGER, Leah

Proxies

- COSGRAVE, Majella (IE) also acting as proxy of DOUGHERTY, Gary (UK) on Monday
- COSGRAVE, Majella (IE) also acting as proxy of DEIM, Szilvia (HU) on Monday and Tuesday Morning and on Friday
- KOUTSODIMOU, Aglaia (EL) also acting as proxy of KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
- LULEVA, Parvoleta (BG) also acting as proxy of KOUSODIMOU, Aglaia (EL) on Friday latter morning
- PISTOLESE, Pietro (IT) also acting as proxy of CAMILLERI, Tristan (MT)
- RUSNAK, Peter (SK) also acting as proxy of ANDRIJEWSKI, Michal (PL) on Monday
- VANDERSTEEN, Kelly (BE) also acting as proxy of BIWER, Arno (LU) from Wednesday noon onwards

Experts and advisers to MSC members
ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
AUST, Nannett (DE) (adviser to FINDENEGG, Helene)
BELVEZE, Corinne (FR) (expert to DRUGEON, Sylvie)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
JONGENEEL, Rob (NL) (expert to TRAAS, Theo)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
LUNDBREGH, Ivar (SE) (expert to FLODSTRÖM, Sten)
MALKIEWICZ, Katarzyna (SE) (adviser to FLODSTRÖM, Sten)
MENDONÇA, Elsa (PT) (expert to ALMEIDA, Inês)
MOELLER, Ruth (LU) (expert to BIWER, Arno)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
PEDERSEN, Finn (DK) (expert to TYLE, Henrik)
SCHWAEGLER, Mark (DE) (expert to FINDENEGG, Helene)
VAN ELSACKER, Paul (BE) (expert to VANDERSTEEN, Kelly)
VOLUJEVIC, Beata (LT) (expert to DUNAUSKIENE, Lina)

MSCA Experts for SEV cases
INDANS, Ian (UK)
LØFSTEDT, Magnus (DK)
MICHEL, Cécile (FR)
SCHULTZ, Thomas (DE)

By WEBEX-phone connection:
Mariana Fernandes de Barros (DG ENTR), Georg Streck (DG ENTR), Giuseppina Luvarà (DG ENTR) and Jacek Rozwadowski (DG ENTR) during agenda items 1-12; Valentina Bertato (DG ENTR) and Anna Borras Herrero (DG ENTR) during agenda items 9 and 10; Betty Hakkert (NL) during agenda items 1-6; Enken Hassold (DE), Anne Giral (DG ENTR), Sandrine Charles (FR), Pierre Lecoq (FR) and Chloé de Lentdecker (FR) during agend item 6b; Ian Doyle (UK) and Steve Dungey (UK) during agenda item 6c; Emiel Rorije (NL) during agenda item 7; Katarina Pirselova (DG ENV) during agenda item 10.

Case owners:
Representatives of the Registrants were attending under agenda item 6b for SEV-DE-005/2012, SEV-DK-011/2012, SEV-FR-015-2/2012, SEV-FR-015-3/2012 and SEV-UK-030/2012 and under agenda item 7b for CCH 116/2013, Petroleum substances and HOPA Alkenes.

Apologies:
CAMILLERI, Tristan (MT)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
WIJMENGA, Jan (NL)

III. Final Agenda

ECHA/MSC-32/2013/A/32

Agenda
32nd meeting of the Member State Committee

4-8 November 2013
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

4 November: **starts at 10:00**
8 November: **ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/032/2013
For adoption

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

Item 4 – Administrative issues

For information

Item 5 – Adoption of minutes of the MSC-31

- Adoption of draft minutes of MSC-31

MSC/M/31/2013
For adoption

Item 6 – Substance evaluation decision-making

Closed session for SEV-FR-015-2/2012(6b) and for 6c
Indicative time plan for 6b is Day 1&2, for 6c Day 2 to 5

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

ECHA/MSC-32/2013/001
For information

b. **Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CAs/ECHA reactions *(Session 1, open session except for SEV-FR-015-2/2012 closed)***

ECHA/MSC-32/2013/002
For information

SEV-DE-005/2012 4,4'-isopropylidenediphenol (EC No. 201-245-8)

ECHA/MSC-32/2013/003-004

SEV-DK-011/2012 Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol (EC No. 700-960-7)[3]

ECHA/MSC-32/2013/005-006

SEV-FR-015-1/2012 Carbon tetrachloride (EC No. 200-262-8)

ECHA/MSC-32/2013/007-008

SEV-FR-015-2/2012 Carbon tetrachloride (EC No. 200-262-8)

ECHA/MSC-32/2013/009-010

SEV-FR-015-3/2012 Carbon tetrachloride (EC No. 200-262-8)

ECHA/MSC-32/2013/011-012

SEV-UK-030/2012 Imidazole (EC No. 206-019-2)

ECHA/MSC-32/2013/013-014

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

As listed above under **6b** and the case returned from written procedure:

SEV-BE-003/2012[4] N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine (EC No. 221-375-9)

Item 7 – Dossier evaluation

Closed session for 7c, partly for 7d and 7e
Indicative time plan for 7b is Day 2&3, for 7c Day 3 to 5

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

ECHA/MSC-32/2013/015
For information

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

For discussion followed by agreement seeking under 7c:

ECHA/MSC-32/2013/016

Compliance checks

CCH 116/2013 2-methylbut-2-ene (EC No. 208-156-3)

ECHA/MSC-32/2013/017-018

CCH 117/2013 Terpineol (EC No. 232-268-1)

ECHA/MSC-32/2013/019-020

Testing proposals

3 Substance name used for listing on the CoRAP was Phenol, methylstyrenated (EC No 270-966-81).

4 Documents available in substance specific folders

HOPA Alkenes

TPE 090/2013	Nonene (EC No. 248-339-5)	ECHA/MSC-32/2013/021-022
TPE 091/2013	Hex-1-ene (EC No. 209-753-1)	ECHA/MSC-32/2013/023-024
TPE 092/2013	Oct-1-ene (EC No. 203-893-7)	ECHA/MSC-32/2013/025-026
TPE 093/2013	Hydrocarbons, C12-30, olefin-rich, ethylene polymn. by-product (EC No. 272-762-4)	ECHA/MSC-32/2013/027-028
TPE 094/2013	Octadec-1-ene (EC No. 204-012-9)	ECHA/MSC-32/2013/029-030
TPE 095/2013	Octadecene (EC No. 248-205-6)	ECHA/MSC-32/2013/031-032
TPE 096/2013	Tetradec-1-ene(EC No. 214-306-9)	ECHA/MSC-32/2013/033-034
TPE 097/2013	Alkenes, C8-10, C9-rich (EC No. 271-212-0)	ECHA/MSC-32/2013/035-036
TPE 098/2013	Hexadecene (EC No. 248-131-4)	ECHA/MSC-32/2013/037-038
TPE 099/2013	Tetradec-1-ene (EC No.214-306-9)	ECHA/MSC-32/2013/039-040
TPE 100/2013	Dodec-1-ene (EC No. 203-968-4)	ECHA/MSC-32/2013/041-042
TPE 101/2013	Alkenes, C10-14 (EC No. 288-213-7)	ECHA/MSC-32/2013/043-044
TPE 102/2013	Alkenes, C11-12 (List No. 931-515-7)	ECHA/MSC-32/2013/045-046
TPE 103/2013	Alkenes, C13-14 (List No. 931-071-4)	ECHA/MSC-32/2013/047-048
TPE 104/2013	Alkenes, C15-18 (EC No. 297-797-2)	ECHA/MSC-32/2013/049-050
TPE 105/2013	Alkenes, C16-18 (List No. 900-050-1)	ECHA/MSC-32/2013/051-052
TPE 106/2013	Alkenes, C20-24 α- (EC No. 300-202-1)	ECHA/MSC-32/2013/053-054
TPE 107/2013	Alkenes, C21-32 linear and branched (List No. 931-505-2)	ECHA/MSC-32/2013/055-056
TPE 108/2013	Alkenes, C24-28 α- (EC No. 300-203-7)	ECHA/MSC-32/2013/057-058
TPE 109/2013	Alkenes, C6-8 (List No. 931-293-1)	ECHA/MSC-32/2013/059-060
TPE 110/2013	C26-28 (even numbered) α-alkenes (List No. 934-268-3)	ECHA/MSC-32/2013/061-062
TPE 111/2013	Dec-1-ene (EC No. 212-819-2)	ECHA/MSC-32/2013/063-064
TPE 112/2013	Decene (EC No. 246-870-7)	ECHA/MSC-32/2013/065-066
TPE 113/2013	C20-C22 (even numbered, linear and branched) and C24 (branched) alkenes (List No. 700-497-0)	ECHA/MSC-32/2013/067-068
TPE 114/2013	Hexadec-1-ene (EC No. 211-105-8)	ECHA/MSC-32/2013/069-070
TPE 115/2013	Hexadec-1-ene (EC No. 211-105-8)	ECHA/MSC-32/2013/071-072
TPE 116/2013	Octadec-1-ene (EC No. 204-012-9)	ECHA/MSC-32/2013/073-074

Petroleum substances

TPE 117/2013	Condensates (petroleum), vacuum tower(EC No. 265-049-4)	ECHA/MSC-32/2013/075-076
TPE 118/2013	Gas oils (petroleum), light vacuum	ECHA/MSC-32/2013/077-078 (EC No. 265-059-9)

TPE 119/2013	Distillates (petroleum), light hydrocracked (EC No. 265-078-2)	ECHA/MSC-32/2013/079-080
TPE 120/2013	Gas oils (petroleum), hydrodesulfurized light vacuum (EC No. 265-190-1)	ECHA/MSC-32/2013/081-082
TPE 121/2013	Fuels, diesel (EC No. 269-822-7)	ECHA/MSC-32/2013/083-084
TPE 122/2013	Fuel oil, no. 2 (EC No. 270-671-4)	ECHA/MSC-32/2013/085-086
TPE 123/2013	Fuel oil, no. 4 (EC No. 270-673-5)	ECHA/MSC-32/2013/087-088
TPE 124/2013	Fuels, diesel, no. 2 (EC No. 270-676-1)	ECHA/MSC-32/2013/089-090
TPE 125/2013	Gas oils (petroleum), hydrotreated light vacuum (EC No. 295-407-5)	ECHA/MSC-32/2013/091-092
TPE 127/2013	Residues (petroleum), vacuum (EC No. 265-057-8)	ECHA/MSC-32/2013/095-096
TPE 128/2013	Residues (petroleum), thermal cracked vacuum (EC No. 295-518-9)	ECHA/MSC-32/2013/097-098
TPE 129/2013	Asphalt (EC No. 232-490-9)	ECHA/MSC-32/2013/099-100
TPE 130/2013	Asphalt, oxidized (EC No. 265-196-4)	ECHA/MSC-32/2013/101-102
TPE 131/2013	Distillates (petroleum), heavy straight-run (EC No. 272-817-2)	ECHA/MSC-32/2013/103-104
TPE 132/2013	Distillates (petroleum), full-range straight-run middle (EC No. 272-341-5)	ECHA/MSC-32/2013/105-106
TPE 133/2013	Distillates (petroleum),straight-run middle (EC No. 265-044-7)	ECHA/MSC-32/2013/107-108
TPE 134/2013	Gas oils (petroleum), straight-run (EC No. 265-043-1)	ECHA/MSC-32/2013/109-110
TPE 135/2013	Extracts (petroleum), deasphalted vacuum residue solvent (EC No. 295-332-8)	ECHA/MSC-32/2013/111-112
TPE 136/2013	Extracts (petroleum), residual oil solvent (EC No. 265-110-5)	ECHA/MSC-32/2013/113-114
TPE 137/2013	Distillates (petroleum), hydrodesulfurized middle (EC No. 265-183-3)	ECHA/MSC-32/2013/115-116
TPE 138/2013	Gas oils (petroleum), hydrodesulfurized (EC No. 265-182-8)	ECHA/MSC-32/2013/117-118
TPE 139/2013	Distillates (petroleum), hydrotreated middle (EC No. 265-148-2)	ECHA/MSC-32/2013/119-120

For information and discussion

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

As listed above under **7b** and any cases returned from written procedure for agreement seeking in the meeting

CCH 098/2013 2,4-di-tert-butylphenol (EC No. 202-532-0)[3]

CCH 099/2013 2,4-di-tert-butylphenol (EC No. 202-532-0)[3]

CCH 104/2013 Triclosan (EC No. 222-182-2)[3]

TPE 141/2013 Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC No. 270-128-1)[5]

For agreement

d. Update on appeal cases *(Partly closed session)*

For information

e. General topics

3) Testing strategies under dossier evaluation ***(Closed session)***

ECHA/MSC-32/2013/123
For discussion

4) Status report on on-going evaluation work

For information

Item 8 – Community Rolling Action Plan (CoRAP) update

- **Introduction of the draft CoRAP update by ECHA and first exchange of views on the draft CoRAP**

ECHA/MSC-32/2013/0126 with Annexes &
ECHA/MSC-32/2013/0127
Justification documents per substance
For information and discussion

Item 9 – SVHC identification

- **Update on the comments received in the public consultation on SVHC proposals**

For information

Item 10 – Prioritisation of Candidate List substances for inclusion in Annex XIV

a. **Update of the Priority Setting Approach for recommending substances for inclusion in Annex XIV**

ECHA/MSC-32/2013/124
For discussion

b. **Progress report after closure of the public consultation on ECHA's Draft 5th Recommendation, Draft RCOMs and Draft Annex XIV entries for prioritised substances**

ECHA/MSC-32/2013/0128-133
For information

c. **Preparations for the opinion on ECHA's Draft 5th recommendation of priority substances to be included in Annex XIV**

- Report by the rapporteur and discussion of the first draft opinion, exchange of views on comments received

ECHA/MSC-32/2013/125
For discussion

[5] To be removed from the agenda if agreed in written procedure in advance of the meeting

Item 11 – Any other business

- **Interaction with stakeholders and case owners on cases with on-going MSC decision making (closed session)**
- **Role and involvement of eMSCAs in the appeal process if a SEV decision prepared by this CA is appealed (closed session)**
- **Communication between evaluating MSCA and Registrants under the Substance Evaluation process**
- **Addressees of an ECHA's decision in the case of SEv – how to consider "new registrants"**
- **MSCAs' involvement in the approach of dealing with complex read-across TPE cases**

For information

Item 12 – Adoption of conclusions and action points

- Table with conclusions and action points from MSC-32

For adoption

Main conclusions and action points
MSC-32, 4-8 November 2013
(adopted at MSC-32)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 5 – Adoption of minutes of the MSC-31	
	MSC-S to upload final version of the minutes on MSC CIRCABC by 12 November 2013.
Item 6 - Substance evaluation decision-making **6 a. 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 decision/cover letter on case agreed in written procedure, as indicated in document ECHA/MSC-32/2013/001.
6 b. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CAs/ECHA reactions *(Session 1, open session except for SEV-FR-015-2/2012 closed)* **6 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-DE-005/2012** 4,4'-isopropylidenediphenol (EC No. 201-245-8) **SEV-DK-011/2012** Oligomerisation and alkylation reaction products of 2-phenylpropene and phenol (EC No. 700-960-7) **SEV-FR-015-1/2012** Carbon tetrachloride (EC No. 200-262-8) **SEV-FR-015-2/2012** Carbon tetrachloride (EC No. 200-262-8) **SEV-FR-015-3/2012** Carbon tetrachloride (EC No. 200-262-8) **SEV-UK-030/2012** Imidazole (EC No. 206-019-2) **SEV-BE-003/2012** N,N'-bis(1,4-dimethylpentyl)-p-phenylenediamine (EC No. 221-375-9)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions/cover letters of the agreed cases.
Item 7 – Dossier evaluation **7 a. Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the report.	**MSC-S** to upload on MSC CIRCABC the final ECHA

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	decision that was agreed in written procedure, as indicated in document ECHA/MSC-32/2013/015. **MSC-S** to provide COM for further decision making with documents (DD, RCOM outcome of the vote, justifications for NO votes) of the case on which MSC did not reach agreement, as indicated in document ECHA/MSC-32/2013/015.
7 b. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MS-CA reactions **7 c. Seeking agreement on draft decisions on testing proposals and compliance checks when amendments were proposed by MS-CA's**	
MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting where appropriate: **Compliance checks** CCH 098/2013 2,4-di-tert-butylphenol (EC No. 202-532-0) CCH 099/2013 2,4-di-tert-butylphenol (EC No. 202-532-0) CCH 116/2013 2-methylbut-2-ene (EC No. 208-156-3) CCH 117/2013 Terpineol (EC No. 232-268-1) **Testing proposals** HOPA Alkenes TPE 090B/2013 Nonene (EC No. 248-339-5) TPE 091B/2013 Hex-1-ene (EC No. 209-753-1) TPE 092B/2013 Oct-1-ene (EC No. 203-893-7) TPE 093B/2013 Hydrocarbons, C12-30, olefin-rich, ethylene polymn. by-product (EC No. 272-762-4) TPE 094B/2013 Octadec-1-ene (EC No. 204-012-9) TPE 095B/2013 Octadecene (EC No. 248-205-6) TPE 096B/2013 Tetradec-1-ene(EC No. 214-306-9) TPE 097B/2013 Alkenes, C8-10, C9-rich (EC No. 271-212-0) TPE 098B/2013 Hexadecene (EC No. 248-131-4) TPE 099B/2013 Tetradec-1-ene (EC No.214-306-9) TPE 100B/2013 Dodec-1-ene (EC No. 203-968-4) TPE 101B/2013 Alkenes, C10-14 (EC No. 288-213-7) TPE 102B/2013 Alkenes, C11-12 (List No. 931-515-7) TPE 103B/2013 Alkenes, C13-14 (List No. 931-071-4) TPE 104B/2013 Alkenes, C15-18 (EC No. 297-797-2) TPE 105B/2013 Alkenes, C16-18 (List No. 900-050-1) TPE 106B/2013 Alkenes, C20-24 α- (EC No. 300-202-1) TPE 107B/2013 Alkenes, C21-32 linear and branched (List No. 931-505-2)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions/cover letters of the agreed cases.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS		ACTIONS REQUESTED
TPE 108B/2013	Alkenes, C24-28 α- (EC No. 300-203-7)	
TPE 109B/2013	Alkenes, C6-8 (List No. 931-293-1)	
TPE 110B/2013	C26-28 (even numbered) α-alkenes (List No. 934-268-3)	
TPE 111B/2013	Dec-1-ene (EC No. 212-819-2)	
TPE 112B/2013	Decene (EC No. 246-870-7)	
TPE 113B/2013	C20-C22 (even numbered, linear and branched) and C24 (branched) alkenes (List No. 700-497-0)	
TPE 114B/2013	Hexadec-1-ene (EC No. 211-105-8)	
TPE 115B/2013	Hexadec-1-ene (EC No. 211-105-8)	
TPE 116B/2013	Octadec-1-ene (EC No. 204-012-9)	
Petroleum substances		
TPE 127B/2013	Residues (petroleum), vacuum (EC No. 265-057-8)	
TPE 128B/2013	Residues (petroleum), thermal cracked vacuum (EC No. 295-518-9)	
TPE 129B/2013	Asphalt (EC No. 232-490-9)	
TPE 130B/2013	Asphalt, oxidized (EC No. 265-196-4)	
MSC could not reach unanimous agreement on the following draft decisions regarding examination of the testing proposal for a two-generation reproduction toxicity study (Annex X, 8.7.3) (Part A of the decision):		
TPE 090A/2013 to TPE 116A/2013 (see the list above)		
TPE 127A/2013 to TPE 130A/2013 (see the list above)		
TPE 117/2013	Condensates (petroleum), vacuum tower (EC No. 265-049-4)	
TPE 118/2013	Gas oils (petroleum), light vacuum (EC No. 265-059-9)	
TPE 119/2013	Distillates (petroleum), light hydrocracked (EC No. 265-078-2)	
TPE 120/2013	Gas oils (petroleum), hydrodesulfurized light vacuum (EC No. 265-190-1)	
TPE 121/2013	Fuels, diesel (EC No. 269-822-7)	
TPE 122/2013	Fuel oil, no. 2 (EC No. 270-671-4)	
TPE 123/2013	Fuel oil, no. 4 (EC No. 270-673-5)	
TPE 124/2013	Fuels, diesel, no. 2 (EC No. 270-676-1)	
TPE 125/2013	Gas oils (petroleum), hydrotreated light vacuum	
TPE 131/2013	Distillates (petroleum), heavy straight-run (EC No. 272-817-2)	
TPE 132/2013	Distillates (petroleum), full-range straight-run middle (EC No. 272-341-5)	
TPE 133/2013	Distillates (petroleum),straight-run middle (EC No. 265-044-7)	
TPE 134/2013	Gas oils (petroleum), straight-run (EC No. 265-043-1)	
TPE 135/2013	Extracts (petroleum), deasphalted vacuum	**MSC-S** to provide COM for further decision

CONCLUSIONS / DECISIONS / MINORITY OPINIONS		ACTIONS REQUESTED
	residue solvent (EC No. 295-332-8)	making with the relevant documents (DD on generation testing, RCOM, minutes, outcome of the vote, justification for the position at the vote).
TPE 136/2013	Extracts (petroleum), residual oil solvent (EC No. 265-110-5)	
TPE 137/2013	Distillates (petroleum), hydrodesulfurized middle (EC No. 265-183-3)	
TPE 138/2013	Gas oils (petroleum), hydrodesulfurized (EC No. 265-182-8)	
TPE 139/2013	Distillates (petroleum), hydrotreated middle (EC No. 265-148-2)	
Item 8 – Community Rolling Action Plan (CoRAP) update Introduction of the draft CoRAP update by ECHA and first exchange of views on the draft CoRAP		
MSC took note of the update.		**MSC members** to provide the Rapporteur/SECR with any contributions on any of the substances listed on the draft CoRAP update.
Item 10 – Prioritisation of Candidate List substances for inclusion in Annex XIV **Item 10 a. Update of the Priority Setting Approach for recommending substances for inclusion in Annex XIV**		
MSC took note of the updated draft priority setting approach.		**MSC members** to send to SECR their remaining written comments on the update of the Priority Approach by 15 November 2013. **SECR** to take into account the comments provided in the meeting and in writing when preparing the revised version of the approach for MSC endorsement in the MSC-33 meeting.
Item 10 b. Progress report after closure of the public consultation on ECHA's Draft 5th Recommendation, Draft RCOMs and Draft Annex XIV entries for prioritised substances		
MSC took note of the secretariat's draft responses to the comments provided during the public consultation.		**SECR** to provide the updated draft recommendation document, draft Background Documents and the updated RCOMs to the MSC Recommendation WG members by 21 November 2013.
Item 10 c. Preparations for the opinion on ECHA's Draft 5th recommendation of priority substances to be included in Annex XIV Report by the rapporteur and discussion of the first draft opinion, exchange of views on comments received		

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	MSC members to provide their comments on the 1st draft opinion to MSC-S by 14 November 2013. **MSC-S** to compile the comments received to be provided to the Rapporteur and WG members for further consideration when revising the draft opinion. **Recommendation Rapporteur and WG members** to consider the MSC comments and the updated documentation provided by SECR in the revised draft opinion of MSC and send it to SECR by 28 November 2013.
Item 12 – Adoption of conclusions and action points	
MSC adopted the conclusions and action points of MSC-32.	**MSC-S** to upload the conclusions and action points on MSC CIRCABC by 11 November 2013.

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

Draft decisions unanimously agreed by MSC in WP:

MSC ID number	Substance name used in draft decision	EC No
CCH 104/2013	triclosan	222-182-2

Draft decisions for which no unanimous agreement was reached via WP:

MSC ID number	Substance name used in draft decision	EC No
TPE 141/2013	Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene	270-128-1

Draft decisions that written procedure was terminated for:

MSC ID number	Substance name used in draft decision	EC No
CCH 098/2013	2,4-di-tert-butylphenol	202-532-0
CCH 099/2013	2,4-di-tert-butylphenol	202-532-0