MSC/M/40/2015
(Adopted at MSC-41)

Minutes
of the 40th Meeting of the Member State Committee (MSC-40)
3-5 February 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 40th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

The Executive Director of ECHA Mr Geert Dancet made a greeting address to the MSC members on the occasion of its 40th meeting elaborating on some of the main challenges for the next 10 meetings ahead. Members were reminded of the expected workload associated with a high number of draft decisions in Substance Evaluation, and to initiate discussions with their hierarchy already in the beginning of the year as yearly commitments for rapporteurships and working groups are required from MSC in order to meet its targets and legal objectives. It was also emphasised that MSC needs to keep delivering on transparency for its stakeholders and that all involved parties are required to meet this goal. MSC could review current approaches to even further improve the contributions and participation of stakeholders. Informal case-owner participation in the evaluation process has created further transparency in MSC's activities and it was suggested that MSC could extract more value from case-owner participation and gain important information that could further guide the decision making.

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 7 (final Agenda is attached to these minutes).

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

One member declared a potential conflict of interest in respect to the substance evaluation case SEV-FR-010/2013 based on the annual declaration as published on the ECHA website, and was therefore considered not to be in a position to participate in the vote for this case. No other potential conflicts of interests were declared by any other members, experts or advisers with any other item on the agenda of MSC-40.

Item 4 - Administrative issues

SECR informed the Committee of the plans for the upcoming migration from CIRCABC to Secure CIRCABC. During the discussion several members and stakeholders expressed their concerns about potential issues that may arise when using the new platform, notably with regard to the availability of documents of past meetings and how 'common accounts' would fit in this new version. Responses were provided by the SECR, and SECR invited MSC members to provide further feedback on their use and need of reference files as currently available on CIRCABC.

SECR thanked the members who had already provided their annual declarations. As not all declarations were received, a reminder email by SECR would be sent to those members.

Item 5 – Adoption of the minutes of the MSC-39 meeting

The minutes of MSC-39 were adopted after an extensive discussion on and some modifications of the parts reflecting the discussion on the identification of SVHCs, 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 the substance evaluation cases *SEV-ES-028/2013 - Diisotridecyl adipate* and on *SEV-UK-035/2013 - 2-methylpropan-2-ol*.

WP was launched on 9 January 2015 and closed on 19 January 2015. By the closing date, responses to WP were received from 24 members with voting rights and from the Norwegian member. Unanimous agreement was reached concerning substance evaluation of *SEV-UK-035/2013 - 2-methylpropan-2-ol* in written procedure. For the case *SEV-ES-028/2013 - Diisotridecyl adipate* WP was terminated by the MSC Chairman on the basis of Article 20.6 of the MSC Rules of Procedure as one MSC member requested clarifications to be discussed at the MSC-40 meeting.

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

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

SEV-FR-010/2013 3,5,5-trimethylcyclohex-2-enone (Isophorone) (EC No. 201-126-0)

Session 1 (open)

Two representatives 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 French CA (FR CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance performed by FR CA on the basis of the initial grounds for concern relating to Human health/CMR (initially focusing on C and M), Exposure/wide dispersive use, worker exposure, aggregated tonnage. The members were guided through the information requirements and explained that additional concerns for the environment, reproductive toxicity and endocrine disruption were identified during the evaluation.

A total of four proposals for amendment (PfAs) were received. During the presentation of the case eMSCA explained that DD was modified for the meeting based on PfAs received. eMSCA accepted and incorporated in the DD most of the PfAs received. Two of the PfA submitters agreed with the way their PfAs were reflected in the DD and these did not require further discussion at the meeting. The PfAs that were discussed at the meeting were related to: 1) a proposal to request for an Extended One Generation Reproductive Toxicity Study (EOGRTS) in rats, oral route (OECD TG 443) with the DNT and DIT cohorts according to the standard OECD 443 test design as no definitive conclusion on pre-, peri- and post- natal effects have been or can be drawn; 2) suggestion to either delete the request for a repeated rat prenatal developmental toxicity (PNDT) study (OECD 414) as the finding of concern might be a chance observation or to modify the request into a limit test to be conducted at 144 ppm. It was also noted that if rats or mice are selected, the same strain should be used for the test as in the original studies.

eMSCA (FR-CA) has responded to the PfAs and agreed to modify DD to reflect the requests in PfAs.

The Registrants provided written comments on two of 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. The Registrants supported the reasoning in one of the PfAs that the observed exencephaly in rats may be a chance finding and therefore there was insufficient concern to conduct an additional prenatal development toxicity study (OECD 414). The eMSCA provided arguments why they do not consider the finding a chance event and why the existing studies do not allow a final conclusion (e.g. test concentrations not high enough). The eMSCA clarified that the same strain of rats as in the original studies should be used for the requested PNDT. The Registrants, further, disagreed with the PfA for conducting EOGRTS in rats, oral (OECD 443) with DNT and DIT cohorts as there were no indications of adverse effects from isophorone in the examined reproduction organs of rats, mice and dogs in several long-term studies, including an One Generation Reproduction Toxicity study. On this basis they considered that effects on fertility and pre-, peri-, and postnatal effects of isophorone at doses, not causing parental toxicity, are not expected. The registrants explained that in their view there are no relevant substance specific triggers for testing the DNT or DIT cohorts as well as the F2-generation as stated

in the draft regulation for amending Directive Nr. 1907/2006 regarding reproductive toxicity in Annex IX and X of REACH regulation.

Session 2 (closed)

MSC concluded that there are grounds for additional concerns on reproductive toxicity, specifically on peri- and post-natal development, as no definitive conclusions can be currently drawn due to the lack of required standard information in the registration dossier.

Regarding EOGRTS in rats, oral route (test method OECD TG 443) with DNT and DIT cohorts MSC agreed during the discussion that it is an appropriate test method for addressing these concerns. However, in absence of the requested study reports on endocrine assays performed in the context of the US EPA Endocrine Disruptor Challenge Programme, it cannot be concluded if the substance has a potential for endocrine disruption. Consequently no definitive design of the EOGRTS (OECD TG 443) can be defined at the moment in regard of the different cohort options described in the OECD guideline and the revised REACH Annexes. Hence, MSC agreed that eMSCA would request such a study with adequate design after the submission of the aforementioned reports based on the entire dataset, unless equivalent information can be provided to fulfil this standard information requirement on reproductive toxicity.

Regarding the requested pre-natal developmental toxicity study (inhalation, rat - same strain as in the original studies) (OECD TG 414) MSC concluded that it should be performed as a limit test described in the OECD 414 guideline using the maximum tolerable and attainable concentration established on a basis of suitably designed sighting study.

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

SEV-FR-012/2013 1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-ene-2,3-dicarboxylic anhydride (EC No. 204-077-3)

Session 1 (open)

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

The eMSCA from FR CA presented the outcome of SEv of the above-mentioned substance performed by FR CA on the basis of the initial grounds for concern relating Human Health/CMR; suspected sensitizer; Environment/suspected PBT; Exposure/ high worker exposure; high release to the environment. The members were guided through the information requirements and explained that because there is sufficient evidence to consider chlorendic anhydride as possible dermal and respiratory sensitiser and substance cannot be considered as PBT or vPvB as there is no evidence of bioaccumulation, further information was required to clarify Human Health/CMR, Environment, Exposure/ high worker exposure.

A total of seven different PfAs were received on 1) short term fish toxicity, 2) genotoxicity testing strategy and 3) deadline of the decision. Regarding the short term fish toxicity, one PfA proposed to give the Registrant the option to use Zebrafish Embryo Toxicity test (ZFET) (OECD 236). Regarding the genotoxicity endpoint PfAs were received on a) specifying the test species, the oral route and the tissues examined for the *in vivo* mammalian alkaline comet assay on the degradation product chlorendic acid (OECD 489); b) specifying in Section II the sequential testing strategy outlined in Section III i.e. the request for the *in vitro* micronucleus (MN; OECD 487) test to precede the *in vivo* comet assay; c) clarifying to the Registrants why an *in vivo* test is requested. Regarding the deadline a PfA was requesting to clarify the deadlines given in the draft decision whilst another PfA proposed to reduce the deadline from 24 months to 12 months with an additional 12 months to submit to ECHA an update of the registration dossiers containing the information from the genotoxicity testing strategy.

The Registrants provided written comments on the PfAs and also on the DD as a whole. The latter were not relevant for this part of the agreement seeking procedure. The Registrants agreed with the option to use ZFTE (OECD 236) however they presented a potential waiving argument which depends on the result of OECD 202 (short-term invertebrate toxicity test) and read-across to available data on fish toxicity for individual constituents. With regards to the *in vivo* comet assay, the Registrants agreed but requested further clarifications on the test design and noted that a full reference to the paper of Bowen et al. (2011) is missing. Regarding the deadline, the Registrants argued that the approaching 2018 registration deadline will cause further delays assuming that the waiting time for available testing slots would increase which would have an impact on sequential testing timings.

Session 2 (closed)

Regarding the option to use ZFET, MSC recognised that the test has limitations which are clearly stated in the test guideline. ECHA indicated it was conducting an internal review of TG236. MSC recognised that its applicability in the regulatory context of REACH is not yet analysed. According to one member, a report was published by ECVAM which recommends the use of the OECD 236 test guideline as a direct alternative to OECD 203 for REACH purposes. MSC also recognised that OECD in its draft revised OECD 203, is considering ZFET as a range finder. According to one member the likely context for this revision was to reduce the number of vertebrate fish used in the TG203.

Following the PfA received, the eMSCA included the ZFET as a direct option for the Registrant to fulfil the information requirement. However, MSC has not yet had a discussion on the ZFET as a generic stand-alone replacement for the OECD 203. In this specific case, given its context, the ZFET could potentially be used if the limitations of the test are fully addressed by the Registrants. Therefore, the request for OECD 203 remains, but the Registrants were reminded in the decision of the options for adaptation.

Regarding the genotoxicity testing strategy MSC concluded that because the data presented by the registrants is showing positive results only at the highest, cytotoxic concentration and the test is neither performed according to GLP, nor according to an OECD guideline, these results are not robust enough to justify a follow-up study *in vivo* at this point of time. Hence, MSC unanimously agreed to the testing specified in the DD originally sent to the Registrants and to ask for the *in vitro* Mammalian Cell Micronucleus Test to be realised first (test method: OECD 487) as tier 1, while dropping the request for the *in vivo* COMET assay at this moment of time. In case of negative result of the *in vitro* Mammalian Cell Micronucleus Test, an *in vitro* Mammalian Cell Gene Mutation Test in L5178Y mouse lymphoma cells at TK locus (test method: EU: B.17/ OECD TG 476) is to be conducted as tier 2. On the basis of the results of the in vitro data requested above, the eMSCA would consider the need to perform additional genotoxicity studies in vivo.

It was clarified that the mutagenicity testing strategy decided upon should lead to a change in the deadline specified in Section II from 24 to 18 months taking into account the time needed to perform the in vitro tests.

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

SEV-DE-016/2013 N,N-dicyclohexylbenzothiazole-2-sulphenamide (DCBS) (EC No. 225-625-8)

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 eMSCA from German CA (DE CA) presented the outcome of SEv of the above-mentioned substance performed by DE CA on the basis of the initial grounds for concern relating Human health/Suspected CMR, Sensitiser, Environment/Suspected PBT/vPvB, Exposure/Wide dispersive use, Consumer use, Worker exposure, Aggregated tonnage. The members were guided through the information requirements and explained that an

additional concern regarding the prenatal developmental toxicity in terms of an information requirement data gap was identified during the evaluation.

A total of four PfAs were received. During the presentation of the case eMSCA explained that DD was modified for the meeting based on PfAs received. eMSCA accepted and incorporated in the DD three of the four PfAs and the discussion at the meeting was related to sequential or parallel testing on biodegradation in sediment (OECD 308) and in soil (OECD 307) to assess the PBT/vPvB properties for DCBS with associated differences in deadlines, and the design of the tests as regards temperature and pH range to be covered.

The Registrants provided comments on the PfAs both in writing and at the meeting. They did not agree with one of the PfAs requesting the soil and sediment simulation tests to be done in parallel which was mentioned as an alternative to sequential testing in the same PfA. They considered the test in sediment as relevant; however, they also reflected on the ongoing CEFIC LRI research on deficiencies of the sediment simulation study and therefore proposed to perform the test in soil first. Furthermore the Registrants stated that it might be very difficult to find two natural aquatic sediment systems that meet the selection criteria of OECD 308 and in addition cover the pH range from 5.5-8.0. Hence results from four soil types should allow the Registrants to make a better selection of two sediment types. The Registrants preferred to conduct the studies at 20^{o}C and identified a need to suggest modifications to the test design to counteract the identified deficiencies for OECD 308 for sediment simulation study.

The Registrants representatives raised a question how the kinetic degradation data on DCBS generated in a project commissioned by the German UBA (amongst other in water-sediment system following an extended OECD 308, artificial pond) were considered during substance evaluation and how they potentially could contribute to fill the data gaps identified by the eMSCA. The corresponding report has been published in 2014. The eMSCA expert explained that the aim of the project was not to test for persistence of DCBS but to generate information on how large sediment mesocosms might be used in the assessment of P in the PBT assessment. DCBS was one of three substances tested; however, the radioactivity recovery rate in the project for DCBS was very low and made the DCBS results unacceptable for use in an assessment for persistency.

Session 2 (closed)

Regarding the order of the soil and sediment simulation tests, i.e., whether sequentially or in parallel, MSC concluded to ask for the test on biodegradation in soil first. In case this test does not allow the Registrants to conclude that DCBS is very persistent an additional test on biodegradation in sediment is required. This lead to the introduction in the decision of a second deadline for submitting the information from the sediment test, if needed, for which an additional 6 months were granted.

One member noted the case was unusual in asking for two persistence tests rather than one. However, in this case they understood the vB status was confirmed, and any additional T investigation would require vertebrate testing. Therefore they could appreciate seeking to confirm whether the substance was vP or not before further assessment of T. They also noted that the registrant had agreed to conduct a second persistence test in the event that the first did not indicate vP.

Regarding the temperature at which to conduct the biodegradation tests, an MSC member argued that the choice of temperature should depend on whether the eMSCA is interested in the metabolites or else in the degradation kinetics of the substance. If the main interest lies on the metabolites a test temperature of 20^{o}C is more appropriate because it results in a faster degradation rate. If the main interest lies on the kinetics of the substance a test temperature of 12^{o}C is more suitable so as to get a more accurate result and avoid introduction of additional uncertainties through normalisation with the Arrhenius equation from 20^{o}C – 12^{o}C. MSC concluded that the test temperature shall be 12°C for the kinetic part of both biodegradation tests, in line with the agreed approach at MSC-32, as for DCBS the main interest is to generate information on the degradation kinetics.

One member expressed reservations to the outcome of MSC-32.

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

SEV-PL-024/2013 Furfuryl alcohol (EC No. 202-626-1)

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 eMSCA from Polish CA (PL CA) presented the outcome of SEv of the above-mentioned substance performed by PL CA on the basis of the initial grounds for concern, i.e. relating to human health and CMR; exposure and wide dispersive use; consumer use; and aggregated tonnage.

Two PfAs were received for the SEv DD. During the presentation of the case eMSCA explained that the DD was not modified for the meeting based on PfAs received. First PfA suggested cancelling the request for a 28-day repeated inhalation toxicity test, as the available studies were considered sufficient to conduct an adequate risk characterisation. Second PfA identified a genotoxicity concern on the basis of potential formation of a possible mutagenic metabolite, and suggested to address this by requiring in vivo mammalian erythrocyte micronucleus testing (MN; OECD 474) and in vivo mammalian alkaline comet assay (OECD 489) or a transgenic rodent assay (TGR; OECD 488). A testing strategy (MN first) and an option to combine the MN with the comet assay were also suggested.

The eMSCA presented that although the DD was not modified for the meeting based on the PfAs, the eMSCA could accept the first PfA that an alternative approach to risk characterisation, including using the lowest observable adverse effect concentration (LOAEC) or the benchmark dose (BMD) as the basis for calculation of proper point of departure is possible.

The Registrants provided comments on both PfAs noting on the first PfA that the new study would be designed to generate data to differentiate between adverse and non-adverse effects through inclusion of a recovery phase, and that such results could not be extrapolated from existing studies. In the Registrant's view, the MSC proposal to use a LOAEC as a point of departure together with additional assessment factors or the BMD methodology would lead to an inappropriate estimation of the DNEL. In addition, they considered the use of Habers law is considered not appropriate for local, irritation effects. With respect to the second PfA they argued against a need for further genotoxicity testing, since in their view established and accepted non-genotoxic Modes of Action (e.g. irritation) could sufficiently explain the observed tumours in the NTP studies, and there was no reason to seek a genotoxic mechanism. The Registrants also argued that the results from modified genotoxicity studies may be of value from a research/mechanistic perspective but that positive results from these tests should not outweigh the results of negative data from established, validated assays.

One MSC member considered that the Registrant had not fully excluded the hypothesis on genotoxic metabolite(s). He acknowledged that furfuryl alcohol also works through irritation, but that the residual uncertainty as regards the genotoxic metabolite would need further investigation. Another MSC member considered the substance to be studied well enough already, but agreed that there was no clear rebuttal of the impact of a potential metabolite.

Session 2 (closed)

MSC agreed there was a residual uncertainty as regards in vivo genotoxic potential of the substance, and considered the comet assay as most cost effective follow-up. To maximize the dose and to avoid potentially confounding inhalatory irritation the oral route was chosen. Based on the above considerations, MSC unanimously agreed to the PfA to remove the request for a 28-day repeated dose toxicity study, and to add a request for an *in vivo* mammalian alkaline comet assay (OECD test guideline 489; in mice, oral route, with examination of stomach, kidney and liver).

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

SEV-ES-028/2013 Diisotridecyl adipate (DITA) (EC No. 247-660-8)

Session 2 (closed)

This SEV case was returned from the written procedure to clarify the considerations of the eMSCA to accept the PfAs and the comments received from the Registrants to drop the biodegradation testing requirements that were conditionally requested. The expert from the Spanish CA explained that whilst originally DITA was considered not readily biodegradable by the eMSCA, following receipt from the Registrant(s) of a new 301F test result and a letter confirming no pre-exposure and pre-adaptation of the inoculum in this test, the eMSCA could now conclude that DITA is readily biodegradable. This leads to the removal of two requests from the DD that was circulated to MSC for agreement via written procedure. Since the justification for the removal of the two requests was not documented the written procedure was stopped. Following the explanation given at the meeting, MSC agreed to drop the information requirements. Following a procedural discussion, the MSC concluded that cases that go to MSC for agreement seeking via written procedure, could indicate the removal of requests in the procedural part of the DD (Section I). The justification of the removal of the request should be documented in the response given by the eMSCA to the PfAs submitted for the endpoint that was removed.

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

d. General topics:

- *Status report on Substance Evaluation*

SECR gave an update to MSC on the numbers of SEV cases planned for 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. SECR also announced a change in the timing of the required submission of documents by the eMSCAs for the MSCA/ECHA consultation on DDs. This raised concerns since it is challenging for an eMSCA to upload the documents for MSCA/ECHA consultation by 13:00 EET on the notification date due to time zone difference, specifically when there are be technical problems in accessing CIRCABC. Hence SECR was asked if there would be other type of technical solution for providing the documents. SECR explained that unfortunately at the moment, there was no better technical solution for the eMSCAs to circulate the documents. Technical problems would need to be tackled as they arise.

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 seven dossier evaluation draft decisions (DD) (see Section V for more detailed identification of the cases). WP was launched on 9 January 2015 and closed on 19 January 2015. By the closing date, responses to WP were received from 25 members with voting right and from the Norwegian member. Unanimous agreement was reached on all seven DDs.

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

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

CCH-286/2014 Ceramic materials and wares, chemicals (EC No. 266-340-9)

Session 1 (open)

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

One PfA on sub-chronic and pre-natal developmental toxicity study submitted by a MSCA suggested rejecting the study requests, indicating that a weight of evidence adaptation could be based on i) the low the solubility of the substance, ii) extremely low bioavailability of the metal-ions (i.e. the potential uptake and body burdens of aluminium and manganese would result in levels 40 and 25 times lower than the normal serum concentration) and iii) consequently, there will not result in toxicological effects. The CA suggested that if the requests have to be maintained ECHA explains in Section III of the DD, why Annex XI adaptations are not suitable to justify the waiving.

Another MSCA's PfA suggested to amend the paragraph referring to the limited human exposure.

Following the receipt of the PfAs and the Registrant's comments indicating support for the weight of evidence approach, the DD was amended in order to advice the Registrant to examine that possibility of WoE adaptation to fulfil the information request, as for procedural reasons updates to the technical dossier were not to be considered after referral of the DD to the MSCAs. Furthermore a slightly revised text in Section III of the draft decision was included to point out that evidence of limited human exposure is not an obligatory element of the adaptation but may support it.

Session 2 (closed)

SECR reiterated the conclusions of the open session and justification of the modifications in the DD was provided. During the discussion the PfA submitters expressed their agreement on the written comments from the Registrants prior to the meeting and on the way of how the DD was amended and consequently the PfAs were answered.

MSC unanimously agreed on the ECHA's DD as provided for the meeting.

TPE-133/2014 2-[(2-methyl-1-oxoallyl)oxy]ethyl (EC No. 244-311-1)

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.

SECR explained that one PfA to ECHA's DD was submitted on *in vivo* mammalian erythrocyte micronucleus test (MN; OECD 474) suggesting that the Registrant should consider – in case of a negative test result of the *in vivo* MN – to perform an in vivo gene mutation test to fully prove there is no mutagenic potential. The note further suggested that the Registrant may consider combining the *in vivo* MN with an *in vivo* comet assay (OECD 488). In case of a positive result from any conducted in vivo somatic cell test, the Registrant should consider to conduct a transgenic rodent assay (OECD 487) to evaluate potential germ cell mutagenicity, unless he could clearly demonstrate the substance does not reach germ cells.

SECR did not modify the DD for the meeting based on the PfA.

The representatives of the Registrant provided comments on the PfA disagreeing with the need for additionally performing a comet assay, which they considered less reliable than the proposed test. They also emphasised that the substance is simple and close to another substance, that has been evaluated earlier and plausible as read across.

One MSC member supported the request of MN testing. The MSC member from the MSCA that made the PfA explained that they had had a concern on mutagenicity as suggested by available data, and also queried the genotoxicity profile of the metabolites. The representatives of the Registrant informed that they would evaluate the metabolites, using available data, to prepare a genotoxicity statement before carrying out the *in vivo* MN. Some MSC members acknowledged the approach taken by the Registrant.

Session 2 (closed)

One MSC member supported the MN study and that the follow up should be determined depending on its result, which could be recommended in a note on follow up in the DD.

Another MSC member agreed there would remain a residual concern if the MN study would result in a negative outcome and there would be no clarity on the possible follow up. One MSC member emphasised that if there would be a scientific concern on the mutagenicity of the substance the suggestions in the PfA should be considered.

SECR noted that in this case, falling under Annex IX, on positive outcome of MN study the follow up could already be covered by requirements in column 2, and that at this tonnage level there is only one *in vivo* study. SECR further noted that in case of misalignment between scientific and legal requirements, the assessment could continue in the substance evaluation process, which could cover further concerns.

Based on the above considerations, MSC agreed unanimously to amend the draft decision by adding a note that if no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered. MSC found unanimous agreement on ECHA's DD as amended at the meeting.

d. General topics

1) Exceptional reasons for modifying a final decision after unanimous MSC agreement *(closed session)*

SECR gave a presentation on the case TPE-022/2012 (Reaction mass of disodium 2,2'-oxydiethanesulfonate and sodium ethenesulfonate, formerly Sodium ethylenesulphonate), where the Registrant had removed testing proposals from the technical dossier. The removal took place after the MSC had unanimously agreed on the case but before the issuance of the final decision (FD), which was delayed with MSC's consent to examine a late identified substance identity issue.

SECR explained this was a very exceptional case, where SECR had not informed the registrant that updates to technical dossier were not considered after a certain date. SECR considered it appropriate to request information on stability in organic solvents, dissociation constant and viscosity, but no more simulation tests in water or soil following their testing proposal removal from the technical dossier. The outcome of the process would be the same with continuing the old process or starting a new one. SECR requested a mandate from MSC to issue a FD and emphasised the potential savings in work to take this practical route. The MSC member that had asked for this item to be placed on the agenda noted that for documents in which MSC is asked to take a decision or issue a mandate, it would for the transparency of the decision making process be better if these were always placed on the agenda, instead of 'on request only'. The same member considered it difficult to judge if the DD would still be coherent and what the effects of the revised FD would be, and several MSC members supported this view.

MSC took note of SECR's proposal on the case TPE-022/2012 and recommended that a revised final decision, which takes into account the changes by Registrant's updates of the technical dossier after original MSC agreement, should not be issued, but that instead a new decision according to the normal procedure for TPE's should be considered by SECR.

2) Reporting on the status update on appeal cases *(closed session)*

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

- **Mutagenicity testing strategy**

SECR gave a presentation on the review of decisions on dossier and substance evaluation cases, where MSC had agreed on transgenic rodent and/or comet assays. These test methods are now internationally recognised and MSC has gained experience on these studies. One MSC member acknowledged that MSC has been consistent in taking decisions in this area and suggested to communicate with the RAC to better understand when comet assay should be proposed. Another member reminded that comet assay has been requested for some time, but it cannot detect mutagenicity.

- **Update in dossier evaluation policy**

SECR presented the contents of the policy update on dossier evaluation, which is aimed to improve efficiency of the dossier evaluation process to all parties by reducing processing times and increasing predictability of the delivery of the final decision to the registrant. For testing proposal examinations, ECHA will only take into account dossier updates received within 30 days after the end of the Registrants commenting period on the DD. For compliance checks, ECHA will not consider any dossier updates received after submitting the DD to the registrant. The policy will be stated both in the DD and the notification letter. The implementation, starting from January 2015, comprises communication to all actors and change of the relevant internal documents. To further increase efficiency and transparency, ECHA will publish periodically a non-exhaustive list of CCH candidate cases (in the context of the CCH strategy).

One stakeholder conveyed the concerns of some registrants whether this would increase the efficiency, as many draft decisions have been terminated based on dossier updates and since there are companies with high number of draft decisions for which they never sent dossier updates. Another stakeholder emphasised that while most improvements are considered fine, companies would prefer to be able to update their registration dossiers up to the referral date consistent with the procedure for Testing Proposals. Such updates could potentially prevent a lot of work on issuing DDs on dossier that were already brought in compliance. This comment was shared by some members. There was also a need to have the policy update clearly communicated especially to SMEs and importers.

A MSC member asked how many DDs were changed on the basis of dossier updates, and how many were terminated, to understand where overall gains in efficiencies would be found. SECR noted that while some cases were terminated based on updates on physico-chemical properties, such terminations did not materialise for information requests on the environmental and human health endpoints. SECR added that the policy update is expected to lead to overall less work on the dossier evaluation cases.

The Chairman noted that the policy update would not immediately affect the work of MSC, and SECR noted that no similar policy changes were expected on substance evaluation.

MSC took note of the information provided by SECR.

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

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

Item 8 – Community Rolling Action Plan (CoRAP) update

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

The Rapporteur presented the draft opinion and its annex and explained the changes made since the December MSC-39 meeting. These changes include 1) withdrawal of one substance based on the update of a registration dossier; 2) changes in years of evaluation and MS conducting the evaluation; 3) updated tonnage bands with those in ECHA dissemination website; 4) initial grounds of concern extended; 5) one entry separated in two separate entries and 6) splitting of one entry into two entries under evaluation by the same MS with a footnote that due to the indication of structural similarity, part of the evaluation of these substances may be combined.

The Rapporteur asked for the view of the MSC on three substances which only fulfilled the hazard-based criteria, but are proposed by a MS under Article 45(5). The Rapporteur and the working group suggested that there are sufficient grounds to consider that these three substances may constitute a risk for the environment and /or human health.

During the discussion SECR explained that further harmonisation of the column listing the initial ground for concern was still needed before the publication of the CoRAP update 2015-2017. SECR explained that whenever a substance is produced greater than 1000

tons, section 5.2 in the justification document (selection criteria met) is ticked. However, the term 'aggregated tonnage' is listed as a concern in the CoRAP table only when Section 5.3 in the justification document (initial grounds for concern to be clarified under substance evaluation) is ticked. The Rapporteur asked for the mandate from the MSC to implement an update to this column in the table annexed to the MSC opinion in this regard after checking once more through the justification documents to ensure consistency in approach.

b. Adoption of the MSC opinion

MSC adopted the opinion on the annual CoRAP update 2015-2017 and its annex by consensus, including the three substances proposed under Article 45(5) that were brought up for discussion by the Rapporteur. MSC also gave the mandate requested by the Rapporteur to update the column in the table Annexed to the MSC opinion in relation to 'aggregated tonnage'. It was concluded that the MSC opinion together with the final update to CoRAP will be published on the ECHA website in March 2015.

Item 9 – Identification of SVHCs

a. Revision of MSC Working Procedures on identification of SVHCs

Motivated by the opinion forming on the SVHC proposals on DEHP, DBP, BBP and DIBP as a follow-up of MSC-39 conclusions, SECR presented a proposal for an update of the SVHC Working procedure of MSC with regard to the opinion development in case MSC fails to reach unanimous agreement on an SVHC proposal. Further, MSC was requested to consider applying the new approach to the opinion development for the opinion forming on the human health parts of the SVHC proposals for DEHP, BBP, DBP and DIBP.

MSC unanimously agreed on the modifications proposed by SECR, with small amendments introduced during the meeting, for revision of the MSC Working Procedures on identification of SVHCs, and requested SECR to publish it on ECHA's website.

Further, after some discussion on the Working procedure workability with regard to the MSC opinion development, MSC agreed on the application of the revised Working procedure for the preparation of the MSC opinions on DEHP, DBP, BBP and DIBP.

b. MSC opinions on SVHC proposals on four phthalates to be referred to the Commission

SECR outlined the final steps in the preparation of the MSC opinions on the human health part of the SVHC proposals for DEHP, DBP, BBP and DIBP, the minority position of disagreeing members and other relevant background documentation, and their referral to the Commission for further decision making in accordance with Article 133 (3) of the REACH Regulation.

Item 10 – Opinion in accordance with Article 77(3)c of REACH on persistency and bioaccumulation of D4 & D5

The Rapporteur presented to MSC an overview of the main issues and comments received during the public consultation focusing on elements for the opinion forming on the persistency and bioaccumulation of substances octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5). Further, MSC took note on the revised time plan for MSC opinion development on this Article 77(3)(c) request.

An industry expert accompanying an MSC observer made some observations referring to their comments submitted in the public consultation period and the way the Rapporteur has considered the information related to the bioaccumulation and biomagnification aspects for the opinion forming.

The Rapporteur thanked the expert and pointed out that it is a task of the CA dossier submitter to consider the new information and respond to the comments submitted in the public consultation, while the task of the rapporteur is to examine whether on the basis of

the available information D4 and D5 meet the criteria of Annex XIII as bioaccumulative and persistent substances, and prepare a draft MSC opinion accordingly.

Item 11 – ECHA's draft recommendations of priority substances to be included in Annex XIV

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

SECR presented the main issues raised in the public consultation in a concise manner and introduced the new format for the response to comments-tables (RCOMs). An MSC member questioned that if the responses are to be prepared per group of substances it is not yet clear what will happen to the response if only part of the group of substances would remain on the recommendation.

b. Preliminary prioritisation results in preparation for ECHA's 7th draft recommendation - substances not assessed for priority previously

MSC took note of the preliminary prioritisation results for the 7th draft recommendation which were provided for the meeting in a table format. This prioritisation results table contains also the 11 new substances that had been included in the Candidate List in December 2013 and June 2014 and which had not been assessed previously for their priority. The aim of the table was to indicate how the newly assessed substances rank among the Candidate List substances that had not yet been part of a recommendation for inclusion of priority substances in Annex XIV. Discussion on the prioritisation results is foreseen in the June 2015 meeting, after the results have been updated taking any registration updates (by 1 April) into account.

Item 12 – Opinion of MSC on the draft 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**

The Rapporteur presented the comments received during the public consultation, and an initial assessment of potential MSC discussion items for later meetings. Members of the Working Group for the MSC opinion forming on the draft 6th recommendation had provided their input to the Rapporteur, and the Rapporteur presented a full summary to MSC.

In the following discussion, some members and an industry stakeholder requested further clarification from SECR on volumes and uses as intermediates (in particular for boric acid and the rest of the group of boron substances and lead compounds) and how those were considered in the prioritisation scores. Difficulties for the nuclear use of boron substances were highlighted which would deserve appropriate management should these substances be recommended for inclusion in Annex XIV. In responding SECR clarified that uses as intermediates are not considered in the priority assessment. However, it could be the case that based on information received during the public consultation the assessment of specific uses regarding their intermediate status might change which would then be reflected in the assessment scores. SECR also reconfirmed that latest registration dossier data have been used. Responding to the questions on validity of groupings as currently applied SECR emphasised that intersubstitutability has been the main driver for the grouping. In response to many questions on exemptions SECR clarified that possible Article 58(2) exemptions do not actually have an effect on the priority. SECR will further continue considering the comments submitted during the public consultation. Draft responses to the comments received during public consultation will be provided for MSC-41.

Item 13 – Report from 2014

SECR provided a report on the MSC work during 2014 on different REACH processes. Some statistical information and Committee's achievements were presented.

Item 14 – Any other business

- **Update to MSC on activities at OECD**

The OECD observer gave an informative presentation on the ongoing activities in OECD with regard to: the Cooperative Chemical Assessment Programme, incl. exposure to multiple chemicals and IATA, the development of adverse outcome pathways, the progress made in the development of the OECD Guidance Document on the Evaluation and Application of IATA for Skin Sensitisation, QSAR ToolBox development, the development of an OECD harmonised guidance for characterising UVCBs and of the pilot GHS exercise.

In the following discussion, several members and an ASO observer expressed their appreciation of the work done in the area of common EU/OECD chemical databases and guidelines development and received clarification on issues raised with regard to the presented OECD activities.

- **Suggestions from members**

No suggestions by members had been received for this agenda item.

Item 15– Adoption of conclusions and action points

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

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)
BELVEZE, Corinne (FR)
COCKSHOTT, Amanda (UK)
COSGRAVE, Majella[1] (IE)
DEIM, Szilvia (HU)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
GAIDUKOVS, Sergejs (LV)
HUMAR-JURIC, Tatjana (SI)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina(CZ)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
LULEVA, Parvoleta (BG)
LUNDBERGH, Ivar (SE)
MARTÍN, Esther (ES)
MIHALCEA UDREA, Mariana (RO)
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
GARCÍA-JOHN, Enrique (DG GROW)
SCHUTTE, Katrin (DG ENV)
Observers
ANNYS, Erwin (Cefic)
DE KNECHT, Joop (OECD)
DEL CASTILLO, Francisco (CONCAWE)
DROHMANN, Dieter (ORO)
MUSU, Tony (ETUC)
PLOTZKE, Kathleen (Cefic)
WAETERSCHOOT, Hugo (Eurometaux)
WILKS, Susie (HSI)

ECHA staff
AJAO, Charmaine
ANDERSSON, Niklas
BAIA, Luis
BERCARU, Ofelia
BIGI, Elena
BONNOMET, Vincent
BROASCA, Roxana
BROERE, William
CALEY, Jane
CARLON, Claudio
CLENAGHAN, Conor
DANCET, Geert
DELOFF-BIALEK, Anna
DE COEN, Wim
DE WOLF, Watze
DREVE, Simina
FEEHAN, Margaret
FALCK, Ghita
HALLING, Katrin
JOHANSSON, Matti
KARHU, Elina
KLOSLOVA, Zuzana
KORJUS, Pia
LE CURIEUX, Frank
LOUEKARI, Kimmo
MÜLLER, Birgit
NAUR, Liina
PELLIZZATO, Francesca
PELTOLA-THIES, Johanna
RODRIGUEZ IGLESIAS, Pilar
RÖCKE, Timo
RÖNTY, Kaisu
SCHOENING, Gabriele
SOBANSKA Marta
SOSNOWSKI, Piotr
UOTILA, Elina
VAHTERISTO, Liisa
VALENTINI, Marco
VASILEVA, Katya
WALKER, Lee
YLÄ-MONONEN, Leena

Proxies

- PISTOLESE, Pietro (IT) also acting as proxy of BUSUTTIL, Ingrid (MT)
- WIJMENGA, Jan (NL) also acting as proxy of DUNAUSKIENE, Lina (LT) during short periods on 3-5 February

Experts and advisers to MSC members

ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BALCIUNIENE, Jurgita (LT) (expert to DUNAUSKIENE, Lina)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
DRAGUSANU, Mihaela (RO) (expert to MIHALCEA UDREA, Mariana)

[1] The member was present only on 3 February 2015.

ENSCH, Svenja (LU) (expert to WAGENER, Alex)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
HORNEK-GAUSTERER, Romana (AT) (expert to STESSEL, Helmut)
INDANS, Ian (UK) (expert to COCKSHOTT, Amanda)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LECOQ, Pierre (FR) (expert to BELVEZE, Corinne)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBRGH, Ivar)
NYITRAI, Viktor (expert to DEIM, Szilvia)
STEPNIK, Maciej (PL) (adviser to ANDRIJEWSKI, Michal)
TRAAS, Theo (NL) (expert to WIJMENGA, Jan)
ZELJEZIC, Davor (HR) (expert to BASTIJANCIC-KOKIC, Biserka)

MSCA Experts for SEV cases
CHARLES, Sandrine (FR)
CIESLA, Jacek (PL)
MANIÈRE, Isabelle (FR)
NEUMANN, Michael (DE)
VEGA, Milagros (ES)

By WEBEX-phone connection:
During the agenda item 6 for SEV-FR-010/2013: Cloé de LENTDECKER (FR)
During the agenda item 6 for SEV-FR-012/2013: Cloé de LENTDECKER (FR), Zakia HEBIB-CHENNIT (FR), Anne-Laure SCELO (FR) and Ian DOYLE (UK)
During the agenda item 6 for SEV-DE-016/2013: Ian DOYLE (UK)
During the agenda item 10: Eric VERBRUGGEN (NL) (expert to the rapporteur) and Steve DUNGEY (UK) (dossier submitter's representative)
During the agenda items 9 and 10 from the European Commission: Valentina BERTATO, Giuseppina LUVARA, Georg STRECK and Jacek RODZWADOWSKI

Case owners:
Representatives of the Registrants were attending under agenda item 6b for SEV-PL-024/2013, SEV-FR-010/2013 and SEV-DE-016/2013 and under agenda item 7b for TPE-133/2014.

Apologies:
BUSUTTIL, Ingrid (MT)
DOUGHERTY, Garry (UK)
DRUGEON, Sylvie (FR)

III. Final Agenda

ECHA/MSC-40/2015/A/40

Agenda
40th meeting of the Member State Committee

3-5 February 2015
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

3 February: **starts at 9 am**
5 February: **ends at 1 pm**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/040/2015
For adoption

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

Item 4 – Administrative issues

For information

Item 5 – Adoption of minutes of the MSC-39

- Adoption of draft minutes of MSC-39

MSC/M/39/2014
For adoption

Item 6 – Substance evaluation

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

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

ECHA/MSC-40/2015/001
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-40/2015/002

MSC code	Substance name	EC number	Document
SEV-FR-010/2013	3,5,5-trimethylcyclohex-2-enone	201-126-0	ECHA/MSC-40/2015/003-4
SEV-FR-012/2013	1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-ene-2,3-dicarboxylic anhydride	204-077-3	ECHA/MSC-40/2015/005-6
SEV-DE-016/2013	N,N-dicyclohexylbenzothiazole-2-sulphenamide	225-625-8	ECHA/MSC-40/2015/007-8
SEV-PL-024/2013	Furfuryl alcohol	202-626-1	ECHA/MSC-40/2015/009-10

For discussion

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

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

SEV-ES-028/2013[2] Diisotridecyl adipate (EC No. 247-660-8)

For agreement

d. General topics

- Status report on substance evaluation
- Appeals update[3] *(Partly closed session)*
- General presentation on mutagenicity testing strategy[4]

For information

Item 7 – Dossier evaluation

Closed session for 7c
Indicative time plan for 7b is Day 1&2

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

ECHA/MSC-40/2015/011
For information

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

ECHA/MSC-40/2015/012

For discussion followed by agreement seeking under 7c:

Compliance checks

CCH-286/2014	Ceramic materials and wares, chemicals (EC No. 266-340-9)	ECHA/MSC-40/2015/013-014

Testing proposal examinations

TPE-133/2014	2-[(2-methyl-1-oxoallyl)oxy]ethyl acetoacetate (EC No. 244-311-1)	ECHA/MSC-40/2015/015-016

For discussion

[2] Documents available in substance specific folders in MSC CIRCABC
[3] A combination of Appeal updates for Substance and Dossier Evaluation may be introduced, if appropriate.
[4] One general presentation on mutagenicity testing strategy with applicability to both Substance and Dossier Evaluation is foreseen

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

- Cases as listed under **7b**

For agreement

d. General topics

1) Exceptional reasons for modifying a Final Decision after unanimous MSC agreement

2) Reporting on the status
   - Appeals update[2]
   - General presentation on mutagenicity testing strategy[3]
   - Revised policy of taking dossier updates into account during dossier evaluation decision making

ECHA/MSC-40/2015/020
For information

Item 8 – Community Rolling Action Plan (CoRAP) update

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

b. Adoption of the MSC opinion

ECHA/MSC-40/2015/019
For discussion and adoption

Item 9 – Identification of SVHCs

a. Revision of MSC Working Procedures on identification of SVHCs

ECHA/MSC-40/2015/017
For discussion and adoption

b. MSC opinions[5] on SVHC proposals on four phthalates to be referred to the Commission

For information

Item 10 – Opinion in accordance with Article 77(3)c of REACH on persistency and bioaccumulation of D4 & D5

- Presentation by Rapporteur on elements for the draft opinion[6]

ECHA/MSC-40/2015/021
For information and discussion

Item 11 – ECHA's draft recommendations of priority substances to be included in Annex XIV

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

[5] MSC opinions on DEHP, BBP, DBP and DIBP and minority position are available in MSC CIRCABC in the Library for SVHCs under 04 MSC opinion development
[6] Draft RCOM documents for D4 and D5 and other background information are available in MSC CIRCABC in the Library 08. ED requests according to Article 77 (3) (c) of REACH

b. Preliminary prioritisation results in preparation for ECHA's 7th draft recommendation - substances not assessed for priority previously

ECHA/MSC-40/2015/018

For information

Item 12 – Opinion of MSC on the draft 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 elements for the draft MSC opinion

For information and discussion

Item 13 – Report from 2014

For information

Item 14 – Any other business

- Update to MSC on activities at OECD
- Suggestions from members

For information

Item 15– Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-40

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

- Status report on dossier evaluation (presentation slides)
- Dossier evaluation: Exceptional reasons for modifying a Final Decision after unanimous MSC agreement (presentation slides, for members only)

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-40, 3-5 February 2015
(adopted at MSC-40)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues	
	SECR to invite feedback from MSC on their use and need of reference files as currently available on CIRCABC. **SECR** to use this feedback in the plan of migration to possible new IT-platform and archiving of existing files.
Item 5 – Adoption of minutes of the MSC-39	
MSC adopted the draft minutes as provided for the meeting and further modified during the meeting based on two member's additional comments.	**MSC-S** to upload final version of the minutes on MSC CIRCABC by 6 February 2015 and 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.	**MSC-S** to upload on MSC CIRCABC the final ECHA decision agreed in written procedure, as indicated in document ECHA/MSC-40/2015/001.
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-FR-010/2013 3,5,5-trimethylcyclohex-2-enone (EC No. 201-126-0) SEV-FR-012/2013 1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-ene-2,3-dicarboxylic anhydride (EC No.204-077-3) SEV-DE-016/2013 N,N-dicyclohexylbenzothiazole-2-sulphenamide (EC No.225-625-8) SEV-PL-024/2013 Furfuryl alcohol (EC No.202-626-1) SEV-ES-028/2013 Diisotridecyl adipate (EC No. 247-660-8)	**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-40/2015/011.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 7 – Dossier evaluation **b. Introduction to and preliminary discussion on draft decisions on compliance checks after MS-CA reactions *(Session 1, tentatively open session)*** **c. Seeking agreement on draft decisions on testing proposal examinations and compliance checks 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): • CCH-286/2014 Ceramic materials and wares, chemicals (EC No. 266-340-9) • TPE-133/2014 2-[(2-methyl-1-oxoallyl)oxy]ethyl acetoacetate (EC No. 244-311-1)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases.
Item 7 – Dossier evaluation **d. General topics** Reporting on the status • Revised policy of taking dossier updates into account during dossier evaluation decision making • Exceptional reasons for modifying a final decision after unanimous MSC agreement	
MSC took note of the revised policy of taking dossier update into account.	
MSC took note of SECR's proposal on the case TPE-022/2012 and indicated that a revised final decision, which takes into account the changes by Registrant's updates of the technical dossier after original MSC agreement, should not be issued.	**SECR** to consider the MSC view for the further processing of the case.
Item 8 – Community Rolling Action Plan (CoRAP) update a. Discussion on the MSC opinion on the draft Community Rolling Action Plan (CoRAP) update b. Adoption of the MSC opinion	
MSC adopted by consensus the draft opinion and its Annex on the draft CoRAP update 2015-2017 as modified in the meeting. MSC mandated MSC-S to include further editorial changes in the Annex as requested by the Rapporteur	**SECR** to upload the MSC CoRAP opinion including its Annex on MSC CIRCABC after the meeting when the editorials have been made. **SECR** to publish the opinion on the ECHA website together with the annual CoRAP update on 17 March 2015.
Item 9 – Identification of SVHCs a. Revision of MSC Working Procedures on identification of SVHCs b. MSC opinions on SVHC proposals on four phthalates to be referred to the Commission	
MSC unanimously agreed on the modifications proposed by SECR, with small amendments introduced during the meeting, for revision of the MSC Working Procedures on identification of SVHCs. MSC agreed to the SECR's proposal to apply the revised MSC Working Procedures on identification of SVHCs retrospectively with regard to the opinion development on human health part of the SVHC proposals for DEHP, DBP, BBP and DIBP.	**MSC-S** to update the MSC Working procedures on SVHC identification, as agreed and to publish the updated procedure on MSC CIRCABC and on ECHA's website **MSC-S** to apply the new approach on the opinion development for the opinion forming on the human health parts of the SVHC proposals for DEHP, BBP, DBP and DIBP[7]. **MSC-S** to refer the MSC opinions on DEHP, BBP, DBP and DIBP, minority positions and supporting documentation to the

[7]MSC opinions on DEHP, BBP, DBP and DIBP developed according to the new approach and minority position of disagreeing members are available in MSC CIRCABC in '03 SVHC' folder

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	Commission latest by end of February 2015
Item 10 – Opinion in accordance with Article 77(3)c of REACH on persistency and bioaccumulation of D4 & D5 • Presentation by Rapporteur on elements for the draft opinion	
MSC took note on the elements for the draft opinion and on the revised Time plan for the opinion forming on D4 and D5 proposals.	**Rapporteur** to submit to MSC-S the 1st draft opinion by 20 February 2015 **MSC-S** to upload the draft opinion to MSC CIRCABC and to launch an MSC consultation on the draft opinion by 23 February 2015 **MSC** to review the draft opinion and comment on it, as necessary by 13 March 2015 **MSC-S** to compile the MSC comments and provide them in MSC CIRCABC for Rapporteur's consideration in the revised draft opinion by 16 March 2015 **Rapporteur** to submit to MSC-S the revised draft opinion, as relevant, by 31 March 2015 for adoption at MSC-41
Item 11 – ECHA's draft recommendations of priority substances to be included in Annex XIV a) Summary of issues raised in the public consultation on ECHA's 6th draft recommendation for inclusion of priority substances in Annex XIV b) Preliminary prioritisation results in preparation for ECHA's 7th draft recommendation - substances not assessed for priority previously	
MSC took note of the summary provided under item a, and the preliminary prioritisation results for the 7th draft recommendation (item b).	
Item 12 – Opinion on ECHA's draft recommendation of priority substances to be included in Annex XIV Preparations for the opinion on ECHA's 6th draft recommendation of priority substances to be included in Annex XIV • MSC discussion on elements for the draft MSC opinion	
MSC took note of the review of the comments as presented by the Rapporteur.	**MSC** to consider the comments and issues presented in advance of MSC-41. **Rapporteur,** with support of the working group, to submit the first draft opinion for discussion at MSC-41
Item 15– Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-40 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC CIRCABC by 5 February 2015.

V. Dossier evaluation cases unanimously agreed by MSC in WP:

Testing proposal examinations (TPE)

MSC ID number	Substance name used in draft decision	EC number
TPE-121/2014	4-(1-methyl-1-phenylethyl)-N-[4-(1-methyl-1-phenylethyl)phenyl]aniline	233-215-5
TPE-127/2014	Heptan-2-one	203-767-1
TPE-132/2014	Polyphosphoric acids, esters with triethanolamine, sodium salts	268-625-3
TPE-140/2014	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with biphenyl-4-ol	500-655-7

Compliance checks (CCH)

MSC ID number	Substance name used in draft decision	EC number
CCH-279/2014	Diethyl 1-(2,4-dichlorophenyl)-5-methyl-4,5-dihydro-1H-pyrazole-3,5-dicarboxylate	603-923-2
CCH-280/2014	Oxidation products of seed oil obtained from Linum usitatissimum, Linaceae (linseed)	272-038-8
CCH-289/2014	Oxalic acid	205-634-3