MSC/M/44/2015
(Adopted at MSC-45)

Minutes
of the 44th Meeting of the Member State Committee (MSC-44)
27-29 October 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 44th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

Item 2 - Adoption of the Agenda

The Agenda was adopted as provided for the meeting by the MSC Secretariat without further changes (final Agenda is attached to these minutes).

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

No potential conflicts of interests were declared by any members, experts or advisers with any item on the agenda of MSC-44.

Item 4 - Administrative issues

SECR informed the Committee of a new voting system for written procedures and invited members to test it before its first application in mid-November.

SECR reminded the Committee of the upcoming migration of the CIRCABC to S-CIRCABC and requested the users of the platform to update their account with the requested details by 30 October.

The Chairman informed the Committee that a new guide for reimbursement will be applied for meetings of 2016 onwards.

Item 5 – Adoption of the minutes of the MSC-43 meeting

The minutes of MSC-43 were adopted as provided for the meeting.

Item 6 – Substance evaluation

6.1 Community Rolling Action Plan (CoRAP) & MSC opinion development

SECR presented the draft CoRAP update for 2016-2018. As per previous years, each substance has an accompanying justification document. The draft CoRAP including the initial grounds for concern and contact details of the evaluating Member State Competent Authorities (eMSCA) was published on the ECHA's website during the MSC meeting on 28 October. Substances in the CoRAP list were identified through the ECHA's common screening activities ACROSS, through IT pre-selection and then through manual screening performed by MSCAs. The draft CoRAP update for years 2016-2018 has a total of 138 substance, 53 new and 85 already included in the 2015-2017 CoRAP update – 47 substances for 2016, 48 substances for 2017 and 43 substances for 2018. SECR and MSCAs are also discussing the groups of structurally similar substances where part of the evaluation of these substances may be combined. SECR also referred to the decision by ECHA's Board of Appeal (BoA) taken on 23 September 2015 on an appeal concerning the substance evaluation decision for carbon tetrachloride (Case A-005-2015). The decision addresses, among other issues, the question how to demonstrate a concern under substance evaluation. This may as well be of relevance for the selection of substances for the CoRAP. Following an analysis of the case, ECHA may suggest to amend the CoRAP in order to reflect the findings of the Board.

The Rapporteur and its working group already started working on this draft CoRAP update aiming to submit a first draft opinion to MSC for MSC-45 meeting in December.

6.2 Decision making process

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

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on three substance evaluation cases (see Section IV for more detailed identification of the cases). WP was launched on 1 October 2015 and closed on 13 October 2015. By the closing date, unanimous agreement was reached on two DDs with no abstentions received. For one DD WP was terminated by the MSC Chair on the basis of Article 20.6 of the MSC Rules of Procedure as at least one MSC member requested meeting discussion of the case. There were no abstentions related to the cases launched for agreement seeking in written procedure.

b) Introduction to and preliminary discussion on a draft decision 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-DK-004/2013 - Benzophenone (EC No. 204-337-6)

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 Denmark (DK-CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance which was performed by the DK-CA on the basis of the initial grounds for concern relating to carcinogenicity, wide dispersive use, consumer use and a high RCR. In the course of the evaluation, the eMSCA concluded that it would not be necessary to propose further tests on carcinogenicity in order to clarify the identified concern, but noted additional concerns regarding endocrine disrupting effects. MSC was guided through the information on the substance (including PfAs, Registrant(s) comments, and the eMSCA's responses to them). The draft decision as discussed at MSC requested for a Larval Amphibian Growth and Development Assay (LAGDA; OECD TG 241) to tackle the thyroid disrupting activity, a Fish Sexual Development Test (FSDT; OECD TG 234) to address the estrogenic and anti-androgenic effects and update of the chemical safety report. The draft decision as discussed at the MSC meeting had been revised so that the initial request for a 28 days repeated dose toxicity study targeting thyroidal effects including serum hormone measurements had been dropped (based on comments from the registrants) whereas the initially requested Amphibian Metamorphosis Assay (AMA, OECD TG 231) had been replaced with LAGDA (based on a PfA). Furthermore different specifications / modifications of the requested FSDT had also been made in accordance with some PfAs (c.f. below).

Eleven PfAs were submitted covering thyroidal, estrogenic and anti-androgenic effects of benzophenone (BP), its environmental fate and exposure. All PfAs were discussed at the meeting.

PfAs related to the possible thyroidal effects of BP mainly suggested: 1) a tiered approach which maintains the original request for an Amphibian Metamorphosis Assay (AMA, OECD TG 231) and in case of evidence of thyroid disruption in this assay to include thyroid relevant endpoints in the FSDT; 2) to replace the AMA request with a request for the Larval Amphibian Growth and Development Assay (LAGDA; OECD TG 241). The AMA is regarded as screening assay providing information assigned to level 3 of the OECD framework where positive results only identify potential endocrine disruptors and which require further follow up testing. The LAGDA is assigned to level 4 of the OECD framework as information on both thyroid (endocrine) activity and adverse endpoints related to this is generated, and positive results can be used directly to identify a substance as an endocrine disruptor; 3) to delete the AMA from the decision based on the view that there are sufficient data to address the human health ED concern (no thyroid-related adverse effects in rodent studies at level 5 of the OECD framework) and that rats and frogs are

equally sensitive, and that the substance is rapidly degradable and has a very low bioaccumulation potential.

PfAs related to the possible estrogenicity and anti-androgenicity of BP mainly suggested to: 1) include in the request to perform the FSDT (OECD TG 234) a minimum of five test concentrations and at least four replicates should be used such that the data may also be used for risk assessment; 2) analytically determine the concentrations of two main hydroxylated derivatives in the exposure media and considers that in case of negative results (neither biotic effects nor analytical detection of the derivatives) further testing with the hydroxylated derivatives may be necessary; 3) include as obligatory, endpoints related to secondary sexual characteristics in fish depending on the choice of the fish test species; 4) reject the FSDT and replace this with a requirement for an OECD TG 229 or OECD TG 230 study (the latter was preferred), as the weight of evidence to justify a level 4 test of the OECD framework using a larger number of vertebrate animals was not considered sufficient. A concern was raised that the effect will not occur at the test concentrations being used and doubts whether there is evidence that the metabolites of concern in the uterotrophic assays are actually formed in fish; 5) discuss all fish testing options and justify why an OECD TG 234 is preferred to the OECD TG 229 and 230 based on the available evidence; 6) clarify whether the test strategy focuses on investigation of metabolites formed within the fish *in vivo*, or metabolites formed in the environment with subsequent *in vivo* fish exposure. This affects how the results should be expressed, and whether concentrations of both metabolites need to be measured in the test.
PfAs related to environmental fate and exposure of BP proposed to request additionally for: 1) photodegradation data (OECD TG 316) as this is relevant for the environmental risk assessment and assess whether photodegradation is a significant issue for maintenance of the test substance concentration in aquatic tests and 2) environmental exposure modelling and providing an assessment and PECs of two hydroxylated derivatives for each life-cycle stage.

The Registrants provided written comments on the PfAs which were reiterated during the discussion by the Registrant representative. The Registrant representative stated that BP has been tested in different oral studies with rats and mice with dosing for up to 2 years. Thyroid and parathyroid examined histologically with no evidence of perturbation of thyroid homeostasis indicating that initial *in vitro* studies are not replicated in *in vivo* rodent studies.

Therefore, taking furthermore the ready biodegradability as well as photodegradation in water and the insignificant bioaccumulation potential of BP into account, the performance of additional experimental studies on vertebrates was in the view of the Registrant representative clearly not justified. Despite it being detected in water and sediment samples in very low concentrations yet it could not be detected in filter feeding molluscs. Results indicate either a very low bioavailability and/or a rapid metabolization of BP even in a species with a great ability in bioaccumulating persistent pollutants.
Available information on fate and behaviour of BP in the environment indicated that the compound, once introduced into the environment, would be rapidly removed by different processes. Exposure of fish to BP did not result in estrogen-like effects affecting reproductivity.

The Registrant representative stressed that reliable experimental data clearly demonstrate that metabolites would not be present in significant amount that cause significant effect. Hence he considered it highly questionable whether further testing would lead to proper risk management referring to the European Ombudsman decision that the concern should be real and not theoretical. Therefore he was of the view that further vertebrate testing was not required.

The Registrants' representatives offered to re-evaluate the study reports available on fate of BP in water and the potential temporary formation of estrogenic metabolites by environmental degradation processes, and obtain available data on BP from the Japanese testing program. They would also improve the environmental exposure modelling and consider the potential metabolites.

During the discussion the eMSCA expert highlighted the special profile of this substance. Whilst evidence shows that the parent compound BP has potential thyroid disrupting activities and no estrogenic activity, its environmental hydroxylated transformation products formed by photolysis have on the other hand, potential estrogenic activity and no thyroid disrupting activity. Furthermore, internal metabolism of BP in rats shows that three primary metabolites are formed with different endocrine activities. These are 4-hydroxy-benzophenone (4-OH-BP), 3-hydroxy-benzophenone (3-OH-BP) and benzhydrol.

One MSC expert referred to the extensive database on human health for BP which shows there are no thyroid tumours and other indications leading to thyroid disrupting activity. Furthermore, in his view rats and amphibians are equally sensitive for such activity, hence if rats showed no thyroid disrupting activity then amphibians will show none leading to the conclusion that there is no need to further test on amphibians. The view was counter argued by the eMSCA representative referring to the limited database for making interspecies comparisons and the difficulty in comparing between organisms like tadpoles exposed via the surrounding medium (water) and oral studies with rodents where exposure occur via food or gavage.

The following discussion made clear that there are diverging views on these aspects including the certainty of making inter species comparisons between widely different vertebrate species (such as amphibians and rodents) where the exposure route furthermore differ and other issues related to commonalities/ differences in the species sensitivity for thyroidal effects and more general for other hormone related adverse effects. MSC discussed the possibility to first focus on the rate of transformation of BP both inside and outside gill breathing vertebrate species. This will facilitate the choice of the test substance (BP or some of its primary metabolites/ transformation products) in case there after an initial follow up evaluation of such requested information would be a need to further clarify either of the two above mentioned concerns for potential endocrine disruptive effects of BP and/ or its metabolites/transformation products.

Session 2 (closed)

During the discussion there was a consensus that in order to address the estrogenic activity and the concern for potential estrogenicity related adverse effects in fish, the hydroxylated transformation products (3-OH-BP & 4-OH-BP) need to be tested. However, procedurally it was not possible to include such a request in this decision since there was no PfA that specifically proposed to ask for the transformation products to be tested when performing the FSDT. Even though PfAs were submitted to measure the hydroxylated transformation products in the test system whilst testing for BP it was recognised that the lighting during the test is so different from real environmental conditions (much dimmer), that it could lead to a negative result due to lack of exposure to the hydroxylated transformation products. It was furthermore considered that also environmental biodegradation by microorganisms in surface water and sediment may result in formation of hydroxylated transformation products of BP, but also that such processes may not be reflected in the flow-through test design normally employed when conducting the FSDT test.

Therefore, MSC unanimously agreed to change the information requested in the decision. Both originally requested vertebrate studies (LAGDA and FSDT) requested in this decision were dropped at this stage and instead a request was made for evaluation of further available information on metabolism in gill breathing vertebrate animals and further information on the fate of BP including transformation of BP with special emphasis on transformation products and kinetics in the aquatic environment and in aquatic toxicity test media. Section III of the draft decision was amended accordingly. If it turns out that the now requested information is not sufficient, further specific studies may need to be requested to create a proper basis for deciding on thyroid and estrogenic relevant testing if any.

During the deliberations on the content of the decision MSC debated in how much detail potential risk management measures should be described, in light of the recent Board of Appeal decision on A-005-2014. There was a general preference to keep the description of

RMM at a rather generic level in this particular decision since it was considered a 'stepping stone' decision in case the now requested fate information does not remove the present concerns related to potential endocrine disruptive effects to aquatic wildlife.

Finally, the change in the requests resulted in a change in the deadline for provision of requested information in dossier update from 18 months to 6 months.

SEV-FR-009/2013 Carbon disulphide (EC No. 200-843-6)

Session 2 (closed)

The written procedure for the draft decision by the eMSCA from France (FR-CA) was terminated by the Chairman of MSC on request of three MSC members suggesting a MSC discussion on the tiered approach strategy for the Extended One Generation Reproductive Toxicity Study (EOGRTS; OECD TG 443) in rats, specifically focused on 1) the determination of the route of exposure as there are significant technical challenges to perform an EOGRTS by inhalation, 2) inclusion of DNT in the study design to address the neurodevelopmental concern, 3) the inclusion and/or exclusion of the cohort 1B with production of the F2 generation and the DIT cohort, 4) clarifications of the text proposed in the DD in the light of the ruling of the BoA in A-005-2014.

The concept of significant exposure and selection of the appropriate route of administration, oral vs. whole body exposure or nose-only in case of inhalation, was discussed. It was agreed that the comparative toxicokinetic assessment should include whole body exposure as this is considered the most common route of administration for inhalation exposure in reproductive toxicity studies. Due to the dermal absorption of this substance the nose-only kinetics may be different from kinetics after whole body exposure. Moreover, dermal absorption of carbon disulfide may occur and whole body exposure is the most realistic route regarding the expected exposure of workers.

In line with the 3-step approach indicated in the BoA decision on A-005-2014, MSC reached consensus that the EOGRTS with DNT was needed to clarify the concern for fertility, developmental neurotoxicity concern and potential endocrine disruption. The results could lead to a more severe classification for reproductive toxicity and potentially the need to set a lower OEL and DNEL due to the expected higher sensitivity of the neurodevelopmental toxicity

One MSCA had submitted a PfA proposing the inclusion of extension of Cohort 1B to produce the F2 generation based on the criteria in the Annex IX and X (i.e. evidence indicating potential for endocrine mode of action and significant exposure) and the DIT cohort also due to alerts for potential immunotoxicity. However, the justification did not include the elements considered specifically important for this substance evaluation in terms of technical challenges in case it is conducted by inhalation. Because developmental neurotoxicity was considered to be the potentially most sensitive endpoint, the inclusion of additional cohorts was not expected to provide added value for risk management. Therefore, in view of proportionality, ECHA decided not to request additional cohorts F2/DIT, but indicated in the decision that the Registrant, with justification, may expand the study if the Registrant obtains information indicating a concern that needs to be addressed.

ECHA's PfA on further detailed information on worker exposure was discussed and MSC took this into account in amending section III together with some editorials modifications on this paragraph.

MSC discussed whether the BoA decision on A-005-2014 should lead to further amendments of the decision; however, doing so could breach the Registrant's right to be heard; therefore, it decided to limit DD amendments to those parts for which PfAs were received.

The deadline to submit the information requested in the decision was extended from 24 to 33 months because of the inclusion of a pre-study ("Tier 1") investigating the comparative toxicokinetics.

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

d) General topics

- **Status report on substance evaluation**

MSC appreciated the report on the progress of the substance evaluation process given by SECR. A discussion on how the MSC could process a higher number of cases per meeting followed this report. It was concluded that in order to increase the efficiency of the process, the MSC members where encouraged to discuss with their eMSCA experts and encourage them to increase bi-lateral communications with their counterparts in other MSCAs, both before submitting PfAs on SEv DDs and after PfAs have been submitted.

- **Status report on the ongoing FET project**

SECR gave a status update of the project that ECHA is performing regarding the analysis of the relevance and adequateness of using Fish Embryo Toxicity (FET) test (OECD 236) to fulfil the information requirements under REACH. The project started in early 2015 where an external contractor was asked to gather, compare and analyse the available data in order to determine boundaries and limitations of the test and suggest the applicability domain in terms of chemical structure and physico-chemical characteristics and regarding metabolism, bioavailability, reactivity. The outcome of these results is not yet available. It was clarified that an outcome of this project will be used to decide on the general applicability of this test to be used to fulfil information requirements under REACH. A stakeholder representative informed MSC on another project on FET carried out in collaboration with Austria which aims at how to incorporate FET testing in a threshold approach.

- **Appeals update**

SECR gave an overview of the BoA decision in case A-005-2014. This was very much appreciated by the MSC. In fact some learnings taken from this appeal decision were discussed and already applied in the two SEv cases that were for decision making at MSC-44.

- **Update of MSC Working Procedures on substance evaluation**

The Chairman expressed to MSC the need to amend the current SEV Working Procedures of MSC. The current working procedures prescribe the eMSCA as the actor deciding whether to use written procedure or meeting discussion for agreement seeking on a substance evaluation. He proposed to update this and make the MSC Chairman responsible for this in close collaboration with the eMSCA and the MSC member from the eMSCA.

The members recognised that this proposed update reflected the current practice since eMSCAs are always very open to receive the advice from MSC-S. It was agreed that the MSC members would report any changes that might be proposed by their eMSCA experts on the proposed changes in the MSC working procedures.

Item 7 – Dossier evaluation

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

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on eight dossier evaluation cases (see Section V for more detailed identification of the cases). WP was launched on 1 October 2015 and closed on 13 October 2015. By the closing date, unanimous agreement was reached on seven DDs with no abstentions received. For one DD, WP was terminated by the MSC Chairman on the basis of Article 20.6 of the MSC Rules of Procedure as at least one MSC member requested meeting discussion of the case at the MSC-44 meeting.

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 a testing proposals and a compliance check when amendments were proposed by MS's *(Session 2, closed)*

TPE-114/2015 1,1,3,3-tetramethylbutyl hydroperoxide (EC No. 227-369-2)

Session 1 (open)

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

SECR explained the three PfAs on two endpoints that were received to ECHA's DD.

The first PfA on simulation testing on ultimate degradation in surface water (EU C.25/OECD TG 309), at 12°C including the identification of the degradation products, suggested deleting this test or if to be retained, it should only be as a possible further step-wise refinement, if the Registrant considered it necessary following the performance of their testing proposal of an OECD TG 303A test (EU C.10). The first PfA, argued that there would be very limited surface water exposure and risk, that the substance has a low bioaccumulation potential and neither fulfilling the PBT nor vPvB screening criteria, and that it was for the Registrant to accept the data for classification purposes. The second PfA, on the same endpoint, suggested accepting the sewage treatment plant (STP) simulation degradation study (OECD TG 303A) and deleting request for OECD TG 309, arguing that the OECD TG 303A test proposed by the Registrant is justified based on considerations concerning the quantitative environmental ($PEC_{surface\ water}/PNEC_{surface\ water}$) risk assessment and the PBT assessment of the chemical safety report (CSR).

The third PfA on long-term toxicity testing on aquatic invertebrates (*Daphnia*) (EU C.20/OECD TG 211) suggested postponing the test and first carrying out a short-term test on fish. It noted that the reference to an industry position paper, which the Registrant used to waive the acute fish test, did not contain sufficient evidence on fish being less sensitive than *Daphnia*. It further suggested first carrying out a short-term test on fish before a chemical safety assessment (CSA) was conducted and the decision about a long-term toxicity testing could be made.

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

The Registrant had provided written comments on the first two PfAs. He noted the support for his proposal for an OECD TG 303A study and an updated risk assessment as the appropriate next step, and would then either propose or waive an OECD TG 309 study.

One MSC member queried whether it was possible to mention the use of OECD TG 236 study (FET, fish embryo acute toxicity) in an approach to adapt the standard information requirements (in line with what was done in an earlier DD on a SEv case). SECR responded that ECHA's assessment on adequateness and relevance of the study for REACH was still ongoing, and there was no full understanding of the limitations and the applicability domain of FET test yet. A stakeholder observer noted that OECD TG 236 has been validated and the option could be provided for the Registrant to consider.

Session 2 (closed)

MSC agreed on the need to request short-term aquatic toxicity tests before the Registrant proceeds with chronic toxicity testing. One MSC member reiterated the preference to mention OECD TG 236 in DD. SECR reminded that there could be limitations to OECD TG 236. MSC recognised that the applicability domain of OECD TG 236 in a regulatory REACH context was not yet concluded by ECHA's evaluation. Also, ECHA could not build all possible adaptation arguments for a Registrant. Due to all these aspects, MSC agreed not to specify the OECD TG 236 as a possible part of an approach to adapt the standard information requirement under the "Note for the consideration of the Registrant" in this case, but to reflect the discussion in the minutes.

MSC agreed to request OECD TG 303A study, noting its use to refine the quantitative risk assessment (PEC_{local} surface water/$PNEC_{local}$ surface water) but not for use for persistency

assessment or classification purposes. MSC agreed to request short-term toxicity testing on fish (OECD TG 203), update CSA and, based on this test, long-term toxicity testing on aquatic invertebrates (*Daphnia magna*, EU C.20/OECD TG 211) and/or fish, early-life stage (FELS) (OECD TG 210). The period for testing was extended to 30 months, in view of the possibility that all three studies would need to be conducted in sequence.

MSC reached unanimous agreement on DD as amended in the meeting.

CCH-072/2015 Titanium tetrachloride (EC No. 231-441-9)

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 two MSC members requesting a MSC meeting discussion.

The discussion focused on the PfAs received on the DD request for a pre-natal developmental toxicity study (PNDT, EU B.31./OECD TG 414). One MSC member considered there was no scientific and technical need to test this substance, which has a very short lifetime and a corrosive hydrolysis product. Another member considered that testing with the registered substance would technically not be possible, referring to the rapid hydrolysis of the registered substance and to Annex XI, section 2 general rules for adaptation of the standard testing regime. SECR noted that data were available for one of the hydrolysis products, TiO_2, although mainly related to the nano form of the registered substance. MSC discussed that it could, in absence of this TiO_2 data in the registration dossier, not establish its relevance, adequacy and acceptability, and also not assume the Registrant's responsibility to prepare a robust read-across justification. One MSC member reminded that the hydrolysis of the registered substance was exothermic, which would further complicate testing the registered substance.

Based on the justifications outlined in the discussion, MSC concluded that testing was required, but agreed to focus the Registrant, to consider the use of available data on TiO_2, and amended DD to reflect this.

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

d. General topics

1) Status report on on-going evaluation work

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

2) Appeals update

See item 6.d.

3) Overview of dossier evaluation OECD TG 303A simulation testing proposal decisions taken

SECR gave a presentation on the review of decisions on dossier evaluation cases, where MSC had agreed on testing proposal examinations on OECD TG 303A. The presented overall observations provided background information for the discussion on case TPE-114/2015.

Item 8 - ECHA's draft recommendation of priority substances to be included in Annex XIV

a) Update on court cases

SECR provided an overview of Court judgments on two cases in relation to the authorisation process. Learnings from these cases were shared as these are relevant issues also to MSC work, one of them on identification of a substance (acrylamide) as a SVHC (Case T-268/10 RENV) and the other one on the scope of Article 58(2) (Case T-

360/13). MSC considered the given overview very useful and had some clarifying questions and discussion in order to better understand the implications of those rulings.

b) Substances for the 7th recommendation: Discussion on the substances suggested for inclusion in the draft recommendation and the respective draft Annex XIV entries prior to public consultation

SECR presented the results from the prioritisation assessment with focus on the substances proposed for the public consultation on ECHA's draft recommendation of priority substances to be included in Annex XIV. This draft recommendation includes a proposal for Annex XIV entries, including the latest application dates and sunset dates, and SECR in its introduction reflected further on the number of substances included and how the latest application dates, now as three suggested groups with latest application dates of 18, 21 and 24 months, were set. Two options for this grouping were presented in order to collect feedback from MSC. In the discussion only few comments were given on the suggested approach to set latest application dates and other technical matters, but most of the discussion took place on the choices for some of the planned inclusions.

A number of questions dealt with NMP, an aprotic solvent, for which other work is also ongoing (such as a restriction process as well as work on OEL/DNEL). Some of the members supported inclusion of NMP, mainly as the substance receives high priority in the assessment, and also - as it groups with two other aprotic solvents – that then all three substances would be at the same stage of the authorisation process (i.e. recommended for inclusion). On the other hand, several members had the view that although not challenging the score assigned to NMP, it would be better to conclude first the ongoing regulatory work before moving forward in the authorisation process (inclusion in Annex XIV). Also a representative of the Commission questioned SECR's intention to include NMP in the public consultation stressing that inclusion would lead to confusion of registrants and that significant work of a technical nature was currently undertaken by several experts from Risk Assessment Committee and Scientific Committee on Occupational Exposure Limits (SCOEL).

For the lead substances under consideration some questions for clarification were raised. One member wanted to understand how clear it will be made in the public consultation that the previously submitted comments are being considered. In responding SECR made reference to one of the meeting documents in which this is outlined, confirming that there will be a clear message on the website on the full consideration of all comments submitted for the four lead substances during last years, public consultation. One MSC observer from a NGO inquired why some lead stabilizers were left out at this stage. Responses from SECR and other meeting participants clarified that actions from the industry voluntary agreement are due by end of this year. This should be reflected by registration updates with potential significant impact on the priority scores. The substances will in any case be evaluated in the next prioritisation round. One industry observer provided views as regards the number of substances in the draft recommendation to be submitted for public commenting and how at this stage a list with more substances than what is likely to remain in the final recommendation from ECHA to the Commission would give more transparency to the overall process. This would provide a more concrete possibility for involved parties to contribute. SECR responded by referring to opposing views given by the members and its own analysis of the approach used for the 6th recommendation which lead to conclude to go back to the approach used in previous rounds of having less substances. Furthermore, SECR reflected other actions taken to increase predictability and transparency of the process, including the foreseen better visibility of the table providing the priority assessment of all substances on the Candidate List.

Some questions were directed to the Commission's activities such as how the comments in the parallel public consultation on socio-economic aspects will be used and when the strategy on all aprotic solvents would be available.

SECR also drew MSC attention to the need to update the document "Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – general approach" as regards exemptions under Article 58(2) of REACH based on the recent court

ruling in case T-360/13. This judgement of the General Court provides further clarifications and thus some examples were added to the text which will also be available on the ECHA website at the start of the public consultation.

As regards the next steps MSC was thanked for the feedback and informed that SECR's plan is to launch public consultation on the 7th draft recommendation of priority substances around 17th November, after considering the feedback and finalising the necessary documentation.

c) Status of MSC members and the mandate of the MSC

Brief exchange of views took place based on a written communication between a MSCA and ECHA concerning the mandate of MSC and its members' role under the recommendation process. This correspondence, which was shared with MSC for information, seemed to confirm common understanding of the MSC mandate to be essentially of technical nature.

Item 9 – Opinion on the draft recommendation of priority substances to be included in Annex XIV

a) Task of the (Co-)Rapporteur in drafting the opinion of MSC

b) Appointment of (Co-)Rapporteur

c) Establishment of a MSC Working Group to support the Rapporteur

MSC agreed on the tasks of the rapporteur and on the mandate of the newly-established working group to support the MSC rapporteur in drafting the MSC opinion on the 7th draft recommendation of ECHA.

Further, MSC appointed a volunteering MSC member as the Rapporteur and volunteering MSC members and experts as members of the working group for supporting the Rapporteur in this opinion development.

Item 10 – MSC Work plan for 2016

MSC took note of the work plan for 2016 which includes six plenary meetings.

Item 11 – MSC Manual of decisions (MoD)

MSC took note and agreed on the SECR's proposal for a revision of the entry 1.1.5 of the MSC MoD concerning the references to the classification of CMR substances in the SVHC proposals, as presented and further modified at the meeting.

Item 12 – Any other business

- **Update on the Danish QSAR Database**

The Danish MSC member introduced MSC with the updated Danish QSAR Database that contains estimates for about 600 000 substances, covers a variety of endpoints related to toxicity, ecotoxicity, environmental fate, physicochemical properties & ADME and uses different model platforms like CASE Ultra, SciQSAR, Leadscope, ACDLabs, EpiSUITE. The database would allow making predictions from 60 QSAR models for around 165 000 substances and is publicly accessible at http://qsar.food.dtu.dk from mid-November 2015 onwards.

- **Suggestions from members**

No further suggestions have been received from the members.

Item 13– Adoption of conclusions and action points

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

Watze de Wolf

Chairman of the Member State Committee

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ANDRIJEWSKI, Michal (PL)
COCKSHOTT, Amanda (UK)
CONWAY, Louise (IE)
COPOIU, Oana (RO)
DEIM, Szilvia (HU)
DIMCHEVA, Tsvetanka (BG)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
GAIDUKOVS, Sergejs (LV)
HERMES, Joe (LU)
HUMAR-JURIC, Tatjana (SI)
KOUTSODIMOU, Aglaia (EL)
KREKOVIC, Dubravka Marija (HR)
KULHANKOVA, Pavlina(CZ)
LONDESBOROUGH, Susan (FI)
LUNDBERGH, Ivar (SE)
MARTÍN, Esther (ES)
PALEOMILITOU, Maria (CY)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
WIJMENGA, Jan (NL)
Representatives of the Commission
SCHUTTE, Katrin (DG ENV)
Observers
ANNYS, Erwin (Cefic)
DROHMANN, Dieter (ORO)
HYNES Jarlath (HSI)
HÖK, Frida (ChemSec)
STAIRS Kevin (Greenpeace)
STODDART Gilly (PISC)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
BERCARU, Ofelia
BROERE, William
CARLON, Claudio
DELOFF-BIALEK, Anna
DE WOLF, Watze
DREVE, Simina
FEEHAN, Margaret
HAUTAMÄKI, Anne
JOHANSSON, Matti
KARHU, Elina
KASARUHO, Anisa
KORJUS, Pia
KREUZER, Paul
LOUEKARI, Kimmo
MÜLLER, Birgit
NAUR, Liina
PELLIZZATO, Francesca
RODRIGUEZ IGLESIAS, Pilar
RODRIGUEZ-RUIZ, Amaia
RÖNTY, Kaisu
SCHOENING, Gabriele
SOBANSKA, Marta
VAHTERISTO, Liisa
VASILEVA, Katya

Proxies

- MARTÍN, Esther (ES) also acting as proxy of DRUGEON, Sylvie (FR)
- HUMAR JURIC, Tatjana (SI) also acting as proxy of BUSUTTIL, Ingrid (MT)
- KOUTSODIMOU, Aglaia (EL) also acting as proxy of HUMAR JURIC, Tatjana (SI) on 29 October starting at 11:00

Experts and advisers to MSC members

BOUWMAN, Tialda (NL) (expert to WIJMENGA, Jan)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
GRINCEVICIUTE, Otilija (LT) (expert to DUNAUSKIENE, Lina)
INDANS, Ian (UK) (expert to COCKSHOTT, Amanda)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBRGH, Ivar)
MICHEL, Cécile (FR) (expert to DRUGEON, Sylvie)
NYGREEN, Beryl C. (NO) (expert to REIERSON, Linda)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)

RISSANEN, Eeva (FI) (adviser to LONDESBOROUGH, Susan)
ZELJEZIC, Davor (HR) (expert to KREKOVIC, Dubravka Marija)

MSCA Experts for SEV cases
PRINTEMPS, Nathalie (FR)

By WEBEX-phone connection:
During the agenda item 6 for SEV-DK-004/2013: Henrik HOLBECH (DK), Ian DOYLE (UK)
During the whole meeting: Enrique GARCIA-JOHN (DG GROW)
During the agenda items 6, 7, 8 and 9 from DG GROW: Valentina BERTATO, Mariana FERNANDES DE BARROS, Giuseppina LUVARA, Jacek RODZWADOWSKI and Georg STRECK

Case owners:
Representatives of the Registrants were attending under the agenda item 6.2b for SEV-DK-004/2013.

Apologies:
BUSUTTIL, Ingrid (MT)
COSGRAVE, Majella (IE)
DRUGEON, Sylvie (FR)
MIHALCEA-UDREA, Mariana (RO)
PISTOLESE, Pietro (IT)
WAGENER, Alex (LU)

II. Final Agenda

ECHA/MSC-44/2015/A/44

Agenda
44th meeting of the Member State Committee

27-29 October 2015
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland
27 October: starts at 9 am
29 October: ends at 12 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/044/2015
For adoption

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

Item 4 – Administrative issues

- Use of new IT-platform to exchange information
- Voting system for written procedures of MSC

For information

Item 5 – Minutes of the MSC-43

- Draft minutes of MSC-43

MSC/M/43/2014
For adoption

Item 6 – Substance evaluation

Closed session for 6.2c
Indicative time plan for 6.2b is Day 1

6.1 Community Rolling Action Plan (CoRAP) & MSC opinion development

Introduction of the annual draft CoRAP update by ECHA

ECHA/MSC-44/2015/012
For members only: ECHA/MSC-44/2015/013
For information and discussion

6.2 Decision making process

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

ECHA/MSC-44/2015/001
For information

b) Introduction to and preliminary discussion on a draft decision on substance evaluation after MS-CA's/ECHA reactions *(Session 1, open session)*:
For discussion followed by agreement seeking under 6.2c:

ECHA/MSC-44/2015/002

MSC code	Substance name	EC number	Documents
SEV-DK-004/2013	benzophenone	204-337-6	ECHA/MSC-44/ 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 **6.2 b** and a case returned from written procedure for agreement seeking in the meeting:

SEV-FR-009/2013[1] carbon disulphide (EC No. 200-843-6)

For agreement

d) General topics

- Status report on substance evaluation
- Appeals update[2]
- Update of MSC Working Procedures on substance evaluation

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-44/2015/005
For information

b) Introduction to and preliminary discussion on draft decision on a testing proposal after MS-CA reactions *(Session 1, open session)*

For discussion followed by agreement seeking under 7c:

ECHA/MSC-44/2015/006

Testing proposal examinations

MSC code	Substance name	EC No./ Documents
TPE 114/2015	1,1,3,3-tetramethylbutyl hydroperoxide	227-369-2 / ECHA/MSC-44/2015/007-8

For discussion

[1] Documents are available in case specific folders in MSC CIRCABC
[2] A combination of Appeal updates for Substance and Dossier Evaluation may be introduced, if appropriate.

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

Case as listed above under **7b** and a case returned from written procedure for agreement seeking in the meeting:

Compliance checks

CCH-072/2015[1] titanium tetrachloride (EC No. 231-441-9)

For agreement

d) General topics

1) Status report on on-going evaluation work
2) Appeals update[1]
3) Overview of Dossier Evaluation OECD 303A Simulation Testing Proposal Decisions taken

For information

Item 8 – ECHA's draft recommendation of priority substances to be included in Annex XIV

a) Update on court cases

For information

b) Substances for the 7th recommendation: Discussion on the substances suggested for inclusion in the draft recommendation and the respective draft Annex XIV entries prior to public consultation

ECHA/MSC-44/2015/014-018
For discussion

c) Status of MSC members and the mandate of the MSC

ECHA/MSC-44/2015/019
For information

Item 9 – Opinion on the draft recommendation of priority substances to be included in Annex XIV:

Tasks and appointment of Rapporteur and possible working group

Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the 7th draft recommendation and for Working Group membership

a. Task of the (Co-)Rapporteur in drafting the opinion of MSC

ECHA/MSC-44/2015/009
For discussion & decision

b. Appointment of (Co-)Rapporteur

For discussion & decision

c. Establishment of a MSC Working Group to support the Rapporteur

ECHA/MSC-44/2015/010
For discussion & decision

Item 10 – MSC Work plan for 2016

ECHA/MSC-44/2015/011
For information

Item 11 – MSC Manual of decisions (MoD)

- Review of one existing entry in MoD

ECHA/MSC-44/2015/020
For decision

Item 12 – Any other business

- Update on the Danish QSAR Database
- Suggestions from members

For information

Item 13– Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-44

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

- *Dossier evaluation status report (presentation slides)*

Outside plenary activities (tentatively during lunch hour of Day 2)**:**
Presentation by ECHA entitled: Potential role of information on epigenetic mechanisms in risk assessment of substances

III. Main Conclusions and Action Points

Main conclusions and action points
MSC-44, 27-29 October 2015
(*adopted* at MSC-44)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues • Use of new IT-platform to exchange information • Voting system for written procedures of MSC	
MSC was informed of a new voting system for written procedures and was invited to test it before its first application in mid-November. MSC was reminded of the upcoming migration of the CIRCABC to S-CIRCABC. MSC was informed that a new guide for reimbursement will be applied for meetings of 2016 onwards.	**MSC CIRCABC users** to update their CIRCABC account with the requested details by 30 October. **MSC-S** to upload in CIRCABC the new reimbursement guide.
Item 5 – Minutes of the MSC-43	
MSC adopted the draft minutes as provided for the meeting.	**MSC-S** to upload final version of the minutes on MSC CIRCABC by 30 October 2015 and on ECHA website without undue delay.
Item 6.1 - Substance evaluation - Decision making process **a) Written procedure report on seeking agreement on draft decisions on substance evaluation** **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)***	
MSC took note of the written procedure report. MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting: SEV-DK-004/2013 benzophenone (EC No. 204-337-6) SEV-FR-009/2013 carbon disulphide (EC No. 200-843-6)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases.
Item 6 - Substance evaluation **6.2 Decision making process** **d) General topics** • Update of MSC Working Procedures on substance evaluation	
	Members to flag to MSC-S if their eMSCA experts would have suggestions on the proposed changes in the MSC Working procedures as indicated in the presentation slides, by 9 November.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	MSC-S to prepare a revised MSC working procedure for discussion at MSC-45
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-44/2015/005.
Item 7 – Dossier evaluation **b. Introduction to and preliminary discussion on draft decisions on testing proposals and compliance checks after MS-CA reactions *(Session 1, tentatively open session)*** **c. Seeking agreement on draft decisions on a testing proposal examination and a compliance check 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): TPE 114/2015 1,1,3,3-tetramethylbutyl hydroperoxide (EC No. 227-369-2) CCH-072/2015 titanium tetrachloride (EC No. 231-441-9)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases.
Item 8 – ECHA's draft recommendation of priority substances to be included in Annex XIV b) Substances for the 7th recommendation: Discussion on the substances suggested for inclusion in the draft recommendation and the respective draft Annex XIV entries prior to public consultation	
MSC took note of the work carried out in preparation of the draft recommendation on inclusion of substances in Annex XIV and provided feedback on the recommendation.	**SECR** to consider further MSC input on substances that are under consideration to be recommended. **SECR** to launch public consultation on the draft recommendation, planned for 17 November 2015.
Item 9 – Opinion on the draft recommendation of priority substances to be included in Annex XIV: **Tasks and appointment of Rapporteur and possible working group** Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the 7th draft recommendation and for Working Group membership **d.** Task of the (Co-)Rapporteur in drafting the opinion of MSC **e.** Appointment of (Co-)Rapporteur **f.** Establishment of a MSC Working Group to support the Rapporteur	
MSC adopted the mandate and the tasks of the rapporteur, and appointed one member as a Rapporteur for drafting the MSC opinion on ECHA's 7th draft recommendation for Annex XIV. MSC established a working group to support the	**SECR** to send the appointment letter to the Rapporteur.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Rapporteur and appointed volunteering members and experts to it.	
Item 10 – MSC Work plan for 2016	
MSC took note of the work plan for 2016.	
Item 11 – MSC Manual of decisions (MoD) Review of one existing entry in MoD	
MSC agreed to update one entry (1.1.5) of the MSC Manual of Decisions and Opinions (MoD), as revised at the meeting.	**MSC-S** to update on MSC CIRCABC the MoD as revised, by 4 November 2015.
Item 13– Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-44 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC CIRCABC by 30 October 2015.

IV. Substance evaluation cases addressed for MSC agreement seeking and agreed in written procedure (WP)

Draft decisions unanimously agreed by MSC in WP:

MSC ID number	Substance name used in draft decision
SEV-DK-005/2013	4,4'-methylenebis[N,N-bis(2,3-epoxypropyl) aniline]
SEV-NL-033/2013	Phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased

V. Dossier evaluation cases addressed for MSC agreement seeking and agreed in written procedure (WP)

Draft decisions unanimously agreed by MSC in WP:

Compliance checks

MSC ID number	Substance name used in draft decision	EC number
CCH-071/2015	Barium dodecairon nonadecaoxide	234-974-5
CCH-093/2015	Antimony	231-146-5
CCH-095/2015	Urea	200-315-5

Testing proposal examinations

MSC ID number	Substance name used in draft decision	EC number
TPE-104/2015	Flue dust, portland cement	270-659-9
TPE-121/2015	Carbonohydrazide	207-837-2
TPE-122/2015	8,9,10,11-tetrachloro-12H-phthaloperin-12-one	244-007-9
TPE-123/2015	p-tert-butylphenyl 1-(2,3-epoxy) propyl ether	221-453-2