MSC/M/41/2015
(Adopted at MSC-42)

Minutes
of the 41st Meeting of the Member State Committee (MSC-41)
20-23 April 2015

I. Summary Record of the Proceedings

Item 1 - Welcome and Apologies

The Chairman of the Committee, Mr Watze de Wolf, opened the meeting and welcomed the participants to the 41st meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Annex II of the minutes).

Item 2 - Adoption of the Agenda

The Agenda was adopted as modified at the meeting based on the draft agenda as provided for the meeting and based on a request from a member for inclusion of one information item under item 13 (for the final Agenda see Annex III attached to these minutes).

The Chairman introduced as an organisational change that Evaluation decision discussion groups meet before and after the plenary meeting to focus the plenary meeting discussions on potential path(s) forward for resolution of any diverging views and improve MSC's efficiency in the decision making. Following review after the meeting, the approach could be used for future meetings.

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

- **Declarations of conflicts of interests at the meetings and their reflection in the minutes**

The Chairman suggested the Committee a new way of recording declarations of conflicts of interests. Main change is to record the name of the participant declaring a potential conflict of interest, and record the declaration and mitigating measures in a table annexed to the minutes. MSC did not raise objections to the Chairman's suggestion to use this approach starting with the minutes of MSC-41.

- **Declarations of conflicts of interest to the items on the Agenda**

The Chairman informed the Committee about the declared conflicts of interests expressed prior to the meeting and requested all participants to declare any potential conflicts of interest to any of the agenda items. One member and the Chairman declared potential conflicts of interest, each to specific agenda items. Details of the declared potential conflicts and the mitigating measures are attached to these minutes as Annex IV.

Item 4 - Administrative issues

No administrative issues were announced or discussed.

Item 5 – Minutes of the MSC-40

The minutes of MSC-40 were adopted as provided for the meeting and further modified, based on members' additional comments.

Item 6 – Substance evaluation

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 one substance evaluation case. WP was launched on 26 March 2015 and terminated by the MSC Chair on 30 March 2015 on the basis of Article 20.6 of the MSC Rules of Procedure since an MSC member requested a meeting discussion.

b. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA's/ECHA reactions (Session 1, tentatively open session)

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

SEV-IT-022/2013 Octabenzone EC No. 217-421-2

Session 1 (open)

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

The evaluating Member State Competent Authority (eMSCA) from the Italian CA (IT-CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance on the basis of the initial grounds for concern relating to human health sensitization, endocrine disruption, exposure on wide dispersive use, consumer use and aggregated tonnage. The members were guided through the information requirements and explained that additional concerns on potential risk for environmental compartments (sediment, soil) and potential human exposure via the environment were identified during the evaluation.

A total of eleven proposals for amendment (PfAs) were received requesting for a) addition of the detailed reasons why the possible endocrine disruption concern is not further assessed for the environmental compartment, b) an extended One Generation Reproduction Toxicity Study (EOGRTS; OECD 443) in rat, oral route in order to clarify the possible concern for endocrine disruption via a tiered testing strategy, starting with an extension of the Pre-natal developmental toxicity study (PNDT) with determination of several hormones in the female animals, c) to conduct an EOGRTS with DNT and DIT cohorts but without F2 in order to further investigate on the possible endocrine disrupting properties of the substance, d) to amend in the DD the deadline of the PNDT in Section II to 18 months from the date of the final decision in line with the specification from Section III point 1, e) to better reflect in the DD the issues raised by the Registrant in his comments on information requests for terrestrial toxicity: the plant test, the soil microorganism test and the OECD 209 test on activated sludge respiration inhibition. Additionally PfAs on editorial changes in the DD were submitted.

During the presentation of the case the eMSCA explained that the DD was modified for the meeting to reflect the PfAs on the deadline, to add a request for an EOGRTS (OECD 443) with DIT and DNT cohorts but without F2, to further reflect on the Registrant's initial comments, and to address the editorial PfAs.

The PfAs that were discussed at the meeting were related to: 1) the requested EOGRTS with DNT and DIT cohorts but without F2, and 2) further investigation on the possible endocrine disrupting (ED) properties of the substance with determination of several hormones in female animals.

The Registrants provided written comments on two of the PfAs prior to the meeting and clarified them at the meeting. In relation to the extension of the PNDT with hormone measurements the Registrant argued against the technical feasibility and scientific relevance of such an extension. In relation to the PfAs on EOGRTS the Registrants were of the opinion that even though the 4-gen study from the dossier is rather old, they considered that the study was conducted and reported in accurate and detailed manner in line with the OECD guidelines, and it was clearly shown as valid with the histopathological examination and reproduction performance showing that Octabenzone is not reprotoxic. The Registrants clarified that the changes observed in the study were not statistically significant, and not related to the doses. In their view animal testing should be performed only as a last resort and an EOGRTS would not be justified. Additionally the Registrants provided further supporting information that Octabenzone should be viewed a passive compound for endocrine disruption.

Session 2 (closed)

Regarding the PNDT study it was agreed to maintain the request as initially specified, but to extend the deadline to submit the requested information.

In relation with the EOGRTS, due to the identified additional concern on reproductive toxicity and the data gap for peri- and post-natal developmental toxicity and fertility and in

order to clarify the endocrine disruption concern for this substance, it was suggested that there is a need to first perform a range finding study according to the draft updated OECD TG 421 and additional parameters regarding immunotoxicity shall be included. Depending on the outcome of the range finding study, and on the basis of the evaluation of the eMSCA, the study design for an EOGRTS can be more readily elaborated. It was also highlighted that a negative outcome for the range-finder will not exclude that a further request to clarify the concerns will be needed.

In conclusion, MSC unanimously agreed 1) to maintain the request for a PNDT study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD 414) in rats or rabbits, oral route, and 2) to request a range finding study in advance of a potential follow-up request for an Extended One Generation Reproductive Toxicity Study (EOGRTS – EU B.56/OECD 443) performed according to draft OECD 421 updated on 05 March 2015, which shall additionally include immunological parameters in maternal animals.

The DD was amended in Section II and Section III accordingly and the deadline to submit all requested information and, where relevant, to update of the CSR, was extended to 21 months. No other major modifications were made to the draft decision at the MSC meeting.

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

SEV-ES-027/2013 Diallyl phthalate EC No. 205-016-3

Session 1 (open)

Two representatives of the Registrants participated in the initial discussion for diallyl-phtalate (DAP). In absence of specific confidentiality concerns an open session was held.

eMSCA expert from the Spanish CA (ES-CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance performed by ES-CA on the basis of the initial grounds for concern, i.e. relating to mutagenicity, exposure/wide dispersive use and consumer use.

One PfA submitted by UK-CA proposed to replace the requested transgenic rodent somatic and germ cell mutation test (TGR; OECD 488), with a mammalian cell spermatogonial chromosomal aberration test (OECD 483) in order to assess the identified concern of germ cell mutagenicity, and to address the potential clastogenicity/aneugenicity.

Another PfA submitted by DK-CA suggested a concern on reproductive toxicity and endocrine disruption for diallyl phthalate (DAP) based on scientific information on structurally closely related phthalates, and that there is a data gap for the Annex IX data requirement, and proposed an EOGRTS (OECD 443), including the DIT and DNT cohorts as a follow up should the evaluation of the required test to clarify the mutagenicity gives a negative result.

During the presentation of the case the ES-CA explained the reasons why the draft decision (DD) was not modified for the meeting based of the proposals for amendments (PfAs) received. On the other hand, the ES-CA noted that section III of the DD has been modified on the basis of the Registrants comments to PfAs.

The Registrants provided written comments on both PfAs prior to the meeting and clarified them at the meeting. In relation to the PfA on mutagenicity the Registrants indicated their agreement with the TGR (OECD 488), suggesting to perform additionally a micronucleus assessment on peripheral blood samples taken from animals exposed to DAP over the 28-day dosing regimen of the OECD TG 488 study, thus addressing a potential concern related with clastogenicity/aneugenicity. In relation to reproductive toxicity the Registrants representatives provided arguments that effects observed after administration of high doses on both males and females are coming from toxicity (hepatotoxicity) of DAP and not from its endocrine disruption properties. The Registrants representatives referred also to structural characteristics of DAP (i.e. carbon chain length below 5) which do not support endocrine disruption properties.

Some clarifying questions from MSC members were addressed to the Registrant's representatives. In their interventions the MSC members discussed if the focus on mutagenicity should be on clastogenicity/aneugenicity more than on gene mutation potential. They also considered the need to request further information once the results of the study are available.

Session 2 (closed)

The e-MSCA presented the modifications on the DD which were introduced after the discussion focused on finding the right way for addressing the combined TGR and micronucleus test to clarify mutagen concerns, as there is no validated protocol available for the combination of both tests. MSC agreed not to change the information requirement but noted in the DD that it was left at the discretion of the Registrants to perform the additional micronucleus assessment on peripheral blood. In addition, a new paragraph was added in the DD for the Registrants to consider that once the results of the study are available, the evaluating MSCA will consider the need to request further information in order to assess any remaining concern for mutagenicity.

MSC found unanimous agreement on this SEv DD as amended at the meeting.

SEV-SE-029/2013 Butyl acrylate EC No. 205-480-7

Session 1 (open)

One representative of the Registrants participated in the initial discussion. In absence of specific confidentiality concerns in draft decision (DD), an open session was held.

The evaluating Member State Competent Authority (eMSCA) from Swedish CA (SE CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance on the basis of the initial grounds for concern relating to Human health/Suspected reproductive and developmental toxicity; Exposure/Occupational exposure; Aggregated tonnage. The members were guided through the information requirements and explained that additional concerns for potential mutagenicity of the substance and derivation of DNEL were identified during the evaluation.

Eighteen PfAs were submitted in total. These were related to EOGRTS with DNT and DIT; pre-natal developmental toxicity test (PNDT), the tiered mutagenicity testing strategy, dermal DNEL and deadlines.

Regarding the EOGRTS PfAs proposed to: 1) specify the exposure route in Sections II and III of the DD; 2) make explicit the reasons and conclusion for rejecting the read-across and WoE including also the data available for metabolites; 3) refer to the technical concerns (feasibility) in relation to conducting the OECD TG 443 by inhalation, especially if the cohorts are included highlighted by the Registrants in the DD; 4) remove requirements for DNT and DIT since it was considered that there is no sufficient scientific justification for the inclusion of these cohorts.

Regarding PNDT it was proposed that if the concern is primarily related to the increased number of resorptions, this could also be addressed with the requested OECD TG 443, potentially leading to classification for developmental toxicity. In that case, it was considered that it would be more appropriate not to request the OECD TG 414 at this stage, but to re-assess the need for further developmental toxicity studies in the follow-up evaluation, by taking into account also the results of the OECD TG 443 on butyl-acrylate, when they become available. Additionally similar as PfAs 1 and 2 for EOGRTS as above were proposed.

The tiered strategy for mutagenicity asked for in vitro mammalian cell micronucleus test (test method: B.49./OECD TG 487) as tier 1. If tier 1 was positive the mammalian erythrocyte micronucleus test (test method: B.12./OECD TG 474) via the most appropriate exposure route or Comet Assay (OECD TG 489) in rats via inhalation, was requested as Tier 2a. If Tier 1 was negative an in vitro gene mutation study in mammalian cells (test method: B.17./OECD TG 476) was requested as Tier 2b. If Tier 2b was positive the transgenic rodent somatic and germ cell gene mutation assay (TGR, OECD TG 488) in mice via inhalation assessing mutation frequency in lung, liver and bone marrow OR Comet

assay in rats via inhalation assessing DNA damage in lung, liver and bone marrow were requested as Tier 3.

It was proposed in the PfAs to 1) justify or remove the request for bone marrow in the Comet assay; 2) justify the request for inhalation exposure route in Comet assay; 3) consider applying the FISH technique for TG 487 (Tier 1) and TG 474 (Tier 2a); 4) reflect under TG 487 (Tier 2a) that whenever the addition of the metabolic activation under Tier 1 would result in the disappearance of the genotoxic effect observed without metabolic activation, and the results would not show mainly induction of aneuploidy (in case the FISH protocol is followed), the OECD TG 489 shall be conducted; 5) specify exposure route for TG 474; 6) clearly address the Registrants' comments on the read-across and the availability of two carcinogenicity studies that made the Registrants to claim that no further mutagenicity testing was needed; 7) make editorial revisions to section III; 8) improve justification for not accepting the new and enhanced read-across arguments by the Registrants; 9) include the request for the in vitro gene mutation study in mammalian cells (TG 476 currently in Tier 2b) within Tier 1. It was considered that this would allow the identification of the relevant genotoxic mechanism(s) to be investigated in any subsequent in vivo testing and clarify any concerns for aneuploidy, clastogenicity and/or mutagenicity. This could require amendment of the existing in vivo testing strategy tiers 2 and 3, including the possibility to request an appropriate combination of tests depending on the results of the in vitro studies, such as a combined in vivo Mammalian Comet and micronucleus assay; 10) remove TG 474 from Tier 2a leaving the Comet Assay unless the Registrant can show that the bone marrow is reached by the substance in an in vivo MN test.

Regarding derivation of dermal DNEL it was proposed to remove the request to provide better justification for not applying the interspecies assessment factor (AF), or to adjust the dermal DNEL. Instead, the Registrants, as they propose in their comments, should be requested to provide an improved qualitative assessment to demonstrate the likelihood that skin sensitisation effects are avoided when implementing the exposure scenarios. Three different deadlines were set for the gathering of the information requirements. It was proposed to 1) amend the deadlines to allow the Registrants option to first conduct the testing required under request 3 (mutagenicity) prior to requests 1 (EOGRTS) and 2 (PNDT); 2) consider setting one deadline in section II for the submission of all information requests; 3) revise deadlines to reflect the timeline that is usually given for the requested tests. The Registrants provided written comments on PfAs and on DD which were reiterated in the meeting by their representative. The Registrants generally commented that the existing data is more than sufficient for risk assessment. They believe that the substance is not immunotoxic and not reprotoxic. However, if it is believed that a potential data gap on reproductive toxicity still exists, then they prefer to perform either a two-generation reproduction toxicity (TG 416) or EOGRTS without DNT and DIT cohorts and without the extension of Cohort 1B to mate the F1 animals to produce the F2 generation. Regarding the latter they objected to the pre-mating exposure for 10 weeks. They supported a more detailed explanation for the rejection of the read-across and category approach.

Regarding the PNDT they re-iterated their disagreement to perform an additional teratogenicity study in rabbit. They also reiterated that the abundant available evidence shows no mutagenic potential neither in vitro nor in vivo, hence they agreed with PfA asking for more detailed reasoning and firmer conclusion on why the Weight of Evidence (including read-across) approach was not regarded as sufficient.

Regarding the DNEL derivation they supported the PfA to use the qualitative assessment and a more detailed description of the RMM since the substance is only used as intermediate.

They also stated that the deadlines given were too short in general.

A MSC member asked why the in vivo chromosomal aberration test was considered unreliable, since if that test would be accepted as valid, the requested in vitro micronucleus study and following in vivo tests would not be needed. The eMSCA expert explained that the study suffers in study design since the one dose tested was not the limit

dose. A minimum of three doses should have been used. Positive control was not reported (missing) and there was no waiving for this. The suitability of a repeated-dose protocol for this test has not been validated and sampling time might have been too short. Another MSC member suggested sequential testing and that mutagenicity should be clarified first, before further tests for reproductive and developmental toxicity are conducted, since if the substance would be classified as mutagen 1B, no further testing for reproductive/developmental toxicity would be necessary. The eMSCA considered that they have a concern with increased resorptions hence they did not consider it justifiable to wait for the mutagenicity testing results in a sequential testing.

The Registrant representative was asked whether any genetic damage happens on the site of contact of the substance, even though the substance hydrolyse quickly into acrylic acid and butanol. The Registrant representative explained that no tumors were detected at site of contact (nasal tissue or lung) in a 2-year carcinogenic study after inhalation. They have in vitro data showing negative results together with other data. In the view of the Registrant representative mutagenic effects, if present, would have happened at the respiratory epithelium but because no tumours were detected in the available carcinogenicity studies, it was regarded as evidence that it is not mutagenic.

On this respect, one MSC member pointed out that a negative carcinogenic test cannot be considered as evidence of no mutagenic potential of the test substance.

Session 2 (closed)

MSC discussed four different options for tackling the mutagenicity concern. It was finally unanimously agreed to start in tier 1 with in vitro mammalian cell micronucleus test (TG 487) as originally proposed with the addition of a chromosome centromere labelling method. In case tier 1 is negative, one proceeds with another in vitro test - an In Vitro Mammalian Cell Gene Mutation Assay using the Thymidine Kinase Gene (test method: new OECD TG 492) as tier 2a; If tier 1 is positive one proceeds with a given selection of in vivo tests depending on demonstration of either aneuploidy (tier 2b) or both structural and numerical chromosomal changes (tier 2c) or clastogenic effects (tier 2d). If tier 2a is positive one proceeds with TGR or Comet assay (tier 3).

Regarding route of administration for the mutagenicity tests, MSC unanimously agreed to ask for oral gavage for tier 2b – 2d with assessment of DNA damage in forestomach, glandular stomach (as sites of contact) and liver (as metabolic active tissue) in the in vivo Comet assay, whilst for tier 3 it was unanimously agreed to request TGR either via inhalation or via oral gavage or Comet assay via oral gavage.

Consequently three deadlines were given depending on whether and which test would need to be performed for the tier 3 mutagenicity testing.

It was also unanimously agreed that, if available, the Registrant may use the information not reported, e.g. the positive controls data, to re-evaluate the reliability of the in vivo chromosomal aberration rat study and may consider using the data in a WoE approach before performing the in vitro micronucleus test and the following conditional in vivo tests as requested in the above mutagenicity testing strategy.

MSC unanimously agree to request Extended one-generation reproductive toxicity study (test method: EU B.56./OECD 443) (EOGRTS) in rats, via the oral route without DNT and DIT and without the F2 generation in parallel with the tiered mutagenicity testing strategy and the Prenatal developmental toxicity study (EU B.31./OECD TG 414) in rabbits, via the oral route.

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

SEV-FR-014/2013 Formaldehyde EC No. 200-001-8

Session 1 (open)

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

The eMSCAs from France CA (FR CA) and Dutch CA (NL CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance on the basis of the initial grounds for concern relating to human health/CMR, exposure/wide dispersive use, worker exposure, aggregated tonnage. The members were guided through the information requirements.

Five PfAs were submitted. Three PfAs were of a generic nature. Two PfAs were on information on emission rates for the most important sources of formaldehyde and their relative contribution to the total indoor air concentration: One proposed to change the air exchange rate of 0.5–1 h in the exposure scenario modelling to 0.2-1 h as this was considered a realistic level in the countries of northern Europe during the winter period; the other PfA proposed to: 1) further clarify the concern for consumers in terms of risks and effects since the reported results appeared to support the view that the reasonable worst case had been addressed and very few results exceeded the concentration threshold for 'new home' subset of cases; 2) specify the scale of the request since it was unclear from the request how the registrant were intended to fulfil this request; 3) clarify how the information was to be used to clarify the initial concern; 4) reflect all the comments of the Registrants in the draft decision.

The Registrants provided written comments on the PfAs and reiterated them at the meeting. The registrants stated the DNEL for consumers is equivalent to the most recent indoor guideline level of WHO namely 0.1 mg/m^3. The Registrants were against the request for the information on emission rates for the most important sources of formaldehyde and their relative contribution to the total indoor air concentration for four reasons: 1) The registrants have doubts on the legal basis to ask for information on emission rates from articles as a result of (urea-formaldehyde) resin hydrolysis, since the articles mentioned are not in the life cycle of formaldehyde and the concentrations of formaldehyde in the mentioned products are too low to necessitate an assessment. 2) It was considered disproportionate and with a doubtful legal basis to request the Registrants to assess and evaluate emission sources unrelated to the substance volumes manufactured and registered under REACH as well as other sources where formaldehyde is a degradation product or a contaminant of a new substance. 3) The reasonable worst case level of formaldehyde emission, which is between the 94th and 99th percentile of measured data, is below the DNEL. The Registrants were willing to set up a kind of 'meta-study' of the studies given in the additional report for a more detailed and in depth analysis of the raw data with the exceptional cases where the DNEL resulted to be above 0.1 mg/m^3. However, they still considered doubtful the legal basis for this information request even if the scope was defined more clearly, and questioned whether the knowledge on different emission rates and modelling parameters could actually help to clarify the initial concern. It was unclear how emission rates and modelling could help to clarify the concern. 4) Formaldehyde registrants are not the actual producers or importers of articles related to suspected formaldehyde emissions.

Additionally the Registrants also provided comments on DD by stating that they agreed with the removal of background information on workers and described their plans for registration dossier update with regards to long term and short term worker DNEL derivation. Furthermore, regarding the request related to considerations of hazards and risks related to the presence of methanol above 10% w/w as an additive in some aqueous solutions of formaldehyde, the Registrants found that it was not adequately reflected in the amended DD that only a limited number of Registrants would be affected by this information request. Hence, Registrants' representatives asked for Section II of DD to be updated to specify that that request is for registrants having methanol over 10%.

During the meeting discussion, clarifying questions were asked to the Registrants' representatives on how they should tackle their contribution of sources of formaldehyde in relation to other sources in order to control emission of formaldehyde and to explain further the intentions of the meta-study that they volunteered to undertake. The Registrants' representatives explained that a study undertaken two years ago included a

very comprehensive literature search on measured indoor levels of formaldehyde addressing man made sources of formaldehyde like wood-based materials, carpets, textiles, paints and mineral wools. The study also included measured values from real homes, which were considered representative These measurements were carried out in new, used and old houses. More than 94% of the values were under the WHO value. Registrants offered to investigate why the measurements in the remaining cases (6%) came to this result. Registrants also offered to undergo the study in a reference room containing panels and measuring formaldehyde over time. However, the Registrants' representatives highlighted that they had severe problems in modelling emissions from candles and fireplaces as well as on how to consider seasonal differences. The eMSCA expert explained that the Registrants are given the possibility to show the emission sources and distinguish between the important sources and those that are less important.

The Registrants' representatives informed MSC that whilst they are working closely with the wood panel industry, yet it has proven difficult to convince other formaldehyde downstream users to provide data from their segment. If downstream users are not willing to share their data, the Registrants would need to buy products from the market, which was considered disproportionate for them. Regarding the meta-study the Registrants' representatives explained that they plan to have a detailed look again in the literature and contact the owners of reports to get more information on the circumstances of the measurements. This could be done within 2 years.

Session 2 (closed)

During the discussion the MSC recognised the proportionality concerns highlighted by the Registrants in the written comment and their representatives at the meeting. Whilst MSC recognised that imported articles and sources of formaldehyde not linked to the Registrant's supply chain - like combustion sources - are relevant information yet the extent to which this information could be requested raises some legal concern. Furthermore the Committee acknowledged that more clarity is needed on how this strategy can clarify the concern.

Hence MSC unanimously agreed to revise the request by asking for literature data and review data from the Registrants with emission rates from indoor sources and performing exposure scenarios using existing data. MSC further clarified the request by making it more specific and explaining the responsibilities of the Registrants on the whole supply chain of the monomer. Further justification was included in the DD to further clarify the concern for consumers in terms of risks and effects hence highlighting the importance of keeping the emission levels below the DNEL. The Registrants were also asked to rank the different sources of formaldehyde based on the measured emission rates and the decrease of emission over time, with the aim of prioritising sources of formaldehyde emissions that may need to be regulated.

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

SEV-DK-006/2013 4,4'-Propane-2,2-diyldiphenol, polymer with 2-methyloxirane (BPA1-4.5 PO) (EC No. 500-097-4)

Session 1 (open)

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

The evaluating Member State Competent Authority (eMSCA) from the Danish CA (DK-CA) presented the outcome of the substance evaluation (SEv) of the above-mentioned substance on the basis of the initial grounds for concern, i.e. relating to Human health/suspected CMR (the scope limited to reproductive toxicity, i.e. fertility and developmental toxicity); exposure/wide dispersive use; aggregated tonnage. The members were guided through the information requirements and explained that additional concerns, based on both data gaps and on substance specific considerations, were identified during the process of the evaluation. These were a concern of toxicity after repeated dose administration and a concern for endocrine disruption as a mode of action for effects on

sexual function and fertility, and developmental toxicity including developmental neurotoxicity and developmental immunotoxicity.

A total of five PfAs were received. During the presentation of the case eMSCA explained that the DD was modified for the meeting based on PfAs received. eMSCA accepted and incorporated in the DD most of the PfAs received. A PfA submitter agreed with the way its two PfAs were reflected in the DD and these did not require further discussion at the meeting. The three other PfAs that were discussed at the meeting were related to the information request for an Extended One Generation Reproductive Toxicity Study (EOGRTS) in rats, oral route (EU B.56./OECD TG 443) with the DNT and DIT cohorts where two PfAs propose to include in the EOGRTS request a requirement for an extension of Cohort 1 B to mate the F1 animals to produce the F2 generation which shall be kept until weaning. While the third PfA's submitter agreed with the eMSCA that there is a concern for reproductive toxicity and an EOGRTS should be requested, its PfA suggested, however, to delay the EOGRTS request as the proposed test design could require revision once the 90-day study results become available as these results may provide additional information on the acceptability of the proposed read-across. The member further clarified his CA's arguments for submitting the PfA requesting for the 90-d RDT study first, i.e. not to use it as a range finding study, but for further specifying the design of the EOGRTS, including the cohort requests

The Registrants provided written comments on the PfAs prior to the meeting and clarified these at the meeting. Comments from the Registrants on other aspects of the DD were not considered by MSC. With regard to the EOGRTS, the registrants highlighted that they are revising the Chemical Safety Report (CSR) where the consumer use of the substance will be removed, and therefore lower the exposure as compared to the one used for the justification of an EOGRTS with an extension of cohort 1B. The registrants further clarified that the exposure occurs only from the residuals of reacting substances and currently manufactured resins and toners are analysed for their content. If no residues are available, this would impact the conclusion regarding the wide dispersive use of the substance. Further, the registrants supported the PfA to remove the EOGRTS request from the DD, but disagreed that the 90-day study data would provide any useful additional information about the area of concern and thus propose to remove the 90-day study from the DD. They proposed a tiered testing strategy, delaying the decision to perform the EOGRTS until the end of this first CoRAP evaluation, to make use of the results from their improved exposure estimates and the requested OECD 455 study (an in vitro oestrogen gene reporter assay), for which no PfAs have been received, in order to detect oestrogen receptor agonistic effects for different components that compose the different grades of the UVCB substance BPA 1-4.5 PO, as the results will be helpful for deciding on the best grade of the substance to be tested.

In response, eMSCA expert reminded that the SEv decision is concern-driven, that there is sufficient information available to identify that components of the substance and/ or their metabolites may have estrogenic activity and that the available exposure information in the dossiers is to be taken into account. He also highlighted that the in vitro method has limitations, as inclusion in the test of a metabolizing system such as S9 or hepatocytes it is not yet validated, indicating problems with test result reliability if the substance undergo metabolism to oestrogenic transformation products. He could therefore not support the sequential or tiered testing strategy proposed by the registrant. However the eMSCA considered that if there is no significant exposure of consumers or professionals the F2 generation may be omitted.

Further, some members referred to the OECD conceptual framework for identification of endocrine disrupting substances and to the ECHA's guidance regarding the testing for reproductive toxicity. The registrants argued that in their view the evidence of estrogenic activity of the substance was not strong but agreed that some observed effects have to be clarified regarding this aspect.

Session 2 (closed)

MSC concluded that there are grounds for additional concerns on reproductive toxicity and endocrine disruption, and that the EOGRTS in rats, oral route (test method OECD TG 443) with BPA 4PO would generate the necessary information to address these concerns.

Motivated by this SEv DD deliberations, some MSC members expressed a generic concern regarding the implementation of the new Annexes of the Test Regulation concerning the use of EOGRTS for reproductive toxicity testing, where conditions for inclusion of F2 and DNT/DIT are provided, that currently lead to different interpretations regarding the amount of evidence needed for triggering of F2 and DNT/DIT. Thus, an observation was made by the expert of eMSCA on the need to develop regulatory interpretation criteria with regard to the new annexes for easier use under REACH.

Regarding the EOGRTS design, on the basis of the information and documentation available in the registration dossiers, MSC concluded that there is a need to include extension of Cohort 1B to produce the F2 generation due to the existing concern on the consumer and professional exposure and an oestrogenic mode of action. It was noted that according to Column 2 of section 8.7.3 of Annexes IX and X of REACH triggering of F2 includes not only consumer use but also exposure to professionals. If the Registrants update their registration dossiers justifying and demonstrating that there are neither consumer, nor professional uses covered in the registration dossiers leading to significant exposure, taking into account consumer exposure from articles, the F2 generation may be omitted in the EOGRTS study design. Further, MSC supported the eMSCA's conclusion on the need to include Cohorts 2A and 2B for developmental neurotoxicity and Cohort 3 for developmental immunotoxicity.

MSC unanimously agreed on this SEV DD as modified at the meeting. One member requested to note the abstention from voting due to some remaining reservations regarding the strength of the argumentation on the need for the cohorts' inclusion.

SEV-UK-038/2013 Hexamethyldisiloxane EC No. 203-492-7

Session 2 (closed)

This SEV case was returned from the written procedure because of a concern addressed in a PfA requesting a PNDT based on possible developmental effects, which are indicated in the available one and two generation studies, and to fulfil a standard information data gap. Two findings indicate increased pup mortality occurring in the high dose groups, which may be an indication of teratogens, and hence a PNDT was considered needed for this substance.

The eMSCA expert agreed that there is some residual uncertainty in this case, and coupled with the data gap for PNDT falling within the scope of this evaluation, they agreed to accept this PfA to request for PNDT study.

MSC unanimously agreed on this SEV DD as modified at the meeting based on the above considerations One member abstained from voting due to general reservations concerning the PBT testing strategy.

d. General topics

- **Status report on substance evaluation**

SECR gave an update to MSC on the number of SEV cases planned for each of the upcoming MSC meetings and reminded MSC on the legal timelines and the obligations of the eMSCAs associated with those timelines. SECR also gave an update on the next steps for consistency screening and substance selection for CoRAP.

Appeals update

See under Item 7d below.

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 eighteen dossier evaluation cases (see Section VI for more detailed identification of the cases). WP was launched on 26 March 2015 and closed on 7 April 2015. 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 fifteen DDs. For three 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 had requested meeting discussion.

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

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

TPE-015/2015 Tert-pentyl hydroperoxide (EC No. 222-321-7)

Session 1 (open)

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

SECR introduced the three PfAs on in vivo mammalian erythrocyte micronucleus test (MN; OECD 474) that were received to ECHA's DD.

The first PfA suggested that the in vivo MN test was not appropriate and to replace it with an in vivo comet assay (OECD 489) via the oral route with examination of site of contact, liver and bone marrow. There was a concern that tissues at the portal of entry would be exposed to a potentially mutagenic substance given the high reactivity of the registered substance and the proposed test cannot address that concern.

The second PfA suggested performing a comet assay noting that it appeared doubtful that an in vivo MN test would give meaningful results, because the substance would hydrolyse quickly in the blood and there were indications that it acted locally (Skin Corr. 1B, Eye Damage 1). The PfA suggested inhalation as route of administration with examination of the upper respiratory tract or, if technically not possible, via oral route with examination of liver, stomach and duodenum/jejunum.

The third PfA suggested conducting an in vivo mammalian erythrocyte MN test, inhalation route. It was to be followed up by an inhalation in vivo comet assay, including analysis of the effects in nasal or lung, liver and a fast proliferating tissue (e.g. bone marrow), if (a) equivocal or negative and convincing evidence was not provided for the substance and/or its metabolites having reached the bone marrow in the MN test, or (b) no negative evidence was provided with a new appropriate Ames test, which should be conducted before in vivo mutagenicity testing. Should the new Ames test indicate in vitro gene mutagenicity, only an in vivo comet assay, as specified above, would be acceptable.

SECR had not modified the DD based on the PfAs.

The representative of the Registrant provided comments on all three PfAs. The Registrant agreed with the first PfA and noted that the analysis of bone marrow seemed of low interest since it was doubtful that the substance would reach it. He disagreed with the second PfA and considered the analysis of duodenum/jejunum to be of low relevance. He commented on the third PfA suggesting that the in vitro gene mutagenicity in bacteria needed no further investigations. The Registrant considered, regarding the second and third PfA, that the inhalation route testing might not be technically possible, as the only two contract research organizations in Europe that could perform a comet assay had not validated the assay on the nasal epithelial cells. Based on his comments on all three PfAs, the Registrant suggested performing a comet assay by the oral route analysing the forestomach (first site of contact) and liver (metabolism).

Session 2 (closed)

Some members raised concerns on the technical difficulties with inhalation as route of exposure, although it could be relevant given the uses of the substance. Several members commented that the substance was considered to be highly reactive, and therefore it

would be important to examine the initial site of contact. One member suggested to use gavage, with which forestomach could be passed as initial site of contact in order to examine the glandular stomach as first site of contact.

While the original tissue considered in the testing proposal was bone marrow, some members raised a concern whether the reactive substance would reach bone marrow. They proposed other tissues to be examined, including liver and – as sites of direct contact – forestomach and glandular stomach.

Some members noted that the high reactivity of the substance also brings a concern on potential mutagenic effects at the first site of contact. The MN test cannot be used for that purpose, as the site of contact tissue is not used in it. They considered a comet assay more appropriate since it can be performed on several tissues including sites of contact.

SECR noted that the test guidelines on comet assay refer to glandular stomach and that in general the comet testing is difficult with forestomach tissue.

Based on the above considerations, MSC agreed unanimously to amend the draft decision by requesting a comet assay with examination of liver, forestomach and glandular stomach, and adding a note that if no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.

MSC agreed unanimously to the DD as amended at the meeting.

TPE-009/2015 2-methoxyethyl acrylate EC No. 221-499-3

Session 2 (closed)

SECR explained that agreement was initially sought in written procedure. The written procedure was terminated by the Chairman of MSC on request of one MSC member suggesting a MSC discussion.

SECR introduced the PfA that was received to ECHA's DD. The PfA on in vivo mutagenicity testing suggested not to conduct either the in vivo chromosome aberration test by gavage (OECD 475) or the in vivo micronucleus test (MN; OECD 474), but instead proposed to request the in vivo mammalian alkaline comet assay (OECD 489). The PfA did not support the originally requested tests as it questioned whether the substance would reach the bone marrow, indicated that structural analogues were all negative in vivo in the bone marrow, and also noted that the potential for gene mutation is not addressed in the MN assay.

SECR had modified the DD for the meeting based on the PfA.

The Registrant had provided written comments on the PfA, in which he reconfirmed that it was comprehensible and he took into account that the statements from REACH Annex VIII, Section 8.4, column 2 on "appropriate" testing proposal for "in vivo mutagenicity studies" only addressed clastogenicity and not gene mutagenicity. However, based on the toxicological profile of the substance indicative of systemic bioavailability and its corrosive properties, the advantage of the in vivo comet assay – compared with the in vivo MN test or in vivo chromosome aberration test – remained questionable. The Registrant acknowledged the available data were neither conclusive nor sufficient on the availability of the test substance in the bone marrow. He supported ECHA's proposal to perform the in vivo mammalian bone marrow chromosomal aberration test (OECD 475) or an in vivo mammalian erythrocyte micronucleus test (MN; OECD 474). The latter would include peripheral blood and bone marrow cells, and – depending on the outcome of the performed study – further steps would be considered to provide conclusive data on the genotoxic potential of the substance.

One member commented that in general acrylates are highly reactive substances, and tests with negative outcome on bone marrow for these substances may also indicate that the substance did not reach the tissue. SECR noted that the updated guidelines of MN require a registrant to show that the substance had reached the bone marrow. One member suggested to include comet assay as third option for the Registrant due to concerns on potential mutagenic effects at the first site of contact, but also including liver as primary site of xenobiotic metabolism, and this approach was supported by MSC.

MSC agreed unanimously to the DD as amended at the meeting.

TPE-017/2015 N-phenyl-N-[(trichloromethyl)thio]-benzenesulphonamide (EC No. 218-915-0)

Session 2 (closed)

SECR explained that agreement was initially sought in written procedure. The written procedure was terminated by the Chairman of MSC on request of one MSC member suggesting a MSC discussion.

SECR shortly introduced the two PfAs that were received to ECHA's DD.

The first PfA concerned the in vivo mammalian erythrocyte micronucleus test (MN; OECD 474) and its follow-up testing. It suggested adding three follow-up in vivo testing options/possibilities in Section II dependent on the results of the MN test. In case of a positive outcome, the additional request is to perform a mammalian spermatogonial chromosome aberration test (OECD 483). In case of a negative outcome, the additional request is to perform an in vivo comet assay (OECD 489), and in case of an equivocal outcome repeat MN test or perform an in vivo comet assay.

The second PfA on MN test suggested to add in the "Note for consideration by the Registrant" in Section III that (a) in case of a negative test result of the in vivo MN test, an in vivo gene mutation test should be performed to fully prove there is no mutagenic potential, (b) in view of 3R to already consider to integrate the proposed in vivo MN test with an in vivo comet assay, and (c) in case of a positive result from the conducted test, the Registrant should conduct an OECD TG 488 to evaluate potential germ cell mutagenicity, unless the Registrant can clearly demonstrate the substance does not reach the germ cells.

SECR had modified the DD for the meeting based on the PfAs.

The Registrant had provided written comments on the PfA indicating that the initial DD provided by ECHA is appropriate and should not be amended in their view. As regards the follow-up testing of the first PfA the Registrant indicated that in case of positive or equivocal results in the MN test all available data should be considered to decide on further testing and/or classification. He did not consider the second PfA about the possibility of combined testing (MN test and comet assay) as an option as dose selection for a combined study might result in non-optimal doses for both endpoints and interpretation of such a study will be difficult and/or limited.

After more detailed review before the meeting, the MSC member suggesting a discussion was satisfied with ECHA's response to PfAs.

MSC agreed unanimously to the DD as amended for the written procedure.

TPE-020/2015 Bis(2,4-dichlorobenzoyl) peroxide EC No. 205-094-9

Session 2 (closed)

SECR explained that agreement was initially sought in written procedure. The written procedure was terminated by the Chairman of MSC on request of one MSC member suggesting a MSC discussion.

SECR shortly introduced the PfA that was received to ECHA's DD. It suggested adding a recommendation to the Registrant in section III of the DD to perform fully conclusive in vitro mutagenicity studies (i.e. a repeat Ames test with TA 98 and a repeat in vitro micronucleus (MN) test) for animal welfare reasons before initiating in vivo mammalian studies, i.e. both the proposed 90-d repeated dose toxicity studies including additional parameters regarding reproductive toxicity and the proposed prenatal developmental toxicity study.

SECR had not modified the DD based on the PfA.

The Registrant provided written comments on the PfA disagreeing with it and considering it unnecessary to repeat the Ames test and the in vitro MN test. The Registrant concluded

the substance is non-mutagenic based on the available data. The Registrant was of the view that the mutagenicity endpoints do not need any further clarification.

After more detailed review before the meeting, the MSC member suggesting a discussion was satisfied with ECHA's response to PfAs, however, providing some general remarks on the advantage in respect to animal welfare and testing cost to first assessing mutagenicity, including germ cell mutagenicity, before initiating new comprehensive higher tier reproductive toxicity testing which is not needed for known germ cell mutagens with appropriate risk management measures. One member referred to risk management measures to reduce the exposure to substances with a Mutagen 1B classification as low as technically possible.

MSC agreed unanimously to the DD as amended at the meeting.

d. General topics

1) Reporting on the status update on appeal cases *(open and closed sessions)*

SECR provided MSC with feedback from the appeal cases on decisions on dossier and substance evaluation and pending court cases.

2) Status report on on-going evaluation work

This information was provided in advance of the meeting, and no further discussion took place.

Item 8 – Opinion in accordance with Article 77(3)c of REACH on persistency and bioaccumulation of D4 & D5

- Revised draft opinion of MSC

The Rapporteur presented the latest version of the MSC opinion on persistency (P/vP) and bioaccumulation (B/vB) of D4 and D5, including some procedural details, summaries of the persistency and bioaccumulation assessments made and the main conclusions on why D4 and D5 meet the criteria for persistency and bioaccumulation according to Annex XIII of the REACH Regulation. Further, the rapporteur explained how the comments received by MSC on the draft opinion have been addressed in the revised draft opinion. In conclusion, he summarised that D4 and D5 clearly fulfil the P and vP criteria, as shown in laboratory sediment-water test where both substances appear very persistent (vP) in sediment, have half-lives above 180 days and their high persistence in sediment (relevant compartment for the P assessment) is confirmed by the available monitoring data. Further, D4 and D5 fulfil the B and vB criteria of Annex XIII, as clearly seen in the reported BCF values from the aquatic bioconcentration tests in fish: BCFs are above 5000 and bioaccumulation is supported by multiple lines of evidence, such as: evidence on biomagnification in dietary studies; elimination half-lives are consistent with the potential to bioconcentrate to high levels and the potential to biomagnify in a dietary bioaccumulation study; the available field data provide evidence that bioaccumulation, and trophic magnification in the environment has been observed; the available information (BMF/TMF in the field), indicating that biodilution occurs in some food chains or in parts of some food chains, does not invalidate the other lines of evidence. Thus, the rapporteur supported the conclusions of the UK CA regarding the persistency and bioaccumulation of D4 and D5.

In the following brief discussion, several members and observers expressed their satisfaction with the thorough assessment done by the Rapporteur and the well-justified, scientifically sound opinion. Referring to the discrepancy between the conclusions in this MSC opinion on the persistency and bioaccumulation of D4 and D5 and the information provided by the registrants of these substances that they are neither persistent, nor bioaccumulative, a member asked how the conclusions of the MSC assessment will be communicated to the registrants that would need to update their dossiers and safety data sheets (SDSs) accordingly.

SECR clarified that MSC provides only a non-legally binding opinion in this Article 77 (3)(c) proceeding that does not set legal obligations according to Article 31 of REACH Regulation for the registrants to update their dossiers if substances are confirmed PBT or vPvB. Thus,

the Commission should consider this aspect when taking a decision on the restriction proposals for these substances. The COM observer pointed out that RAC can recommend to the COM to include in the restriction entries for these two substances an obligation to consider the PBT status of D4 and D5 and to set an obligation for registrants with regard to their SDS updates. The industry expert accompanying the Cefic observer noted the clear remit of MSC, the grounds for this opinion and that D4 and D5 could be found in sediments, however, the concerned industry believes that the D4 and D5 levels in the organisms will not cause harm to neither organisms, nor the environment and they will continue the monitoring on these substances.

The dossier submitter representative from UK CA present at the meeting recommended to the industry observers to include MSC's conclusion on persistency and bioaccumulation ("vPvB") in their downstream user communications. He thanked to the rapporteur and MSC for the thorough and comprehensive review, the support given in this MSC opinion to their proposals, and expressed a hope that the registrants of D4 and D5 would start updating their dossiers already now based on the MSC opinion.

MSC adopted by consensus the revised draft opinion as presented at the meeting.

In conclusion, the MSC Chairman thanked the Rapporteur and his team for the excellent work done with during this particular opinion development process under Article 77 (3)(c) of REACH.

Item 9 – ECHA's draft recommendation of priority substances to be included in Annex XIV

Format and structure of response documents

SECR explained the new format and structure of response documents as well as the related 'Comments and References to responses documents (ComRef). Both these documents are arranged along the thematic blocks: 1) Prioritisation, 2) Transitional arrangements and 3) Exemptions. With these changes SECR aimed to avoid repetitions and to improve readability. In responding to the SECR's invitation for feedback on this development one stakeholder observer from industry acknowledged the clear improvement in this regard noting that not only clarity but also better assessment of the comments seems to have resulted from this.

Responses to the issues raised in the public consultation on ECHA's 6th draft recommendation for inclusion of priority substances in Annex XIV

The responses to issues raised in the public consultation were arranged at the meeting along thematic blocks: 1) Prioritisation, 2) Exemptions and 3) Transitional arrangements. Both agenda items 9 and 10 were addressed as a combined topic. SECR presented first the general issues per thematic block raised in the public consultation of ECHA's 6th draft recommendation for inclusion of substances in Annex XIV, and Secretariat's responses to them, followed by specific comments received on groups of substances. SECR also indicated for which substances some refinements in the scorings were foreseen, based on the comments received. After each group of substances this was followed by the MSC Rapporteur presenting the MSC draft opinion on that group and theme, followed by MSC discussion.

Main discussion points for both items 9 and 10, including some SECR responses, are captured under item 10 below. Further general issues were discussed after the discussions on the first three thematic blocks.

Item 10 – Opinion of MSC on the draft 6th recommendation of priority substances to be included in Annex XIV

Preparations for the opinion on ECHA's draft 6th recommendation of priority substances to be included in Annex XIV

- MSC discussion on the 1st draft MSC opinion

The Rapporteur presented the first draft opinion for discussion and comments (see also above). In the review of substances and the comments received the Rapporteur had been supported by MSC Working Group for the opinion forming on the draft 6th recommendation for inclusion of substances in Annex XIV.

In the context of the thematic block **Prioritisation** and some other general issues SECR presented the main comments received and ECHA's responses. Industry stakeholders raised the issue of unclarity on interpretation of the intermediates definition. According to them differences between national industries, different sectors, and from one substance to another substance all contribute to misunderstandings on this matter. This adds to unclarity in general, which in return leads to unfair situations and distortion of the market. Therefore activities to further discuss the 'grey zone' with member states and enforcement agencies were welcomed. SECR in responding agreed that it is in everyone's interest to increase clarity. In addition SECR noted that the further guidance and practical advice published on ECHA's website, as well as the targeted letter campaigns to registrants, aimed at improving clarity.

As regards 'nonylphenol branched and linear, ethoxylated', 1-bromopropane (n-propyl bromide), and the phthalates group (seven phthalates) no reservations were raised in the discussion on the prioritisation. Reservations against prioritisation of lead substances were indicated by one member and supported by few other members. In this context some members remarked that political decisions were not in the remit of MSC, and that MSC should focus on the outcome of the prioritisation approach. The Rapporteur also reminded members that a possible minority position would require clear arguments that address the minorities view on the prioritisation approach and its outcome. As regards the grouping of lead substances, MSC seemed to support consideration of not including pyrochlore antimony lead yellow, acetic acid lead salt basic and silicic acid lead salt with the other lead substances in absence of sufficient reasons to combine those substances into one group. Furthermore, one member indicated that they were in favour of postponing the inclusion of the coal stream substances pitch, coal tar, high-temp. and anthracene oil in the 6th Recommendation, as the original intention when the SVHC proposals to identify the coal stream substances were submitted had been to identify all substances containing benz[a]pyrene before proceeding to the recommendation stage. One industry stakeholder observer indicated satisfaction in general on how the comments were recognised in the review of the ranking. He also pointed out that in case of large number of registrants for one substance it may prove almost impossible to have all the registration dossiers updated in a coherent manner and therefore he called for a more holistic assessment of the information on uses. One stakeholder observer from NGOs supported the grouping approach applied for lead substances in order to avoid substitution in adverse manner and another one supported authorisation process as such as a way of finding viable alternatives for dangerous substances. On the boron compounds the use as an essential element in fertilizers, and the technically important and highly controlled use in nuclear power plants were raised by some members. The industry expert from the ~~Inorganic~~ Industrial Minerals Association although not challenging the priority of the boron compounds expressed disappointment that the aim of substitution, in case borons would be included in Annex XIV, would only apply to 5% of the boron volume as the remainder - according to his analysis - was used either in exempted uses or in uses in which boron cannot be replaced and is of vital importance. He also felt that it was discriminatory to include some substances in the draft recommendation without a RMO as for many substances such was available but not all. SECR reminded that the prioritisation is based on the total tonnage and even if the uses regarded as essential by industry representatives would not be counted, the volume in other uses in the scope of authorisation is high and justifies the highest volume score.

On the **exemptions,** no issues were raised on 'nonylphenol branched and linear, ethoxylated', 1-bromopropane, and the phthalates group when MSC discussed this thematic block after SECR had presented its responses to the comments received and repeated the principles ECHA had applied on exemptions in each recommendation round until now. Reacting to the exemption discussion in more general terms, one observer from industry expressed a concern that the review of the other legislation should not be done in

a too narrow manner in terms of finding the name of a substance in existing legislation. He named Coal Tar Pitch High Temperature as an example where the substance itself may not be regulated, but its PAH constituents and impurities are regulated. A Commission observer noted that they are starting their discussions on Article 58(2) exemptions and hence what ECHA is presenting now should be considered as ECHA views on this topic. She also noted the need for a push for substitution from other legislations. For the lead substances questions were raised whether the binding OEL could be sufficient, and how to interpret the legal text of the ROHS and ELV directives as regards exemptions from a general ban. MSC reflected on these issues and requested the Commission to look closer into this. The Commission also referred to an ongoing court case which is expected to provide some further clarification in relation to the application of Art. 58(2). The Rapporteur was invited to review the wording in the draft opinion such that this does not give too categorical interpretations on possible exemptions. For the boron compounds there was a discussion on the use in the nuclear industry and a general understanding that the Euratom directives only address radioactive substances. One member requested that the wording of the opinion and recommendation would be more flexible in this regard, and this was supported by several members. One member suggested waiting for a simplified authorisation procedure, in effect requesting postponement of listing the boron compounds. This in their view would alleviate also the issue with the fertilizer use. This approach was supported by another MSC member as well as one expert from industry. However, other members noted that it will take a while before substances recommended now were included in Annex XIV at which point the simplified procedure might be in place. As in addition this would not impact the prioritisation, these members did not see a reason to postpone substances now based on these arguments. In conclusion, some preliminary discussion on possible options for the MSC view on the exemptions took place but further views will need to be discussed at the next MSC meeting. SECR also offered to check the current wording used in the Annex XIV entries approach paper regarding exemptions, and possibly try to improve clarity for future rounds.

Regarding **transitional arrangements** no issues were raised for 'nonylphenol branched and linear, ethoxylated', 1-bromopropane, the group of phthalates and the coal stream substances when MSC discussed the thematic block 3. For the lead group and boron substances the main discussions revolved around the complexity of supply chains, and how this could translate into latest application dates (LADs). An industry observer indicated that a direct comparison with chromium VI substances, as suggested in the discussion, was not fair, and learnings from that case could be applied and used for identification of potential criteria for assessing such supply chain complexity. According to this observer, industry experience until now allows to identify major factors that impact the time needed for preparing for authorisation applications. SECR thanked for the intervention and the useful information. However, SECR highlighted that it may be difficult for SECR to obtain sufficient information on those major factors mentioned by industry at the prioritisation stage. Nevertheless, SECR will reflect and work further on these issues to be used in future rounds.

In the boron discussion one member indicated that the legal text does not provide specific review timings, and that also longer than 12 years review period can be granted. She opted for having a general statement about this possibility in the MSC opinion, whereas another member considered this would fall in the remit of RAC and SEAC, not MSC. Setting longer transitional arrangements for borons as well as for the lead substances was supported by some members, and some considered LADs more as a policy decision.

Additional **general issues** that were raised during the discussion referred to the review of the priority scoring system, the number of substances to be included in ECHA's recommendation, and whether ECHA anticipates an update of the draft 6th recommendation before the next MSC-meeting. In responding to the last issue SECR reminded that ECHA has an obligation to take the MSC opinion into consideration when finalising the recommended list of substances for submission to the Commission.

Before closing the discussion the Rapporteur invited for written feedback in order to be able to reflect MSC views as much as possible in the next draft opinion that is to be tabled for adoption at the next MSC meeting in June.

Item 11 – General approach for admission of observers from Accredited Stakeholder Organisations to MSC work

a. Proposal for revision of the MSC General approach for ASO observers admission

SECR presented its proposal for a revision of the General MSC approach[1] for admission of ASO to MSC, which aims to increase the transparency to the MSC work by ensuring active and engaged participation of the invited ASO observers, as well as to harmonise, as appropriate, the ASO admission procedures across ECHA's Committees.

In the following discussion, several members expressed their satisfaction and support to the proposal made. A remark was made on the importance of keeping the balance of the ASO-represented interests in the MSC quotas[2] and a clarification was requested on whether a previously invited ASO as a regular observer, in case of non-attendance/'no show', could be still kept as a Committee's observer. SECR confirmed that the intention is to keep the currently established balance of interests in MSC, and not change unless the Committee decides otherwise during the next MSC ASO review. It was also clarified that the non-active ASO observers invited on a regular basis will be kept in the list of the MSC ASO observers, but their status will be changed from 'regular' to 'occasional' observers, so they could still participate in the MSC work on occasional basis (in line with the MSC General approach) while other more active and engaged ASO will replace them as regular observers.

MSC unanimously agreed with the revised General MSC approach for admission of ASO as provided for the meeting.

b. Update on participation of stakeholder organisations in MSC meetings

SECR provided some statistics on the meeting participation for the past four plenary meetings (following MSC Annual review at MSC-37) of the regular MSC observers invited to follow the work of MSC on regular basis.

Item 12 – MSC Manual of decisions

SECR presented proposals for two new entries and possible review of existing entries in the MSC Manual of Decisions and Opinions (MoD). The new entries comprised test temperature for soil simulation test and personal protective equipment, and the items for potential revision covered the classification in Annex XV dossiers for SVHC identification and the withdrawal of substances from the Candidate list. In the discussion MSC welcomed the proposals for inclusion in the MoD and agreed to consider the two proposals for potential revision of the existing entries. MSC requested the SECR to prepare draft entries and revisions on these items for discussion and decision at the next meeting.

SECR explained the access of members and accredited stakeholder organisation (ASO) observers to the existing MoD, noting that the text was an extract of different meeting minutes. When discussing new entries the text may, for example, include a link to a decision that has not yet been published. However, the updated MoD would contain only non-confidential information. SECR requested MSC to provide feedback by 27 May 2015 on granting access to the MoD to ASO observers.

Item 13 – Any other business

MSC welcomed the presentation on the ECHA/RIVM project "Substance properties indicative for respiratory tract effects" on the joint investigation of the association between

[1] http://echa.europa.eu/documents/10162/13578/general_approach_aso_in_msc_work_en.pdf

[2] The total number of MSC ASO observers' seats (14 observer seats) is divided in the following quotas: 7 seats assigned to the Industry quota (i.e. six seats General Interest/Sectorial Industry Organisations and one Academic Organisation) and 7 seats assigned to the NGOs quota (i.e. one seat to trade unions, five seats to Environmental and Human health NGOs and one seat to Animal Welfare NGOs)

skin/eye corrosion or irritation and respiratory tract irritation, making use of available registration information. The authors would highly appreciate inputs and scientific comments from MSC participants by 13 May 2015, or to receive an indication at which stage it would be possible to provide the feedback. Thereafter the authors would proceed to publishing the results.

Some MSC members requested SECR to provide information on the project on zebra fish embryo test (ZFET). SECR agreed to circulate a presentation via MSC CIRCABC or by e-mail.

Item 14– Adoption of conclusions and action points

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

SIGNED

Watze de Wolf

Chairman of the Member State Committee

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ANDRIJEWSKI, Michal (PL)
BASTIJANCIC-KOKIC, Biserka (HR)
BUSUTTIL, Ingrid (MT)
COCKSHOTT, Amanda (UK)
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
GAIDUKOVS, Sergejs (LV)
HUMAR-JURIC, Tatjana (SI)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina(CZ)
LULEVA, Parvoleta (BG)
LUNDBERGH, Ivar (SE)
MARTÍN, Esther (ES)
MIHALCEA UDREA, Mariana (RO)
PALEOMILITOU, Maria (CY)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
WAGENER, Alex (LU)
WIJMENGA, Jan (NL)
Representatives of the Commission
BERTATO, Valentina (DG GROW)
SCHUTTE, Katrin (DG ENV)
Observers
ANNYS, Erwin (Cefic)
BÖNIGK, Winfried (Cefic)
DOOME, Roger (IMA-Europe)
DROHMANN, Dieter (ORO)
HÖK, Frida (Chemsec)
KERÄNEN, Hannu (Concawe)
PLOTZKE, Kathleen (Cefic/Dow)
STAIRS, Kevin (Greenpeace)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
BERCARU, Ofelia
BERNASCONI, Giovanni
BONNOMET, Vincent
BROERE, William
CARLON, Claudio
CLENAGHAN, Conor
DELOFF-BIALEK, Anna
DE WOLF, Watze
DREVE, Simina
FABJAN, Evelin
FEEHAN, Margaret
HAUTAMÄKI, Anne
HUUSKONEN, Hannele
JOHANSSON, Matti
KARHU, Elina
KLOSLOVA, Zuzana
KREUZER, Paul
KUITTINEN; Marko
LE CURIEUX, Frank
MÜLLER, Birgit
NAUR, Liina
PELLIZZATO, Francesca
PELTOLA-THIES, Johanna
REUTER, Ulrike
RODRIGUEZ IGLESIAS, Pilar
RÖCKE, Timo
RÖNTY, Kaisu
SCHULTHEISS, Christian
UOTILA, Elina
VAHTERISTO, Liisa
VALENTINI, Marco
VASILEVA, Katya
VÁZQUEZ RODRÍGUEZ, Jesus
VIEIRA LISBOA, Duarte
WOLLENBERGER, Leah

Proxies

- COSGRAVE, Majella (IE) also acting as proxy of COCKSHOTT, Amanda (UK) on 20 April and 23 April late afternoon
- COSGRAVE, Majella (IE) also acting as proxy of DUNAUSKIENE, Lina (LT) during short periods on 21-22 April

Experts and advisers to MSC members

ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BALCIUNIENE, Jurgita (LT) (expert to DUNAUSKIENE, Lina)
BOUWMAN, Tialda (NL) (adviser to WIJMENGA, Jan)

DRAGUSANU, Mihaela (RO) (expert to MIHALCEA UDREA, Mariana)
GARCÍA HERNÁNDEZ, Patricia (ES) (expert to MARTÍN, Esther)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
GUDBRANDSEN, Marius (NO) (expert to REIERSON, Linda)
INDANS, Ian (UK) (expert to COCKSHOTT, Amanda)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBRGH, Ivar)
MOLDOV, Raili (EE) (expert to VESKIMÄE, Enda)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
PEDERSEN, Finn (DK) (expert to TYLE, Henrik)
RISSANEN, Eeva (FI) (adviser to TALASNIEMI, Petteri)
TRAAS, Theo (NL) (expert to WIJMENGA, Jan)
ZELJEZIC, Davor (HR) (expert to BASTIJANCIC-KOKIC, Biserka)

MSCA Experts for SEV cases
LØFSTED, Magnus (DK)
MANTOVANI, Alberto (IT)
MASLANKIEWICZ, Lidka (NL)
PÁRRAGA, Helena (ES)
WITASP HENRIKSSON, Erika (SE)

By WEBEX-phone connection:
During the whole meeting (except items 8, 10 and 11): Cécile MICHEL (FR)
During the agenda item 6 for SEV-IT-022/2013: Dania ESPOSITO (IT)
During the agenda item 6 for SEV-FR-014/2013: Cloé de LENTDECKER (FR), Nathalie PRINTEMPS (FR), Nina LE DREAU (FR), Jeremy DE SAINT JORES (FR), Johanna BARTHELEMY (FR), Betty HAKKERT (NL) and Dimitra THEODORI (NL)
During the agenda item 6 for SEV-UK-038/2013: Ian DOYLE (UK)
During the agenda item 8: Romana HORNEK-GAUSTERER (AT), Eric VERBRUGGEN (NL), Emiel RORIJE (NL), Marian RUCKI (CZ), Michael NEUMANN (DE), Emilie BIGORGNE-VIZADE (FR), Anne-Laure SCELO (FR)
During the agenda items 9 and 10: Gary DOUGHERTY (UK)
During the agenda item 13: Nathalie PRINTEMPS (FR) and Johanna BARTHELEMY (FR)
During the agenda items 6, 9 and 10 from the European Commission: Valentina BERTATO, Giuseppina LUVARA, Enrique GARCÍA-JOHN, Jacek RODZWADOWSKI and Wim RIEPMA

Case owners:
Representatives of the Registrants were attending under the agenda item 6b for SEV-IT-022/2013, SEV-ES-027/2013, SEV-SE-029/2013, SEV-FR-014/2013 and SEV-DK-006/2013 and under the agenda item 7b for TPE-015/2015.

Apologies:
DOUGHERTY, Gary (UK)

III. Final Agenda

ECHA/MSC-41/2015/A/41

Agenda
41st meeting of the Member State Committee

20-23 April 2015
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

20 April: **starts at 10:00 am**
23 April: **ends at 6:00 pm**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/041/2015
For adoption

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

- Declarations of conflicts of interests at the meetings and their reflection in the minutes

ECHA/MSC-41/2015/024
For discussion

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

Item 4 – Administrative issues

For information

Item 5 – Minutes of the MSC-40

- Draft minutes of MSC-40

MSC/M/40/2014
For adoption

Item 6 – Substance evaluation

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

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

ECHA/MSC-41/2015/001

For information

b. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA's/ECHA reactions *(Session 1, tentatively open session)*:
For discussion followed by agreement seeking under 6c:

ECHA/MSC-41/2015/002

MSC code	Substance name	EC number/ Document number
SEV-IT-022/2013	Octabenzone	EC No. 217-421-2 ECHA/MSC-41/2015/005-006
SEV-ES-027/2013	Diallyl phthalate	EC No. 205-016-3 ECHA/MSC-41/2015/007-008
SEV-SE-029/2013	Butyl acrylate	EC No. 205-480-7 ECHA/MSC-41/2015/009-010
SEV-FR-014/2013	Formaldehyde	EC No. 200-001-8 ECHA/MSC-41/2015/011-012
SEV-DK-006/2013	4,4'-Propane-2,2-diyldiphenol, polymer with 2-methyloxirane	EC No. 500-097-4 ECHA/MSC-41/2015/003-004

For discussion

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

Cases as listed above under **6b** and the case returned from written procedure for agreement seeking in the meeting

SEV-UK-038/2013	Hexamethyldisiloxane	EC No. 203-492-7 ECHA/MSC/D/2015/063-64[3]

For agreement

d. General topics

- Status report on substance evaluation
- Appeals update[4]

For information

Item 7 – Dossier evaluation

Closed session for 7c
Indicative time plan for 7b is Day 1

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

ECHA/MSC-41/2015/013
For information

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

For discussion followed by agreement seeking under 7c:

ECHA/MSC-41/2015/014

[3] Documents are available in substance specific folders in MSC CIRCABC under 06. Substance evaluation.
[4] A combination of Appeal updates for Substance and Dossier Evaluation may be introduced, if appropriate, may be held partly in closed session.

Testing proposal examinations

MSC code	Substance name	EC No./Doc n:o
TPE-015/2015	Tert-pentyl hydroperoxide	222-321-7

ECHA/MSC-41/2015/015-016
For discussion

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

Cases as listed above under **7b** and any cases returned from written procedure for agreement seeking in the meeting[5]

MSC code	Substance name	EC No.
TPE-009/2015	2-methoxyethyl acrylate	221-499-3
TPE-017/2015	N-phenyl-N-[(trichloromethyl)thio]-benzenesulphonamide	218-915-0
TPE-020/2015	Bis(2,4-dichlorobenzoyl) peroxide	205-094-9

For agreement

d. General topics

1) Status report on on-going evaluation work

- Appeals update[2]

For information

Item 8 – Opinion in accordance with Article 77(3)c of REACH on persistency and bioaccumulation of D4 & D5

Indicative time plan: Day 3

- Revised draft opinion of MSC

ECHA/MSC-41/2015/018 & 023
For adoption

Item 9 – ECHA's draft recommendation of priority substances to be included in Annex XIV

Indicative time plan: Day 4

Responses to the issues raised in the public consultation on ECHA's 6th draft recommendation for inclusion of priority substances in Annex XIV

ECHA/MSC-41/2015/025-053
For information

Item 10 – Opinion of MSC on the draft 6th recommendation of priority substances to be included in Annex XIV

Indicative time plan: Day 4

Preparations for the opinion on ECHA's Draft 6th recommendation of priority substances to be included in Annex XIV

- MSC discussion on the 1st draft MSC opinion

ECHA/MSC-41/2015/017

[5] Documents are available in substance specific folders in MSC CIRCABC under 05. Dossier evaluation.

For discussion

Item 11 – General approach for admission of observers from Accredited Stakeholder Organisations to MSC work

Closed session

a) Proposal for revision of the MSC General approach for ASO observers' admission

ECHA/MSC-41/2015/019

For discussion and decision

b) Update on participation of stakeholder organisations in MSC meetings

ECHA/MSC-41/2015/020

For discussion

Item 12 – MSC Manual of decisions

- Proposal for new entries and possible review of existing entries

ECHA/MSC-41/2015/021

For discussion

Item 13 – Any other business

- ECHA/RIVM draft project report on 'Substance properties indicative for respiratory tract effects'
- Suggestions from members

For information

Item 14– Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-41

For adoption

Information documents:

Information documents are not allocated a specific agenda time but the documents are available on MSC CIRCABC before the meeting. Based on the listed documents and the meeting agenda, if any MSC member considers that information documents may merit a discussion under any agenda point, they should inform MSC Secretariat

- *Report from other ECHA bodies (ECHA/MSC-41/2015/022)*
- *Dossier evaluation status report (presentation slides)*

Outside plenary activities:

- Presentation on Exposure models used in CSRs
- Presentation by ECHA on WHO/ IPCS Harmonization of approaches to the assessment of risk from exposure to chemicals:
  - Weight of Evidence and Mode of Action Framework
  - Uncertainty Analysis in Hazard Assessment
  - WHO Chemical Risk Assessment Network

IV. The following participants declared potential conflicts of interest with the indicated agenda items (according to Art 9 (2) of MSC RoPs)

AP/Dossier	MSC member/alternate	Reason for potential CoI/ mitigating measures
AP 6 bc SEV-FR-014/2013	Wagener Alex, MSC member	Annual declaration as published on the ECHA website. No participation in the Committee's deliberation and voting.
AP 6 bc SEV-FR-014/2013	Watze de Wolf, Chairman	Annual declaration as published on the ECHA website. Appointed Acting Chair: Pilar Rodriguez Iglesias
AP 6 bc SEV-SE-029/2013	Wagener Alex, MSC member	Annual declaration as published on the ECHA website. No participation in the Committee's deliberation and voting.
AP 6 bc SEV-SE-029/2013	Watze de Wolf, Chairman	Annual declaration as published on the ECHA website. Appointed Acting Chair: Pilar Rodriguez Iglesias

V. Main Conclusions and Action Points

Main conclusions and action points
MSC-41 20-23 April 2015
(adopted at MSC-41 meeting on 23 April 2015)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 5 – Adoption of minutes of the MSC-40	
MSC adopted the draft minutes as provided for the meeting and further modified during the meeting.	**MSC-S** to upload final version of the minutes on MSC CIRCABC by 27 April 2015 and on ECHA website without undue delay.
Item 6 - Substance evaluation **a. Written procedure report on seeking agreement on a draft decision on substance evaluation**	
MSC took note of the report as presented in document ECHA/MSC-41/2015/001.	
Item 6 - Substance evaluation **b. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA's/ECHA reactions *(Session 1, tentatively open session)*:** **c. Seeking agreement on draft decisions when amendments were proposed by MS-CA's/ECHA *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting: SEV-DK-006/2013 4,4'-Propane-2,2-diyldiphenol, polymer with 2-methyloxirane (EC No. 500-097-4) SEV-FR-014/2013 Formaldehyde (EC No. 200-001-8) SEV-IT-022/2013 Octabenzone (EC No. 217-421-2) SEV-ES-027/2013 Diallyl phthalate (EC No. 205-016-3) SEV-SE-029/2013 Butyl acrylate (EC No. 205-480-7) SEV-UK-038/2013 Hexamethyldisiloxane (EC No. 203-492-7)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases.
Item 7 – Dossier evaluation **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 decisions agreed in written procedure, as indicated in document ECHA/MSC-41/2015/013.
Item 7 – Dossier evaluation **b. Introduction to and preliminary discussion on draft decisions on testing proposals after MS-CA reactions *(Session 1, tentatively open session)*** **c. Seeking agreement on draft decisions on testing proposal examinations when amendments were proposed by MS-CA's (Session 2, closed)**	
MSC reached unanimous agreement on the following ECHA draft decisions (as modified in the meeting, where appropriate):	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
TPE-009/2015 2-methoxyethyl acrylate (EC No.221-499-3) **TPE-015/2015** Tert-pentyl hydroperoxide (EC No. 222-321-7) **TPE-017/2015** N-phenyl-N-[(trichloromethyl)thio]-benzenesulphonamide (EC No. 218-915-0) **TPE-020/2015** Bis(2,4-dichlorobenzoyl) peroxide (EC No. 205-094-9)	
Item 8 – Opinion in accordance with Article 77(3)c of REACH on persistency and bioaccumulation of D4 & D5 • Revised draft opinion of MSC	
MSC adopted by consensus the revised draft opinion on persistency and bioaccumulation of D4 and D5 with some modifications done in the meeting.	**MSC-S** and the **Rapporteur** to finalise the MSC opinion for publication by 28 April 2015 **MSC-S** to submit the MSC opinion to the RAC Chairman by end of April 2015 for RAC consideration in their opinion forming on the D4 and D5 restriction proposals **MSC-S** to upload the MSC opinion in MSC CIRCABC by end of April and to publish it on ECHA's website without undue delay
Item 9 – ECHA's draft recommendation of priority substances to be included in Annex XIV Responses to the issues raised in the public consultation on ECHA's 6th draft recommendation for inclusion of priority substances in Annex XIV	
MSC took note of the draft responses to the comments received during the public consultation.	**SECR** to consider the comments received at MSC-41 and amend the responses where appropriate
Item 10 – Opinion of MSC on the draft 6th recommendation of priority substances to be included in Annex XIV Preparations for the opinion on ECHA's Draft 6th recommendation of priority substances to be included in Annex XIV • MSC discussion on the 1st draft MSC opinion	
	MSC to provide any written comments and feedback on the draft opinion to the Rapporteur via MSC functional mailbox **by 7 May 2015**. **MSC-S** to compile the comments received to be provided to the Rapporteur and WG members **by 8 May 2015** for further consideration when revising the draft opinion, together with the feedback received at MSC. **Rapporteur** to provide revised opinion to MSC-S by **27 May 2015** for uploading in CIRCABC by **28 May 2015**.
Item 11 – General approach for admission of observers from Accredited Stakeholder Organisations to MSC work a) Proposal for revision of the MSC General approach for ASO observers' admission b) Update on participation of stakeholder organisations in MSC meetings	
MSC unanimously agreed on the revised MSC General approach for ASO observers' admission without further modifications.	**MSC-S** to publish the revised ASO approach on MSC CIRCABC and on ECHA's website after the meeting

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	MSC-S to inform the Secretariats of RAC, SEAC and BPC of this MSC decision after the meeting **MSC** to apply the revised approach in the next ASO annual review (envisaged in September 2015)
Item 12 – MSC Manual of decisions • Proposal for new entries and possible review of existing entries	
MSC discussed the inclusion of two new items in the MSC Manual of decisions (MoD) and agreed to bring them for agreement seeking at the next meeting. Further, MSC agreed to consider the SECR's proposals for potential revision of two of the existing entries in the MSC MoD.	**MSC-S** to prepare draft entries on these items for MSC consideration and decision at MSC-42 meeting in June 2015 **MSC-S** to prepare a proposal for revision on the entries specified in document ECHA/MSC-41/2015/021 for MSC consideration and decision at MSC-42 in June 2015 **MSC** to provide feedback **by 27 May 2015** on granting access to the MSC MoD to ASO observers
Item 13 – Any other business	
	SECR to provide a brief document/slides to MSC on ZFET project in MSC-41 "Follow-up" folder in MSC CIRCABC or by e-mail
Item 14– Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-41 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC CIRCABC by 24 April 2015.

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

a) Draft decisions unanimously agreed by MSC in WP:

Testing proposal examinations (TPE)

MSC ID number	Substance name used in draft decision	EC number
TPE-010/2015	Bisisobutyryl peroxide	3437-84-1
TPE-011/2015	Dimethyl sebacate	106-79-6
TPE-013/2015	Reaction mass of 2-(1,1-dimethylpropyl) anthraquinone and 2-(1,2-dimethylpropyl) anthraquinone	915-623-1
TPE-016/2015	Tert-butyl peroxyisobutyrate	203-650-5
TPE-018/2015	2-ethylanthraquinone	201-535-4
TPE-022/2015	2,3-epoxypropyl o-tolyl ether	218-645-3
TPE-026/2015	2-[methyl[(nonafluorobutyl) sulphonyl]amino]ethyl acrylate	266-733-5
TPE-042/2015	Tetramethylthiuram monosulphide	202-605-7
TPE-043/2015	1,3-diethyl-2-thiourea	203-308-5

Compliance checks (CCH)

MSC ID number	Substance name used in draft decision	EC number
CCH-006/2015	1,2,4-trimethylbenzene	202-436-9
CCH-007/2015	6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol	204-327-1
CCH-010/2015	Citral	226-394-6
CCH-011/2015	Citral	226-394-6
CCH-012/2015	2-phenylpropene	202-705-0
CCH-013/2015	2-phenylpropene	202-705-0