MSC/M/39/2014
(Adopted at MSC-40)

Minutes

of the 39th Meeting of the Member State Committee (MSC-39)

8-11 December 2014

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 39th 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

The Chairman informed the Committee that an MSC member had been contacted by a company on an SVHC dossier that is being discussed in the MSC. This type of activity does not respect the General Principles and Guidance for Committees' members of ECHA as it may breach the basic right of members for independence in the decision-making process. Consequently the Chairman requested members to inform MSC-S of any such future communications. When notified by the MSC member the Chairman submitted a complaint to the company who subsequently send an apology and clarification. They believed to have had approached Member State Competent Authority contact points for Classification and Labelling matters (MSCA CLP) using publically available information, and where unaware some of them were also MSC member. At the meeting the Chairman asked the Stakeholder Observers to take learnings from this incident forward and to inform their counterparts that acts to intentionally contact MSC members regarding a dossier that is ongoing in MSC is not considered acceptable. Some further exchange of views took place on this matter, and the Chairman was charged to send an email to the Registrant to accept his apology.
One member declared a potential conflict of interest in respect to the SVHC proposals DOTE and reaction mass of DOTE and MOTE as the member had been contacted by a company on the above dossiers, and therefore considered himself not to be in a position to participate in the vote for those cases.

One member declared a potential conflict of interest in respect to the SVHC proposal DBP 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.

One member declared a potential conflict of interest in respect to the substance evaluation case SEV-NL-025/2012 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.

The Chairman declared a potential conflict of interest in respect to the SVHC proposal DBP and therefore Pilar Rodríguez Iglesias was acting as chair for the specific part of the meeting related to the aforementioned proposal.

No other potential conflicts of interests were declared by any other members, experts or advisers with any other item on the agenda of MSC-39.

One member raised a question in closed session whether it is possible to allow an alternate member to appoint a proxy in cases in which the alternate replaces the member for a reason of potential conflict of interest. In responding SECR referred to Article 19(2) of the MSC Rules of Procedure by which an alternate can vote instead of the member in case of a conflict of interest. Furthermore, Article 5(6) provides that if prevented from participating in a meeting or from sending an alternate, in case one has been appointed, members of the Committee having the right to vote may vote by proxy. It was further clarified that by virtue of Article 5(4) it is not excluded that an alternate can vote by proxy as it states that all other provisions of these Rules of Procedure for the members are, where relevant, applicable also to the alternate members, except the possibility of acting as a rapporteur or co-rapporteur.

The member raising the issue noted that the aforementioned articles of the RoP could also be explained differently, as they could be read in such a way that they deliberately excluded the

possibility to appoint a proxy in the situation where the alternate could not attend the meeting for those agenda items where the member had declared a CoI.

SECR responded that in such cases it should be recalled that the members of MSC are representing a Member State and that caution should be exercised in barring a Member State from expressing its position.

The member that raised the issue supported this response of SECR and decided to accept for this meeting the way in which SECR applied the RoP.

Item 4 - Administrative issues

The Chairman informed the Committee that one member has volunteered as the Rapporteur to the Article 77(3)c request introduced in the MSC-38 meeting, and has now formally been appointed.

Item 5 – Adoption of the minutes of the MSC-38 meeting

The minutes of MSC-38 were adopted as provided for the meeting with the small revision introduced during the commenting period prior the meeting.

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 two substance evaluation cases: SEV-FI-008/2013 - Methylcyclohexane (EC No. 203-624-3) and SEV-DE-015/2013 - Tetrahydrofuran (EC No. 203-726-8). WP was launched on 13 November 2014 and closed on 24 November 2014. By the closing date, responses to WP were received from 25 members with voting rights and from the Norwegian member. From the total of 28 MSC members with voting rights, 25 MSC members voted in favour for the first draft decision, and for the second draft decision a number of 24 members voted in favour and one member abstained from voting declaring a potential conflict of interest. The Norwegian member voted in favour to both draft decisions. Unanimous agreement was reached on the two draft decisions on 24 November 2014.

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-NL-025/2012 Silicon dioxide (EC No. 231-545-4)

Session 1 (open)

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 Dutch CA (NL CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance performed by NL CA on the basis of the initial grounds for concern, i.e. relating to substance characterisation, nanoparticles and toxicity of different forms of the substance.

A total of twenty one 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. In fact because most of the PfA submitters agreed with the way their PfA was reflected in the DD not all PfAs were discussed at the meeting. The PfAs that were discussed at the meeting were related to: 1) provide the possibility to group several individual (not surface treated/ surface treated) Synthetic Amorphous Silica (SAS) forms as an alternative to provide information on physico-

chemical properties per each individual form in Section II and to refer to Annex XI, 1.5. of REACH in Section III; 2) delete the requests for surface areas for different forms and measurement of hydroxylation states; 3) delete the request for number-based particle size distribution (due to technical difficulties in making such measurements) and 4) reject the request for a 90-day toxicity study for four SAS forms or 5) submit already available data.

Deletion of the request for surface areas for different forms and measurement of hydroxylation states was proposed because it is not clear how such information would be used for regulatory purposes. Alternatively, a more thorough explanation of how it would be used was proposed to be given. The request for number-based particle size distribution was proposed to be deleted unless further justification for the methods chosen cannot be added in Section III. Otherwise the choice of method should be left to the Registrants. The request for a 90-day toxicity study for four SAS forms was proposed to be rejected since in the view of the PfA submitter it does not provide any useful additional information for classification or risk characterisation of SAS. The exposure-response relationship of surface (and non-surface) treated SAS has been well investigated in a number of inhalation studies in rats and this data appears to be sufficient to support classification of synthetic amorphous silica for repeated dose toxicity. Therefore, in their view, any additional information would only inform on relative potency differences between forms. On the other hand, providing as an option already available data would be equally suitable and less onerous to obtain the same level of information as by requiring new study results.

The Registrants provided written comments on the PfAs, and clarified them at the meeting. They agreed with the PfA on grouping approach however disagreed with the statement that only the Registrants of the substance know the details of each of its form since the Registrants claimed that downstream users may also perform proprietary surface treatment of untreated SAS and this would constitute confidential business information. Hence they regarded the request for physicochemical properties of each individual surface treated SAS form as disproportionate and the respective proposed request should be rejected. The Registrants explained that the joint registrants have not registered their surface treated SAS nor have they included the existing data on surface-treated SAS in the registration dossier, which in their view is in line with ECHA FAQ 0038 where according to the Registrants, SAS has been explicitly used as example. However, they indicated their willingness to provide existing toxicology data for surface-treated SAS. They agreed with the PfA to delete the request for number-based particle size distribution since there is no scientific proof that decreasing particle size increases the hazards (of SAS). They also agreed to an extension of the deadline.

The Registrants disagreed with the PfA 1) requesting for data representative of production; 2) recommending the use of measurement of tap and pouring density; 3) requesting 90-day inhalation toxicity study with four pyrogenic forms, since the correlation between surface area and hydroxylation state would result in a situation that similar SAS forms would have to be tested twice; 4) requesting an assessment of human exposure and risk since the substance is not classified as hazardous; 5) requesting toxicological information on surface-treated SAS on the basis of an toxicology expert's report which justifies why the toxicology information on untreated SAS can be used to assess the safety of surface treated SAS.

As a response to questions raised by MSC members during the meeting, the Registrant's representatives confirmed that 1) the recently conducted 90-day study was carried out on precipitated silica and not pyrogenic silica and 2) the information requested in DD on surface area and hydroxylation state is not currently available for aerosil 200 (in the key study of Reuzel at al. (1991)).

Session 2 (closed)

Regarding the grouping approach there was a general consensus to include it as an option to request for physico-chemical properties of each individual SAS form. However a more robust justification on proportionality was further elaborated upon and included in the draft decision.

Regarding the requests for surface areas for different forms and measurement of hydroxylation states it was insufficiently shown that there is a linear correlation between surface area and hydroxylation state for SAS as produced. Furthermore, it had not been established that the supposed correlation covers the full range of surface areas and hydroxylation states for the registered forms of SAS, hence the request in the DD was considered valid.

Regarding the request for number-based particle size distribution, the PfA submitter accepted the justification presented by the eMSCA for keeping the request in the DD.

Regarding the request for a 90-day toxicity study for four SAS forms eMSCA explained that the joint registration contains hundreds of forms. The proposed decision contains requests to test on only four of these forms, i.e. testing on the most relevant forms. The eMSCA expressed concern that the differences in surface area clearly indicated by the Registrants could lead to differences in toxicity hence they are requesting for a 90-day inhalation study on four SAS forms. MSC agreed not to wait for the physical-chemical characterisations before asking for toxicological data, and it was agreed to provide the option to the Registrants to use available sub-chronic toxicity studies for any of the four pyrogenic SAS forms to be tested taking into account the modifications to OECD 413 indicated in the decision and that such tested form is fully characterised.

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

SEV-UK-036/2013 Triphenyl phosphite (TPP) (EC No. 202-908-4)

Session 1 (open)

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

The evaluating Member State Competent Authority (eMSCA) from United Kingdom CA (UK CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance performed by UK CA on the basis of the initial grounds for concern, i.e. relating to suspected CMR (reproductive toxicity); sensitiser; suspected endocrine disruptor; exposure/wide dispersive use; consumer use and aggregated tonnage. Additional concerns were identified during the course of the evaluation. These were repeated-dose toxicity; genotoxicity; hydrolysis; biodegradation; tonnages of and risk management measures in place for transported isolated intermediate use.

A total of ten 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. PfAs discussed at the meeting were related to 1) request for an *in vitro* micronucleus study (MN; OECD 487) to tackle the genotoxicity concern; 2) extended one-generation reproductive toxicity study (EOGRTS; OECD 443); 3) pre-natal developmental toxicity (PNDT; OECD 414) test; 4) 90-d repeated dose toxicity test (RDT; OECD 408); 5) biotic and abiotic degradation of TPP (OECD 301D, OECD 314, OECD 303, OECD 309) and 6) aerobic and anaerobic transformation in soil (OECD 307).

The Registrants provided comments on the PfAs both in writing and at the meeting. They agreed with the use of the tiered testing strategy in the DD since it is practical and efficient. In their view the EOGRTS and developmental toxicity testing should only be considered as a second tier based on the outcome of their proposed hydrolysis research. The Registrants stressed that TPP hydrolyses rapidly into phenol as primary product with a half-life of 0.5 – 1 hour in neutral pH. They explained that hydrolysis rate increases with increasing acidity. They agreed to conduct additional hydrolysis research to provide the best estimates of TPP hydrolysis rates including the rates in simulated stomach acid. If these results demonstrate rapid and complete level of hydrolysis of TPP to phenol then they consider using the phenol 2-generation reproductive data to address the missing endpoints without additional animal testing. Hence since in the view of the Registrants the substance is readily hydrolysed to phenol it is not expected to reach soil in significant quantities. The Registrants mentioned

that the classification of phenol was updated to aquatic chronic 2 as a self-classification by the Registrants. The dossier for TPP would be updated with the new scenarios for downstream users and with classification of skin sensitisation, acute toxicity 4 and specific target organ toxicity STOT-RE2. Furthermore, the Registrants advised not to conduct the PNDT on rabbit.

Regarding genotoxicity/mutagenicity testing i.e. *in vitro* MN study, the PfA submitter requesting additionally for 1) a Bacterial reverse Mutation test concerning DNA cross links/oxidative mutagenesis (i.e. test method EU B13/14, OECD 471 with and without metabolic activation) and 2) Mammalian cell gene Mutation test (test method: EU B17, OECD 476), explained that such PfA was submitted since under REACH it is a standard information requirement to ask for an *in vitro* gene mutation study. The MSC discussion highlighted it that a gene mutation test should only be requested if the other tests are negative. eMSCA was of the view that a third *in vitro* assay does not increase sensitivity but reduces specificity, in line with the UK's Committee on Mutagenicity conclusions. Hence, eMSCA could agree to ask for the bacterial reverse mutation test and the *in vitro* micronucleus test but not the mammalian cell gene mutation test.

Regarding EOGRTS, the PfAs submitted were requesting for DNT and DIT cohorts and F2 generation. The eMSCA was, however, of the view that there was not enough evidence for triggering the DIT cohort or F2.

To tackle the concern for developmental toxicity PfAs were received requesting for PNDT in rats or rabbit as an option. eMSCA could agree to request for a PNDT as a second study in a tiered approach following the EOGRTS.

Regarding repeated dose toxicity testing (OECD 408) one PfA requested for a sub-chronic toxicity study (90-day) since repeated dose toxicity is an additional concern identified and combined with the human exposure and risk management concern warrants requesting OECD TG 408. eMSCA was of the view that the information provided by the OECD 422 study is sufficient to conclude that TPP meets the criteria for classification as STOT-RE. On such grounds a separate 90-day sub-chronic toxicity study may be waived in accordance with the Annex IX section 8.6.2., column 2 adaptation.

Regarding the environmental endpoints (biotic and abiotic degradation and aerobic and anaerobic transformation) the main concern leading to these PfAs was the adsorptive nature of TPP. Hence for degradation it was proposed to replace OECD 301D and OECD 314 with OECD 309 including both a pelagic and a suspended sediment part with high carbon content because of the current uncertainty regarding whether strong sorption to organic particulate and dissolved matter in natural water bodies prolongs the degradation rate. Another PfA proposed to check the fate of TPP in the soil compartment by requesting for aerobic and anaerobic transformation in soil (test method: OECD 307).

Session 2 (closed)

Regarding genotoxicity/mutagenicity testing it was agreed not to ask for the Mammalian cell gene Mutation test as a first tier testing but to explain to the Registrant that in accordance with Annex VIII, 8.4.4., column 2, the outcome of the *in vitro* micronucleus study and the Bacterial reverse Mutation test would determine the need for follow-up tests.
Regarding the EOGRTS the eMSCA further explained that they do not consider that there is a trigger to the DIT cohort since the increase in thymus weight was only in one group of females and not in males, females in the 28-day repeated-dose cohort, nor in males or females of the F1 generation furthermore, decrease in the thymus weight is generally observed with chemicals that are toxic to the immune system. There were no changes to other immune organs like the spleen and no changes in white blood cell count. Other views highlighted that the increase in thymus weight as a finding is of concern which requires follow-up. The discussion was concluded by providing the Registrant the option to include the DIT-cohort.

In conclusion, MSC unanimously agreed to request for 1) a bacterial reverse mutation test to investigate the potential for DNA cross links/oxidative mutagenesis in addition to the *in vitro* MN study; 2) an EOGRTS in rats by oral route with the DNT cohort without F2 generation; 3) a PNDT in rats or rabbits by oral route (request dependent upon the outcome of the EOGRTS); 4) to keep the request for the aerobic sludge treatment, A: activated sludge units, B: biofilms (test method OECD 303A or B); 5) to request for Aerobic Mineralisation in Surface Water Simulation Biodegradation Test (test method EU C.25/OECD 309) and with natural freshwater amended with sediment, including both the kinetic transformation and the pathway of transformation at 12°C; 6) to modify Section III statement of reasons on the details and rationale for requesting the information respectively and 7) to set the deadline for submitting the information at 30 months.

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

d. Update to MSC working procedures on substance evaluation

SECR presented an update to MSC's working procedures for processing of draft decisions resulting from substance evaluation process. The update was introduced as an attempt to streamline the process and to align the two evaluation procedures of MSC. After some further edits at the meeting MSC adopted its updated working procedures for substance evaluation.

e. Short general update by the secretariat

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

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 13 November 2014 and closed on 24 November 2014. By the closing date, responses to WP were received from 26 members with voting right and from the Norwegian member. Unanimous agreement was reached on six DDs. The MSC Chairman terminated the written procedure for one DD on the basis of Article 20.6 of the MSC Rules of Procedure as at least one MSC member requested discussion at the MSC-39 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 testing proposals when amendments were proposed by MS's *(Session 2, closed session)*

CCH-249/2014 The product from burning of a combination of carbonaceous materials (EC No. 931-597-4)

Session 1 (open)

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

One PfA on pre-natal developmental toxicity study (PNDT, OECD 414) in rats or rabbits, oral route suggested rejecting the study, indicating the most significant human health hazards of the registered substance relates to the lead content. A 28-day study with ash reported no other toxicological changes than elevated blood lead levels. The risk management of the registered substance would be dominated by the need to manage lead exposure.

Following the receipt of the PfA, SECR had added in Section II of the DD a general note for consideration by the Registrant on adaptations of the testing requested. In Section III of the DD, SECR had added further clarification with regard to the applicability of risk management measures pursuant to Annex I, section 0.5 of the REACH Regulation stating that "in accordance with section 3 of Annex XI in some cases it may not be necessary to generate

missing information because risk management measures and operational conditions which are necessary to control a well-characterised risk may also be sufficient to control other potential risks, which will not therefore need to be characterised precisely". However, in the present case ECHA found that the risk or hazard posed by the registered substance had not yet been "well-characterised".

Registrant's comments on PfAs of CAs and discussion

The Registrant provided comments on the PfA and the DD and supported the approach proposed in the PfA for rejecting the PNDT. He also outlined new information that might be relevant, but was not included in the registration dossier.

During the discussion, it was explained to the Registrant that a dossier update with justified adaptation can also be submitted after ECHA has issued the final decision. ECHA will evaluate the submission and draw a conclusion on whether the dossier is considered to be compliant in the follow up process.

Session 2 (closed)

SECR reiterated the conclusions of the open session and justification of the modifications in the DD was provided. During the discussion it was brought up that currently the Registrant has not specified the concentration range of the toxic constituents of substance, neither has he justified explicitly why the other constituents, in addition to lead, are not relevant in terms of the toxicity of the substance. Furthermore, no PNDT study on lead or on any other constituent or the substance has been provided. Also no adaptation based on data in the dossier or in the Registrant's comment to the PfA, has been suggested.

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

CCH-260/2014 4,4'-ethylidenediphenyl dicyanate (EC No. 405-740-1)

Session 1 (open)

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

Four PfAs were received in total to ECHA's DD. A general PfA indicated that the substance has harmonised classification Aquatic Chronic 1, but in the dossier is marked Aquatic Chronic 2. Three PfAs suggested, relating to three requested study summaries (*in vivo* skin irritation and sensitisation, and *in vitro* gene mutation study in bacteria), to let the Registrant decide whether to revise the existing summary or to perform a new experiment.

The Registrant had provided comments on the PfAs stating that he will contact the owner of relevant data and then update the dossier.

The MSC Chairman introduced the case, which is the first one in MSC dealing with data sharing with former cases on substances that have been notified under Directive 67/548/EEC (also called NONS), to inform MSC members and stakeholder observers on data sharing provisions within REACH.

A general presentation on data sharing provisions following inquiries prior to registration was provided as background information for MSC. SECR noted that the NONS dossier contains, among other data, an *in vivo* study on skin irritation, which can satisfy the needs of the requirement for *in vitro* testing, and a study on skin sensitisation. One MSC member noted that there is no reason to believe that the studies in the NONS dossier would not be valid.

Regarding the gene mutation testing, another member questioned the quality of the Ames test in the NONS dossier, where generally the battery of strains did not include a bacterial strain to investigate cross-linking agents as now prescribed in the updated OECD test method. MSC agreed that the study summary for this endpoint should be upgraded or a new test be carried out.

One stakeholder observer appreciated the use of existing data in order to reduce both animal testing and costs.

Session 2 (closed)

One MSC member suggested to refer to the scientific guidance on integrated testing for skin irritation that is now available in the OECD Guidance Document 203 (*New guidance document on an integrated approach on testing and assessment (IATA) for skin corrosion and irritation*).

MSC found unanimous agreement on ECHA's DD as amended at the meeting.

CCH-268/2014 Diphenyl ether (EC No. 202-981-2)

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 suggesting a MSC discussion.

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

The first two PfAs suggested that additional information should be requested on respectively simulation testing of ultimate degradation in surface water and sediment and on soil simulation testing. The Registrant's waiving of the simulation tests was not considered justified, as the available screening data do not provide enough evidence to conclude that the substance was readily biodegradable. The PfAs refer to five studies in the dossier.

The third PfA related to revised environmental exposure assessment and risk characterisation suggested to request information on (a) the lack of environmental exposure and risk assessments and lack of justification for assuming absence of environmental releases in four exposure scenarios (ES); and (b) applicability of sector specific environmental release category(spERC) for ES2.

The Registrant had provided comments on the PfAs and on the DD. In his comments he believes that the water and sediment simulation test and the soil simulation test are not necessary, but proposes to repeat the biodegradation screening study in water (OECD 301F) to confirm the readily biodegradability of diphenyl oxide. In addition, he agreed to the PfA on environmental exposure assessment and risk characterisation.

MSC was satisfied with ECHA's response to the third PfA whilst the two first PfAs were discussed by MSC at the meeting.

Several members considered the referred studies in the technical dossier could not unambiguously clarify whether the substance is readily biodegradable, for example an enhanced ready biodegradability test would be informative. In the discussion on triggers for simulation testing it was considered such tests are to inform persistence assessment and have relevance for the quantitative risk assessment. SECR informed that the log Koc of the substance was 3.3, and questioned whether this was enough to consider the substance to have a high potential for adsorption and to trigger a request for a simulation test in soil (OECD 307) or in sediment (OECD 308). Several MSC members believed that if a simulation test is requested, it should preferably be conducted in water (OECD 309). SECR expressed the view that an OECD 309 test could not be asked at this stage, as it has not been referred to in the DD or in the PfA.

SECR suggested that as the Registrant proposed to perform an OECD 301F test, in the view of SECR exceptionally at this stage MSC should not address the soil simulation testing but ascertain adequate follow up of the case. When the results of the OECD 301F study become available, ECHA would assess the outcome and, if necessary, initiate a new compliance check to address whether biodegradation simulation testing is needed. Should the Registrant not perform the OECD 301F test or clarify in a sufficient way the biodegradability of the registered substance, ECHA also committed to initiate a new compliance check to request further biodegradability testing which may include simulation testing (e.g. in water, sediment or soil).

Based on the above considerations, MSC supported to add a note in Section III acknowledging that the Registrant suggested carrying out an OECD 301F test and that the

follow up to the decision will consider the compliance of the endpoints on a biodegradation and decide on further regulatory measures.

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

TPE-072/2014[4-[p,p'-bis(dimethylamino)-benzhydrylidene]-cyclohexa-2,5-dien-1-ylidene] dimethylammonium m-[[p-anilinophenyl]azo]-benzenesulphonate (EC No. 265-449-9)
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.

SECR explained that one PfA was received in total to ECHA's DD agreeing with ECHA's request for the comet assay, which has a recently adopted OECD Testing Guideline (TG 489), but requested to also investigate potential germ cell mutagenicity in case of somatic mutations through inclusion of gonadal cells in the test examination.

The Registrant did not provide comments on the PfA.

MSC was satisfied with the response of ECHA to the PfA to add a note to consider including a sampling also of gonadal cells in the testes tissue. However, in the discussion some members referred to the potential technical difficulties, for example on freezing the cells for later investigation. SECR suggested it would be best to study the gonadal cells immediately at the same time as the studies were conducted in the somatic cell samples.

A member emphasized that if the mutagenicity in somatic and germ cells were investigated simultaneously and both resulted in positive outcomes, germ cell mutagenicity could be concluded without the need for new animal tests (for instance on toxicokinetics or through TGR assay on germ cells). One stakeholder supported to include the note as the examination of gonadal cells would optimize the use of animals.

Session 2 (closed)

MSC found unanimous agreement on ECHA's DD as amended at the meeting.

d. General topics

1) New compliance check strategy

SECR presented its new CCH strategy being implemented in 2015 and focusing on checking information on substances that have biggest impact on improved protection of people and the environment. CCH will be better integrated with other REACH and CLP processes and also be better coordinated with non-regulatory measures, in order to maximise the impact on the safe use of chemicals. The main focus in CCH is on eight "super" endpoints, which are also the key ones for identification of substances of concern.

One MSC member inquired about by the statement in the SECR presentation that the substance identity would be assessed 'to the extent relevant'. SECR clarified that once a dossier is opened for CCH, and prior to the evaluation of any other information, the substance identity would be screened and used to define the scope of the CCH (with regard to both substance identity and other information requirements). One stakeholder observer considered further use of non-regulatory tools useful and encouraged SECR to focus on reporting and to share learnings of the new strategy, in particular if more expert judgement is involved in the assessment. SECR considered that the "catalytic effect" could be enhanced for example by improved Article (54) reporting and by strengthening the MSC Manual of Decisions.

2) Status report on on-going evaluation work

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

e. Short update on appeals *(Closed session)*

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

Item 8 - Community Rolling Action Plan (CoRAP) update

Preparations for the MSC opinion on the draft Community Rolling Action Plan (CoRAP)

- Report by the Rapporteur and discussion on the first draft opinion of MSC followed by exchange of views on the draft opinion

The Rapporteur introduced the working group (WG) members and explained how they have organised the work in order to come up with the draft opinion. The documents as a basis for their opinion were the draft CoRAP Update 2015-2017, the 2011 selection criteria and the justification documents prepared by the evaluating MSCA on each substance found in the draft CoRAP Update. The WG and the rapporteur were of the opinion that for most substances on the draft CoRAP there are sufficient grounds to consider that the substance may constitute a risk for the environment and/or human health, thus the draft opinion supports the draft CoRAP. However for three substances only hazard related selection criteria were listed in the justification document (JD), consequently the initial grounds for concern are hazard based. MSC discussed whether it is considered sufficient to support their inclusion under CoRAP when no exposure or risk related criteria are included. It was suggested that if exposure is not the main concern for a substance to be on put on CoRAP, the legal basis for the substance to be included in CoRAP could be Article 45(5).

One stakeholder observer appreciated the transparency of ECHA in this process, since ECHA published already on 30 October 2014 the draft CoRAP including the non-confidential substance names, CAS and EC-numbers, the tentative year of evaluation, and the contact details of the proposed evaluating Member State as well as a brief indication of the initial area of concern on ECHA website.

MSC was invited to send comments to the Rapporteur on the Annex and draft opinion by 9 January 2015 and to remind their evaluating CA to update the justification documents of the substances they are evaluating latest by 19 December 2014.

Item 9 – SVHC identification

a. Written procedure report on seeking agreement on identification of SVHCs

SECR gave a brief report on the outcome of the written procedure for SVHC agreement seeking on the identification of four substances, as follows: *cadmium fluoride* and *cadmium sulphate* are proposed to be identified as SVHC based on Article 57 (a), (b), (c) and (f) as carcinogenic, mutagenic, toxic for reproduction and as substances of equivalent concern (kidney and bone effects) to the substances identified as SVHCs under Article 57 (a)-(e) of the REACH Regulation; *2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)* and *2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)* are proposed to be identified as SVHC based on Article 57 (d) and (e) as PBT and vPvB substances. It was explained that MSC agreed unanimously on identification of *cadmium fluoride, cadmium sulphate, UV-320* and *UV-328* as an SVHC in the written procedure launched on 17 November 2014 and closed on 27 November 2014. SECR explained that the final documents will be made available on MSC CIRCABC and on the ECHA website and the substances will be included in the Candidate List of SVHCs.

b. Seeking agreement on Annex XV proposals for identification of SVHC

- **Bis(2-ethylhexyl) phthalate (DEHP)** (EC No. 204-211-0)
- **Dibutyl phthalate (DBP)** (EC No. 201-557-4)
- **Benzyl butyl phthalate (BBP)** (EC No. 201-622-7)
- **Diisobutyl phthalate (DIBP)** (EC No. 201-553-2)

The dossier submitter (DS) representative from the Danish CA presented to MSC the Annex XV proposals for additional identification of the above-mentioned four substances (already identified under Article 57 (c) due to their toxicity to reproduction) as SVHCs under Article 57 (f) due to their endocrine disrupting properties for which there is evidence of probable serious

adverse effects to both **human health** and the **environment** giving rise to equivalent level of concern (ELoC) to CMR, PBT and vPvB substances under Article 57 (a)-(e). DS explained the rationale for preparing the dossiers and pointed out that the proposals for **human health** for the four substances are largely based on experimental data on mode of action and adverse effects in mammalian species in particular rodent species. In relation to the **environment**, the proposals for **DEHP** and **DBP** have been prepared on the basis of experimental data on mode of action and adverse effects in rodents and fish and/or amphibians, while for **BBP** mode of action was based on test data from rodents, fish and amphibians while read across from DEHP and DBP was employed in relation to adverse effects on non-mammalian wildlife and for **DIBP** mode of action and adverse effects was based on test data from rodents and a read across approach from DEHP and DBP had been applied for mode of action and adverse effects in non-mammalian wildlife species.

The DS outlined the main comments received in the public consultation on these proposals and the DS's responses to them. DS expressed the view, based on a detailed comparison between the text of REACH art. 57 (f) and the wording of the WHO/IPCS definition of endocrine disrupters, that only the probability of serious adverse effect should be evaluated in the ELoC assessment under Article 57 (f). The DS also emphasised that there is no legal requirement that information about environmental fate and exposure should be considered at this stage and that no reference is made to this in art. 57 (f), which only refers to probable serious effects due to e.g. endocrine properties. The DS was of the view that exposure-related criteria (such as wide dispersive use and tonnage) are instead relevant during the later stages of the authorisation process and referred in this context to the exposure related proxies such as "wide dispersive use" and "high tonnage" listed in article 58.3 related to the prioritisation of the already identified SVHCs for inclusion in the Authorisation List. It would, in the view of the DS, not be logical as proposed by some comments to include exposure related issues already in the identification of endocrine disrupters in accordance with art. 57 (f), where exposure related issues are not referred to. In particular, the DS argued this would not be logical as such considerations according to art. 58.3. have to be done at the later stages of the authorisation process namely when prioritisation of the identified SVHCs for inclusion on the Authorisation List takes place and in the authorisation application and decision making phase.

In the following discussion, MSC sought further clarification with regard to a number of issues including: the added regulatory value of the additional identification of these substances as SVHCs under Article 57 (f) to the existing one due to their toxic for reproduction effects; and concerns on practical implications and regulatory consequences from this additional identification process for the currently processed applications for authorisation of these substances. The Commission's observer explained that if the four substances are identified as SVHCs under Article 57 (f), following amendment of the Candidate List the Commission would have to update the Annex XIV entries including setting up relevant transitional arrangements (timing of the update is uncertain). If the substances were identified as SVHC under Art 57(f) for the **environment**, uses that are currently exempted from the authorisation requirement because the existing identified SVHC property "toxic for reproduction" only refers to health hazards (e.g. uses in cosmetic products or in food contact materials) may become subject to authorisation. If a new identified SVHC property (57(f) endocrine disruption) is to be included in the entries in Annex XIV, a lower concentration limit of 0.1% would apply to the use of the substances in mixtures with regard to authorisation obligations, whereas currently a concentration limit of ≥0.3% applies. However, the Commission would need to amend Annex XIV before these potential further authorisation obligations would start to apply. The Commission representative stated that in accordance with Article 60(3) applicants may have to apply for authorisation under the socio-economic route unless a threshold in accordance with Section 6.4 of Annex I can be determined.

With regard to **DEHP** and the **environment**, MSC supported the DS's conclusions, that on the basis of data from mammalian and ecotoxicological (fish) studies, DEHP has been shown to adversely affect the endocrine system of mammals and non-mammalian wildlife giving rise to serious effects. A MSC industry observer noted that different species should be considered and addressed by MSC. In response, MSC amended the support document to reflect on mammalian species diversity and potential differences in sensitivity but also noting that

endocrine-related adverse effects have been recorded in several of the few vertebrate species that have been adequately tested.

In conclusion, when available information from mammalian and ecotoxicological studies are combined, **DEHP** can be considered an endocrine disruptor (ED) for the **environment** as it fulfils the WHO/IPCS definition of an endocrine disruptor and hence the recommendation of the European Commission's Endocrine Disrupters Expert Advisory Group to base the identification of a substance as an endocrine disruptor on this definition.

As regards **DBP** and the **environment**, data was presented on endocrine mode of action and adverse effects from studies on mammals, fish and amphibians. While the MSC agreed that DBP did exhibit an endocrine mode of action, additional views specifically for this substance were expressed indicating that there was a need to strengthen the ELoC justification. In particular, concern was expressed that ED effects in fish were observed at experimental concentrations which may not be found in the environment, and based on the environmental fate data, it was questioned whether it was probable that there would be serious effects on mammals in the environment. The DS reiterated the view that environmental fate and exposure were not relevant at this stage; and pointed out the serious adverse ED effects of population relevance that this substance can have on wildlife species.

As regards **BBP** and the **environment** data was presented on endocrine mode of action from studies on mammals, fish and amphibians and as regards **DIBP** and the **environment** data was presented on endocrine mode of action from studies on mammals. Data on both substances was presented regarding adversity of ED effects in mammals. Concern was expressed regarding the lack of specific experimental data for both these substances regarding adversity in non-mammalian wildlife, and questioning the validity of the applied read across approach from **DEHP** and **DBP** for drawing conclusions on the effects on non-mammalian wildlife. In addition, based on the environmental fate data, it was questioned whether it was probable that there would be serious effects on mammals in the environment. The MSC member who is affiliated with the MSCA that had performed the risk assessment for **BBP** under the former Existing Substance Regulation, informed MSC that in the follow-up studies it has been identified that **BBP** and **DBP** form the same highly toxic metabolite in very quick metabolic reactions, whereas a NOEC could not be established (only a LOEC) as effects were found at very low concentrations.

As regards the **human health** parts of Denmark's proposals, the same considerations were brought forward for all four phthalates. Some members expressed the view that the main concerns from these substances are already sufficiently covered by their Repr. 1B classification, based on which the substances have been identified under Article 57 (c). As the same dataset is used for the ELoC assessment, this was seen as 'double counting' while in their view, Article 57(f) is to be used only as a safety net. Other members supported the DS's argumentation that not all elements (e.g. endocrine mode of action and the established link between the endocrine activity and the identified adverse effects) have been considered with the Repr. 1B classification and the identification under Article 57 (f) could compliment the regulatory management of these substances ensuring their safe use.

SECR stated that from a legal point of view, MSC has a task to conclude whether a substance meets one or more criterion as set out in Article 57(a)-(f). Substances have been identified based on several grounds, including as both PBT (Article 57 (d)) and vPvB (Article 57 (e)). It is also possible that an ED substance could be first identified as SVHC under Article 57 (f) and then subsequently identified as SVHC under Article 57 (a)-(c) following a relevant harmonised classification.

An MSC observer representing the environmental and human health NGOs expressed concerns regarding an interpretation of the REACH regulation that would not permit SVHC identification of a substance and its inclusion in the Candidate List based on more than one identification ground and the possible communication consequences to the public in this regard in a case where a substance is considered as an ED. Several MSC members supported this observation and noted that MSC should focus on whether there is sufficient evidence of probable serious ED mediated effects which would merit SVHC identification under Art 57(f).

Considering the likelihood for reaching unanimous agreement on the SVHC identification proposals and recognising the arguments and observations made, the dossier submitter

requested splitting each of the four Annex XV proposals into two, with one proposal covering the human health part of the original proposals and the other part covering the environment, such that voting separately on each of the eight proposals was possible. After further consideration, the dossier submitter informed MSC of its decision to **withdraw** its proposals for identification of **DBP, BBP and DIBP** under Article 57 (f) as giving rise to an equivalent level of concern due to endocrine disrupting properties in relation to the **environment** in order to further elaborate on the justifications provided in the documentation.

MSC reached unanimous agreement on identification of **DEHP** as SVHC under Article 57(f) as giving rise to an equivalent level of concern due to endocrine disrupting properties in relation to the **environment**.

MSC went through the proposal for **DEHP** identification for **human health** and unanimously agreed the text of the Support Document with amendments introduced at the meeting, except section 6.7 where the conclusion of Equivalent Level of Concern (ELoC) could not be supported by some MSC members. A similar outcome was reached for the Support Documents of **DBP**, **BBP** and **DIBP**. In conclusion, MSC unanimously acknowledged that for all four substances there is scientific evidence on the endocrine activity and on the link between this activity and the adverse effects to human health. However, MSC did not reach unanimous agreement on identification of DEHP, DBP, BBP and DIBP under Article 57(f) as giving rise to an equivalent level of concern due to endocrine disrupting properties in relation to human health.

When the MSC agreement documents and support documents were brought to a vote, a majority of the members agreed the available information for **DEHP, DBP, BBP and DIBP** was sufficient to conclude that there is scientific evidence of probable serious effects giving rise to an equivalent level of concern in relation to **human health** (i.e. to substances listed in points (a) to (c) in Article 57 of the REACH Regulation).

Five members abstained from the vote.

A minority of four members were of the view that the concern related to endocrine disruption is already covered by the existing identification as SVHC due to toxicity for reproduction.

Consequently these members did not agree on the identification of DEHP, DBP, BBP and DIBP under Article 57(f) as giving rise to an equivalent level of concern in relation to **human health** (i.e. to substances listed in points (a) to (c) in Article 57 of the REACH Regulation). The minority view submitted after the meeting in writing will be annexed to the MSC opinion.

Referring to the minority position arguments presented after the vote, several MSC members raised concerns that new elements were introduced, particularly regarding Risk Assessment Committee (RAC) deliberations, which were not raised during the MSC discussions. These members expressed a concern that by introducing the link to RAC at such a late stage, MSC was denied an in-depth scientific discussion on these objections.

Following the MSC agreement seeking and in accordance with Article 59 (9) of the REACH Regulation, SECR presented to the committee a tentative timeframe for the MSC opinion development based on the view of the majority of the members (with minority position attached to the opinion) on the **human health** related aspects of the SVHC proposals of **DEHP**, **DBP**, **BBP** and **DIBP** under Article 57(f) for which MSC did not reach unanimous agreement. MSC agreed on the timeframe without further changes.

The Chair thanked the dossier submitter for the challenging proposals submitted to the SVHC identification process, and MSC for its deliberations on them and the unanimous agreement reached with regard to the **DEHP** effects to the **environment**.

- **2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)** (EC No. 239-622-4)

- **Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)** (EC No. -)

The DS representative from the Austrian CA presented to MSC the two Annex XV proposals for DOTE and the reaction mass of DOTE and MOTE based on Article 57 (c) (toxic for reproduction 1B). She indicated that DOTE has harmonised classification and labelling (CLH) as toxic for reproduction 1B in Annex VI of the CLP Regulation. DOTE and the reaction mass of DOTE and MOTE (covering all reaction masses with DOTE $\geq$10%) is proposed for SVHC identification based on the harmonised classification of DOTE (as Repr. 1B) as a main constituent in the reaction mass(es). Majority of the comments in the public consultation were in favour of the DS's proposals. Comments from industry challenging the scientific basis of the harmonised classification of DOTE had been submitted, as well as preliminary results of prenatal developmental toxicity studies

In the following discussion, it was further explained that following the submission of the new hazard information, even though detailed test reports were provided after the end of the public consultation, the MSCA for CLP of the DS had assessed it and came to the conclusion that there was at this moment in time insufficient evidence to prepare a dossier for CLH re-evaluation that might lead to potential change in the CLH conclusions for this substance's toxicity for reproduction. Therefore, they considered it was appropriate to continue the SVHC identification process.

An MSC member from another MS, which had been approached by industry with the same request for preparation of re-classification proposal, also confirmed that in their MSCA's view, despite the new data provided by industry, there are still open questions and at this point in time the MSCA could not sufficiently examine the data to come to a decision on preparation of a CLH re-classification proposal. Another MSC member noted that his MSCA was also approached in this regard. The member pointed out that at first look the information that was shared with his MSCA may allow a re-classification, but as not all data was available and a full data evaluation had therefore not been concluded by the time of the MSC deliberation, he considered himself not in a position to vote on these proposals.

Two MSC industry observers pointed out that industry made an effort to generate and submit new information on these proposals even though it came late in the process and made a plea that such is properly considered and used in the regulatory decision making.

It was further clarified that although a substance is included in the Candidate list or in Annex XIV, if the legal basis for its identification as an SVHC changes, it is possible to remove it from these lists or for modification of the entries made as a result of new information on the relevant SVHC properties of the substance, i.e. the Commission has a possibility to remove a substance from Annex XIV or modify the entry made and ECHA may do the same for substances in the Candidate list. In this regard, a MSC member reminded that MSC has already considered such situations in previous SVHC cases and took decisions listed in the MSC Manual of decisions on how to deal with new information submitted outside the public consultation and on how modify/remove entries from the Candidate list.

In conclusion MSC unanimously supported the proposals that DOTE and the Reaction mass of DOTE and MOTE should be identified as SVHCs under Article 57(c) due to the harmonised classification of DOTE as toxic for reproduction. MSC unanimously agreed on the support documents and agreements for both substances as provided for the meeting. One member as referred above abstained from the voting.

The Chairman thanked the dossier submitter for the support provided in the SVHC identification process and MSC for the unanimous agreements reached.

Item 10 – ECHA's draft recommendations of priority substances to be included in Annex XIV

a. Update on ECHA's 6th draft recommendation for inclusion of priority substances in Annex XIV – public consultation outcome

SECR gave a brief update after the closure of the public consultation indicating that comments had been received on all 22 substances. All comments had been made available to MSC and its stakeholder observers. Some further details about the distribution of comments per each substance and the type of commenters were made available during the meeting but SECR noted that it was too early to try to summarise the content. Instead, SECR outlined the

planned next steps for the next half a year, including when the responses to the comments were expected.

b. Indicative time plan for the opinion development on ECHA's 7th draft recommendation for inclusion of priority substances in Annex XIV

SECR briefly introduced the meeting document indicating that it confirms the timing plan for ECHA's 7th recommendation for inclusion of substances into Annex XIV as was already orally presented to MSC in October. Timing of the development of MSC's opinion on that recommendation follows much the one of the 6th recommendation, and consequently there will be some overlap of the two processes. SECR stated that the plan is to submit a recommendation of further substances for inclusion in Annex XIV to the Commission annually.

Item 11 – 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

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

MSC's Rapporteur gave MSC a brief report from the work of the Working Group which had met earlier that week and a first reflection on some of the comments. The large volume of comments, in particular for borates and lead compounds will require further analysis but according to the Rapporteur many of the arguments that had been put forward in the previous recommendations were repeated. A first draft opinion will be referred to MSC in March but a status update by the Rapporteur is also to be expected in the February meeting. Responding to a question about opinion drafting and availability of ECHA's responses and a possible update to ECHA's recommendation after the public consultation SECR emphasised that in this round the whole process has been put forward differently, and that there is actually more time for MSC to develop its opinion than in the previous recommendation rounds. SECR recalled that it had been an explicit wish of MSC members to make more use of the information provided in the public consultation for the decision on which substances from the draft recommendation to include in the final recommendation. SECR will use the comments and MSC's opinion when finalising its recommendation for submission to the Commission. It was further mentioned that substances not included in the 6th recommendation are likely to be of high priority in future recommendation rounds and all work done now will be useful in future. It is anticipated that predictability and transparency of the whole process, in particular for industry, is increased.

Item 12 – Work plan of MSC for 2015

SECR introduced the work plan of MSC for 2015 and the tentative meeting dates for six meetings currently planned: 2-6 February, 20-24 April, 8-12 June, 14-18 September, 26-30 October and 7-11 December. Actual length of the meeting would be specified only once the agendas become clearer.

Item 13 – Any other business

No suggestions have been received by members under this agenda item.

Item 14– Adoption of conclusions and action points

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

SIGNED

Watze de Wolf

Chairman of the Member State Committee

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ANASTASI, Audrey Anne (MT)
ANDRIJEWSKI, Michal (PL)
CONWAY, Louise (IE)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
GAIDUKOVS, Sergejs (LV)
HUMAR-JURIC, Tatjana (SI)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina(CZ)
LONDESBOROUGH, Susan (FI)
LOVRIC, Zdravko (HR)
LULEVA, Parvoleta (BG)
LUNDBERGH, Ivar (SE)
MARTÍN, Esther (ES)
MIHALCEA UDREA, Mariana (RO)
PALEOMILITOU, Maria (CY)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK Peter (SK)
STESSEL, Helmut (AT)
TYLE Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
WAGENER Alex (LU)
WIJMENGA, Jan (NL)
Representatives of the Commission
SCHUTTE, Katrin (DG ENV)
STRECK, Georg (DG ENTR)
Observers
ANNYS, Erwin (Cefic)
DEL CASTILLO, Francisco (CONCAWE)
DROHMANN Dieter (ORO)
PALERMO, Chrissy (Cefic)
TAYLOR, Katy (ECEAE)
VAN VLIET, Lisette (HEAL)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
ANDERSSON, Niklas
BERCARU, Ofelia
BIGI, Elena
BONNOMET, Vincent
BROERE, William
CARLON, Claudio
CESNAITIS, Romanas
DELOFF-BIALEK, Anna
DE WOLF, Watze
DREVE, Simina
FALCK, Ghita
HALLING, Katrin
JACQUET, Cyril
JOHANSSON, Matti
KAPANEN, Anu
KARHU, Elina
KARJALAINEN, Anne-Mari
KORJUS, Pia
LEPPER, Peter
LOUEKARI, Kimmo
MÜLLER, Birgit
NAUR, Liina
O'FARRELL, Norah
RODRIGUEZ IGLESIAS, Pilar
RÖCKE, Timo
RÖNTY, Kaisu
SCHOENING, Gabriele
SCHULTHEISS, Christian
SOMPOLSKI, Daniel
VAHTERISTO, Liisa
VASILEVA, Katya
YLÄ-MONONEN, Leena
QUINN, Bernadette

Proxies

- ALMEIDA, Inês (PT) also acting as proxy of DRUGEON, Sylvie (FR)
- ALMEIDA, Inês (PT) also acting as proxy of MARTÍN, Esther (ES) in the afternoon of 11 December
- VANDERSTEEN, Kelly (BE) also acting as proxy of DOUGHERTY, Gary (UK) in the afternoon of 11 December
- VANDERSTEEN, Kelly (BE) also acting as proxy of SCHWAEGLER, Mark (DE) during the decision making on SEV-NL-025/2012
- WIJMENGA, Jan (NL) also acting as proxy of DUNAUSKIENE, Lina (LT) during short periods on 8-10 December

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)
DOBRAK-VAN BRELO, Agnieszka (BE) (expert to VANDERSTEEN, Kelly)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
HAKKERT, Betty (NL) (adviser to WIJMENGA, Jan)
HÖLZL, Christine (AT) (expert to STESSEL, Helmut)
KJUUS, Berit Eyde (NO) (expert to REIERSON, Linda)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBRGH, Ivar)
MENDONÇA, Elsa (PT) (expert to ALMEIDA, Inês)
MICHEL, Cécile (FR) (expert replacing DRUGEON, Sylvie)
NYITRAI, Viktor (expert to DEIM, Szilvia)
PEDERSEN, Finn (DK) (expert to TYLE, Henrik)
RISSANEN, Eeva (FI) (adviser to LONDESBOROUGH, Susan)
SUUTARI, Tiina (FI) (adviser to LONDESBOROUGH, Susan)
TRAAS, Theo (NL) (expert to WIJMENGA, Jan)
ZELJEZIC, Davor (HR) (expert to LOVRIC, Zdravko)

MSCA Expert for SEV cases
McGARRY, Helen (UK)
VAN KESTEREN, Petra (NL)

MSCA Expert for SVHC cases:
BOBERG, Julie (DK)
WIMMER, Martin (AT)

By WEBEX-phone connection:
During the whole meeting: Sylvie DRUGEON (FR) and Frauke AVERBECK (DE)
During the agenda item 6 for SEV-NL-025/2012: Eric BLEEKER (NL), Corinne BELVEZE (FR), Mark SCHWAEGLER (DE), Tom GEBEL (DE), Christine GUHE (DE), Ulrike BERNAUER (DE), Frank HERZBERG (DE)
During the agenda item 6 for SEV-UK-036/2013: Simon HOY (UK), Eric BLEEKER (NL) and Daniel SÄTTLER (DE)
During the agenda item 7 for CCH-268/2014: Daniel SÄTTLER (DE)
During the agenda item 9 for phthalates: Ian DOYLE (UK), Esther ROSENTHAL (DE) and Thomas SCHULZ (DE)
During the agenda items 6, 7, 8, 9, 10, 11 and from the European Commission: Valentina BERTATO, Mariana FERNANDES DE BARROS, Enrique GARCÍA-JOHN, Henrik LAURSEN, Giuseppina LUVARA, Maila PUOLAMAA and Wim RIEPMA

Case owners:
Representatives of the Registrants were attending under agenda item 6b for SEV-UK-036/2013 and SEV-NL-025/2012 and under agenda item 7b for CCH-249/2014.

Apologies:
BASTIJANCIC-KOKIC, Biserka (HR)
BUSUTTIL, Ingrid (MT)
COSGRAVE, Majella (IE)
DRUGEON, Sylvie (FR)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
TALASNIEMI, Petteri (FI)

III. Final Agenda

MSC/MSC-39/2014/A/39

Agenda
39th meeting of the Member State Committee

8-11 December 2014
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

8 December: **starts at 1 pm**
11 December: **ends at 6 pm**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/039/2014
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-38

- Adoption of draft minutes of MSC-38

MSC/M/38/2014
For adoption

Item 6 – Substance evaluation
Closed session for 6c
Indicative time plan for 6b is Day 2-Day 4

Decision making process

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

ECHA/MSC-39/2014/027

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-39/2014/028

- **SEV-NL-025/2012** Silicon dioxide (EC No. 231-545-4)
ECHA/MSC-39/2014/029-030

- **SEV-UK-036/2013** Triphenyl phosphite (EC No. 202-908-4)
ECHA/MSC-39/2014/031-032

For discussion

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

Cases as listed above under **6b**

For agreement

d. Update to MSC working procedures on substance evaluation

ECHA/MSC-39/2014/033

For adoption

e. Short general update by the secretariat

For information

Item 7 – Dossier evaluation

Closed session for 7c and e
Indicative time plan for 7b is Day 3(am)-Day 4

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

ECHA/MSC-39/2014/019

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-39/2014/020

For discussion followed by agreement seeking under 7c:

Compliance checks

MSC code	Substance name	EC No.	Document
CCH-249/2014	The product from burning of a combination of carbonaceous materials	931-597-4	ECHA/MSC-39/2014/023-024
CCH-260/2014	4,4'-ethylidenediphenyl dicyanate	405-740-1	ECHA/MSC-39/2014/025-026

Testing proposal examinations

MSC code	Substance name	EC No.	Document
TPE-072/2014	[4-[p,p'-bis(dimethylamino)-benzhydrylidene]-cyclohexa-2,5-dien-	265-449-9	ECHA/MSC-39/2014/021-

	1-ylidene]dimethylammonium m-[[p-anilinophenyl]azo]-benzenesulphonate	022

For discussion

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

CCH-268/2014[1]	Diphenyl ether	EC No. 202-981-2

For agreement

d. General topics

1) Presentation on new compliance check strategy
(see also Information Documents Table, entry #3)

2) Status report on on-going evaluation work

For information

e. Short update on appeals *(Closed session)*

For information

Item 8 – Community Rolling Action Plan (CoRAP) update

Day 4

Preparations for the MSC opinion on the draft Community Rolling Action Plan (CoRAP)

- Report by the Rapporteur and discussion on the first draft opinion of MSC followed by exchange of views on the draft opinion

ECHA/MSC-39/2014/036
For discussion

Item 9 – SVHC identification

Indicative time plan for item 9 is Day 1-Day 3

a. Written procedure report on seeking agreement on identification of SVHC

ECHA/MSC-39/2014/034 (Room document)
For information

b. Seeking agreement on Annex XV proposals for identification of SVHC

- Bis(2-ethylhexyl) phthalate (DEHP) (EC No. 204-211-0)
  ECHA/MSC-39/2014/010-012
- Dibutyl phthalate (DBP) (EC No. 201-557-4)
  ECHA/MSC-39/2014/001-003
- Benzyl butyl phthalate (BBP) (EC No. 201-622-7)
  ECHA/MSC-39/2014/004-006
- Diisobutyl phthalate (DIBP) (EC No. 201-553-2)
  ECHA/MSC-39/2014/007-009
- 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) (EC No. 239-622-4)

ECHA/MSC-39/2014/013-015

- Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE) (EC No. -)

ECHA/MSC-39/2014/016-018
For discussion and agreement

Item 10 – ECHA's draft recommendations of priority substances to be included in Annex XIV

Day 4

a) Update on ECHA's 6th draft recommendation for inclusion of priority substances in Annex XIV – public consultation outcome

For information

b) Indicative time plan for the opinion development on ECHA's 7th draft recommendation for inclusion of priority substances in Annex XIV

ECHA/MSC-39/2014/039
For information

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

Day 4

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

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

For information and discussion

Item 12 – Work plan of MSC for 2015

ECHA/MSC-39/2014/035
For information

Item 13 – Any other business

- Suggestions from members

For information

Item 14– Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-39

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

#	Document title	Identification number
1	*Update from other ECHA bodies and activities*	ECHA/MSC-39/2014/037
2	*Improving compliance with the second-species prenatal developmental toxicity standard information requirement (For members only)*	ECHA/MSC-39/2014/038
3	*Compliance check strategy (document on ECHA website):* Safer chemicals - focusing on what matters most	http://echa.europa.eu/documents/10162/13608/echa_cch_strategy_en.pdf

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-39, 8-11 December 2014
(adopted at MSC-39)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 5 – Adoption of minutes of the MSC-38	
MSC adopted the draft minutes with the small revision introduced during the commenting.	**MSC-S** to upload final version of the minutes on MSC CIRCABC and ECHA website by 16 December 2014.
Item 6 - Substance evaluation **a. Decision making process** **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 decisions agreed in written procedure, as indicated in document ECHA/MSC-39/2014/027.
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-NL-025/2012** Silicon dioxide (EC No. 231-545-4) **SEV-UK-036/2013** Triphenyl phosphite (EC No. 202-908-4)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases.
Item 6 - Substance evaluation **d. Update to MSC working procedures on substance evaluation**	
MSC adopted the update to the MSC Working procedures as edited at the meeting.	**SECR** to upload to MSC CIRCABC and ECHA website the adopted MSC working procedure on processing of SEV Draft decisions.
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-39/2014/019.
Item 7 – Dossier evaluation **b. Introduction to and preliminary discussion on draft decisions on compliance checks after MS-CA reactions *(Session 1, open session)*** **c. Seeking agreement on draft decisions on compliance checks when amendments were proposed by MS-CA's *(Session 2, closed session)***	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
MSC reached unanimous agreement on the following ECHA draft decisions (as modified in the meeting, where appropriate): • **CCH-249/2014** The product from burning of a combination of carbonaceous materials • **CCH-260/2014** 4,4'-ethylidenediphenyl dicyanate • **TPE-072/2014** [4-[p,p'-bis(dimethylamino)-benzhydrylidene]-cyclohexa-2,5-dien-1-ylidene]dimethylammonium m-[[p-anilinophenyl]azo]-benzenesulphonate • **CCH-268/2014** Diphenyl ether	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases.
Item 8 – Community Rolling Action Plan (CoRAP) update Preparations for the MSC opinion on the draft Community Rolling Action Plan (CoRAP) • Report by the Rapporteur and discussion on the first draft opinion of MSC followed by exchange of views on the draft opinion	
MSC took note of the update.	**MSC members** to send comments to Rapporteur on the draft CoRAP opinion by **9 January** 2015.
Item 9 – SVHC identification **a. Written procedure report on seeking agreement on identification of SVHC**	
MSC unanimously agreed to identify the following substances as SVHC in written procedure: • Cadmium fluoride • Cadmium sulphate • 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) • 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	**SECR** to add the newly identified SVHCs (in written procedure) to the Candidate List. **SECR** to upload the agreements and support documents on MSC CIRCABC and to publish them, as well as the RCOMs, on the ECHA website.
Item 9 – SVHC identification **b. Seeking agreement on Annex XV proposals for identification of SVHC**	
MSC unanimously agreed to identify the following substances as SVHCs (and unanimously agreed on their SDs and agreements): • 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) (EC No. 239-622-4) • Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (Reaction mass of DOTE and MOTE) (EC No. -) MSC reached unanimous agreement on additional identification of Bis(2-ethylhexyl) phthalate (DEHP) (EC No. 204-211-0) as SVHC under Article 57(f) as giving rise to an equivalent level of concern due to endocrine disrupting properties in relation to the environment. MSC took note on the dossier submitter's decision to withdraw its proposals for additional identification of DBP, BBP and DIBP under Article 57 (f) as giving rise to an	**SECR** to add the newly identified SVHCs to the Candidate List (update foreseen by 17 December 2014). **SECR** to upload the agreements and support documents on MSC CIRCABC and to publish them, as well as the RCOMs, on the ECHA website.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
equivalent level of concern due to endocrine disrupting properties in relation to the environment in order to further elaborate on the justifications provided in the documentation. While the MSC agreed on the mode of action and established link between the endocrine activity and the adverse effects underlying the probable serious effects of the substance to human health, MSC did not reach unanimous agreement on identification of • Bis(2-ethylhexyl) phthalate (DEHP) (EC No. 204-211-0) • Dibutyl phthalate (DBP) (EC No. 201-557-4) • Benzyl butyl phthalate (BBP) (EC No. 201-622-7) • Diisobutyl phthalate (DIBP) (EC No. 201-553-2) under Article 57(f) as giving rise to an equivalent level of concern due to endocrine disrupting properties in relation to human health.	Disagreeing MSC members to send to SECR their minority views by 15 December 2014. **SECR** to draft opinion based on the view of the majority of the members (with minority position attached) and send it for MSC commenting by 16 January 2015. **MSC** to submit their comments on the draft opinion by 26 January 2015. **SECR** to revise the draft opinion accordingly and upload it to MSC CIRCABC by 30 January 2015 (for possible adoption at MSC-40 meeting).
Item 14– Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-39 at the meeting.	**MSC-S** to submit draft minutes of MSC-39 for commenting by 16 January 2015. **MSC-S** to upload the main conclusions and action points on MSC CIRCABC by 12 December 2014.

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-062/2014	Poly-(1,4-diisopropylbenzol)	449-400-0
TPE-067/2014	Nickel, 5,5'-azobis-2,4,6(1H,3H,5H)-pyrimidinetrione complexes and melamine	939-379-0

Compliance checks (CCH)

MSC ID number	Substance name used in draft decision	EC number
CCH-251/2014	Polysulfides, di-tert-dodecyl	270-335-7
CCH-264/2014	Sulphuric acid, compound with graphite	235-819-4
CCH-266/2014	1-bromopropane	203-445-0
CCH-267/2014	1-bromopropane	203-445-0