MSC/M/42/2015

(Adopted at MSC-43)

Minutes

of the 42nd Meeting of the Member State Committee (MSC-42)

8-11 June 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 42nd 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-42. The Chairman declared a potential conflict of interest to a specific agenda item. Details of the declared potential conflicts and the mitigating measures are attached to these minutes as Annex IV.

Albeit not a conflict of interest one member announced during the first voting procedure (SEV-SK-026/2013) that due to an ongoing election and potential government change in his country he had received instructions from his organisational hierarchy to abstain from any voting on the items on the agenda.

Item 4 - Administrative issues

As a preparatory step towards migration to Secure CIRCABC platform, SECR informed the Committee of the plans for removing old files from MSC CIRCABC and invited MSC members to provide feedback on the presented plans. After the MSC-42 meeting and further to some feedback received and technical considerations, SECR reconsidered the plan and decided that all the files in MSC CIRCABC will be moved to MSC Secure CIRCABC.

Item 5 – Adoption of the minutes of the MSC-41 meeting

The minutes of MSC-41 were adopted as provided for the meeting with some slight modifications introduced at the meeting based on a member's additional comments.

Item 6 – Substance evaluation

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 five substance evaluation cases (see Section VI for more detailed identification of the cases). WP was launched on 18 May 2015 and closed on 28 May 2015. By the closing date, unanimous agreement was reached on four draft decisions (DD). 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 a discussion of the case at the MSC-42 meeting.

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

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

SEV-PT-025/2013 Biphenyl (EC No. 202-163-5)

Session 1 (open)

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

An expert from the evaluating Member State Competent Authority (eMSCA) from Portugal (PT-CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance performed by PT-CA on the basis of the initial grounds for concern relating to potential PBT properties and high aggregated tonnage. The members were guided through the information requirements and explained that additional concerns for reproductive toxicity of the substance were identified during the evaluation.

Ten proposals for amendment (PfA) were submitted covering the persistence testing, extended one generation reproductive toxicity study (EOGRTS), mutagenicity and the deadline given in the DD. The eMSCA accepted most of the PfAs in advance of the MSC meeting. However, the PfAs related to the persistence (P) testing that were not fully addressed by the eMSCA required more detailed discussion. These were the PfAs proposing to request only the aerobic biodegradation in the sediment simulation test and not the anaerobic part, and to include additionally as Tier-2 of the P testing, a request for inherent biodegradability (OECD test guideline (TG) 302B or 302C).

Regarding EOGRTS, PfAs requiring more detailed discussion were those related to the study design. One PfA requested the deletion of the request for developmental neurotoxicity and immunotoxicity (DNT/DIT) cohorts as the Member State Competent Authority (MSCA) that submitted the PfA could not independently assess the basis of the eMSCA's assessment of neurotoxicity studies and repeated dose toxicity data. eMSCA justified the request for DNT cohorts on an indication that the substance may be neurotoxic in occupationally exposed human adults implying that the eMSCA considers the observed effects to be sufficiently severe. Another PfA proposed to request for the extension of Cohort 1B to produce the F2 generation and to further justify the inclusion of cohorts DIT and DNT in Section III of the DD by referring to the listing in the TEDX List of potential endocrine disruptors on evidence indicating endocrine mode of action. Additionally they recommended that the Registrant and/or eMSCA considers if "the steady state" criteria are met.

Mutagenicity was a new concern identified in a PfA based on the fact that the substance yielded a positive result in two *in vitro* and one *in vivo* tests. The PfA requested a comet assay (OECD 489) by oral route in rat in glandular stomach or duodenum/jejunum and liver.

Regarding deadlines, a PfA proposed to justify why the deadline was extended from 27 months to 30 months and to reconsider appropriate deadline as requested by the Registrant.

The Registrants provided written comments on the PfAs. These were reiterated by the Registrants' representative during the MSC discussion. With regards to the Persistency testing they supported the PfA indicating that the substance is not P however if MSC would include requests for P testing, the Registrants proposed a tiered approach: tier 1 – ready biodegradability testing as enhanced ready biodegradability test; tier 2 - inherent biodegradation testing; tier 3 – sediment simulation testing without anaerobic test; tier 4 – soil simulation testing. The Registrants' representatives explained that the anaerobic part of the test seems to be difficult to perform for many organic chemicals.

With regards to EOGRTS Registrants disagreed with the request to extend Cohort 1B to the F2 generation due to the additional, significant animal usage and because the substance is used under highly controlled conditions with negligible worker or population exposure

(even though dissemination website appears to indicate 'professional use'). They also disagreed with the inclusion of the DNT/DIT cohorts as they considered these were not well justified. The relatively weak literature evidence makes it difficult to establish a clear link between the substance and the effects that were seen during the studies. Furthermore, it was argued that the neurotoxic effects in the occupational settings were not 'serious or severe' and were unspecific, and that extensive data reviewed by US EPA in 2013 indicate that the nervous system is not the primary target of biphenyl's toxicity but that kidney, urinary bladder and liver were affected in repeated dose studies (USEPA 2013, IRIS review).

The Registrants disagreed with the assessment that biphenyl has an endocrine mode of action. Even though *in vitro* observations showed endocrine disruption yet *in vivo* studies indicated liver and kidney as target organs for systemic toxicity. Hence, in the view of the Registrants, the *in vivo* studies should take precedence over the *in vitro* studies, also considering the fact that a recent study showed that biphenyl is eliminated within 24 hours by 95%.

Regarding mutagenicity, the Registrants disagreed that there is a mutagenicity concern for the substance. The ambiguous/weakly positive responses in some of the assays were observed in the presence of metabolic activation indicating that this is caused by a biphenyl metabolite. In general, the Registrant believes that a micronucleus test would be more appropriate to follow this up and *in vivo* biphenyl tested negative in such a test. The Registrants were referred to a USEPA conclusion that the available genotoxicity database indicates that genotoxic responses seen with biphenyl under some experimental conditions are secondary responses to oxidative damage from major biphenyl metabolites and cytotoxicity. USEPA stated that under certain conditions, these biphenyl metabolites may be causing genotoxicity.

Regarding the deadlines, the registrants stated that if the sediment and soil simulation tests were requested sequentially 36 months would have been needed, but with requests for only a sediment simulation study and the EOGRTS, 30 months is achievable.

The discussion in open session on the P testing strategy focused on whether to include the inherent biodegradation study or not. It was argued that an inherent biodegradation study following a ready biodegradation study would not give more information than the ready biodegradation study. Hence, an enhanced ready biodegradation test was a more preferred route. The Registrant explained that in their strategy they proposed the OECD 301F instead of the OECD 301D since OECD 301F has lower inoculum. On the other hand, the eMSCA chose OECD 301D because of the volatility of the substance.

A discussion followed on the study design of the EOGRTS, i.e. whether there is enough evidence to extend Cohort 1B to produce F2 generation and to include the DNT/DIT cohorts. Extension of Cohort 1B depends on the condition that there are indications of an endocrine disrupting mode of action combined with the condition of significant exposure to professionals or consumers. With regards to the endocrine disrupting mode of action there was a common understanding amongst the MSC members from the data available that the hydroxyl metabolites of biphenyl are stronger binding endocrine disruptors than the parent. However, these hydroxylates seem to be excreted within 24 hours which made one member question the relevance of the *in vitro* test in comparison to the *in vivo*. On the other hand, it was pointed out that for the triggering of the cohorts one needs a suspicion that can be substantiated and not proof of endocrine disruption. In fact biphenyl and the hydroxylated forms performed in a very similar manner to well-known endocrine disruptors *in vitro*, i.e. affinity is in the same concentration range, and regards the level of activation of the receptor biphenyl is showing higher efficacy. One expert questioned the relevance of these data as biphenyl was unable to displace 17B oestradiol, the endogenous ligand, in a competition assay even at 10,000 fold excess.

With regards to exposure, the Registrant representatives explained that the differentiation made in the registration dossiers between industrial use and professional use lies with the

size of the labs. Some large labs are part of an organisation/industry (hence industrial use) whilst others are smaller labs operating independently as labs or within the industrial setting of a production site (hence professional use).

With regards to the DNT/DIT cohorts one member highlighted some uncertainties in the scientific papers that were quoted by the eMSCA. However, the eMSCA highlighted the importance of the concern from a weight of evidence perspective.

Regarding the mutagenicity concern that was identified in a PfA, the MSC member from the PfA submitting country noted that, in his view, the standard information requirement for mutagenicity was not clearly incompliant and therefore he accepted not to pursue the PfA on this endpoint.

Session 2 (closed)

During the closed session, MSC discussed what is part of the toxicity (T) assessment in the PBT assessment. Two main views were expressed, with one view to assess the available toxicology endpoints without considering or asking to fulfil any data gaps on human health toxicity, whereas the other view was to also look at the mammalian database to assess the human health endpoints that could give rise to CMR or STOTS classification, and check whether there is a data gap and ask for any data gaps to be fulfilled. It was reminded that in the ECHA substance evaluation workshops some flexibility on what to evaluate was introduced. The lack of information on a standard information requirement could be used to require information in substance evaluation to ensure that certain effects can be excluded. It was agreed that a lack of standard information within the initial concern should be addressed, however, when it is outside the concern then there is discretion for the MS. Looking at the PBT assessment one might need to evaluate mammalian toxicity ("T-mammalian") at a certain point in time to conclude on PBT. Since PBT assessment follows a strategy of first clarifying P and B, if the substance is not P and not B then the information on T-mammalian is not immediately needed to address the initial concern. However, this still may be requested as an additional concern, depending among others on efficiency considerations.

MSC also discussed the extent to which scientific papers that are not included in the registration dossiers but are publicly available can be taken into account by the MSC during their deliberations. It was generally agreed that the main aim is to make the justifications as clear as possible to both the Registrants and the MSC members, hence, on a case by case basis inclusion of such papers can be considered appropriate.

With regards to the PBT assessment, MSC agreed to request first a ready biodegradability test, which may be enhanced by extending its length. If the pass level is not met then degradation simulation testing in sediment is the next step. It was also agreed to drop from the DD the request for soil simulation testing and to identify the degradation products in simulation testing.

MSC agreed to 10 weeks premating with inclusion of the DNT- and DIT-cohorts. For the production of the F2-generation from Cohort 1B, MSC agreed that the condition that there are indications of an endocrine disrupting mode of action was met but not the exposure condition of significant exposure to professionals or consumers based on the information in registration dossier that the only professional uses are as laboratory chemicals. It was concluded that the Registrant should expand Cohort 1B with production of the F2 generation (in that case with 2 weeks premating) if new information on uses indicates significant exposure of these protection targets. The inclusion of the DNT-cohort was based on weight of evidence of human neurotoxicity data and supported also by the estrogenic mode of action. The conclusion on estrogenic mode of action was the condition that lead to inclusion of the request for the DIT-cohort.

MSC agreed not to include the mutagenicity endpoint following the suggestion for withdrawal of the PfA, and that this part of the "T-mammalian" of the PBT can also still be further assessed in follow-up.

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

SEV-SE-032/2013 Bis(isopropyl)naphthalene (EC No. 254-052-6)

Session 1 (open)

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

An eMSCA expert from Swedish CA (SE-CA) presented the outcome of substance evaluation of bis(isopropyl) naphthalene (hereinafter DIPN) performed by SE-CA on the basis of the initial grounds for concern, i.e. relating to the environment aspects of the PBT concern only, while the human health part was not evaluated.

During the presentation of the case the SE-CA explained that the DD was modified for the meeting based on the proposals for amendments (PfAs) received. The SE-CA had reflected all PfAs received in the DD, including the EOGRTS and replaced the sediment simulation study with a water simulation study. The focus was on the two PfAs mentioned, although all of them were addressed in the discussion.

Five PfAs in total were submitted. The first PfA on the aerobic transformation in aquatic sediment systems (EU C.24/OECD 308) suggested to add details in the DD why the carbon 14 (C14) radiolabelling is considered needed, feasible and proportionate in this case.

The second PfA suggested that for persistence an alternative testing strategy should be followed, and a tiered approach should be followed, firstly requesting a surface water simulation study (EU C.25/OECD 309) with two isomers 1,3- and 1,4-DIPN.

The third PfA suggested deleting the request for a sediment simulation test and instead requesting a surface water simulation study, focussing in particular on two isomers 1,3- and 1,4 DIPN. The study would have the same specifications as those described in the sediment simulation test, noting additionally that both the kinetic and the degradation pathway part of the study would be conducted.

The fourth PfA on the *Daphnia magna* reproduction test (EU C.20/OECD 211) suggested editorial changes in the DD related to aquatic toxicity and on potential follow-up requests on further fish testing depending on the outcome of the requested tests.

The fifth PfA suggested adding a request for an EOGRTS, according to the standard information requirements of REACH, with the extension of Cohort 1B to produce F2 generation, inclusion of the DNT and DIT cohorts, and a 10-week premating period to thoroughly evaluate the PBT properties of the registered substance.

The representative of the Registrant confirmed his written comments on the PfAs objecting to the need for further higher tier biodegradation studies requested by eMSCA. He considered the requests for the surface water and sediment simulation studies (OECD 308 and OECD 309) to be disproportionate against the properties of DIPN. Regarding bioaccumulation in aquatic media and sediment the Registrant expressed the opinion that both monitoring data and scientific publications indicate that the values obtained with the lower exposure concentration are best fitted to demonstrate the non vB potential of DIPN and that it is unlikely for DIPN to bioaccumulate along the food chain. In the Registrants' representative's view a concept to address all individual constituents via radiolabelling is not considered viable for UVBC substances and creates an imbalance for multiconstituent substances. He did not see an urgent need for EOGRTS as in his view the experimental repeated dose data and toxicokinetic results provide evidence that DIPN shows no specific toxicity and shows no signs of accumulation.

Some clarifying questions from MSC members were addressed by the representative of the Registrant. The Chairman thanked him and explained that the comments would be further considered during the closed session deliberations of MSC.

Session 2 (closed)

The discussion addressed the testing on two constituents of the substance, the 1,3- and 1,4- DIPN, which showed no primary biotic degradation in the most reliable biodegradation screening study, and which exhibit high bioaccumulation potentials. One member confirmed that eMSCA had interpreted his PfA to request the surface water simulation test. The eMSCA noted that surface water was a relevant compartment which is considered generally easier to perform and the results are easier to interpret than the results obtained from sediment simulation tests. However, SECR noted that the outcome of the requested tests and the revised PBT assessment might lead to follow-up on further requests. Regarding the use of C14, the eMSCA noted that primary biodegradation could be assessed by measuring the total residual concentration of test substance with a sensitive and specific analytical method, instead of using radiolabelling techniques. As for EOGRTS, SECR noted that it was not in the original information requirements and therefore there is a procedural limitation in cases where scientific or technical arguments for an appropriate study design are to be used, which have not been introduced in proposals for amendment.

Based on the above considerations, MSC agreed unanimously to maintain the information request for *Daphnia magna* reproduction (test method: EU C.20/OECD 211); add an information request on aerobic mineralisation in surface water (test method: EU C.25 /OECD 309), preferably using C14 ring-labelled test substance or a sufficiently sensitive analytical method, to primarily determine the degradation half-life for at least two components with high B-values (isomers 1,3- and 1,4-DIPN); remove the information request for testing on degradation in the sediment compartment; add a note that in the follow-up, depending on the outcome of the requested tests and the revised PBT-assessment, the eMSCA may request a sediment simulation degradation test and/or the fish long-term toxicity test; not to include in this decision possible concerns for human health including the concern for reproductive toxicity of the substance identified in a proposal for amendment, requesting an extended one-generation reproductive toxicity study (test method: EU B.56/OECD TG 443), in rats, oral route. Section III of the draft decision was amended accordingly.

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

SEV-DE-018/2013 1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivs. – BENPAT (EC No. 273-227-8)

Session 1 (open)

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

The eMSCA from Germany CA (DE-CA) presented the outcome of substance evaluation of BENPAT performed by DE-CA on the basis of the initial grounds for concern as BENPAT was suspected PBT/vPvB, having wide dispersive use, its concerns on consumer use and aggregated tonnage. The members were guided through the information requirements by the expert from the eMSCA who explained that additional concerns on gene mutations in mammalian cells, repeat dose toxicity, carcinogenicity and reproductive toxicity were identified during the evaluation.

A total of nine PfAs were received referring to mutagenicity endpoint – comet assay, a tiered testing approach to the biodegradation simulation testing in sediment/surface water, performance of the test at a higher temperature and correction of the result to 12°C using the Arrhenius equation, justification for the location of the radiolabel on BENPAT molecule, and hydrolysis as a function of pH in the presence/absence of oxygen.

During the presentation of the case the eMSCA explained that the DD was modified in advance of the meeting to reflect the PfAs (a) in Section II.1 replacing the reference to comet assay with a reference to the OECD TG 489, (b) in Section III requesting to perform

the test at 20°C but to correct back to 12°C using the Arrhenius equation to avoid the need to extend the test duration to 120 days, and (c) to add in DD the requirement for the justification for the location of the radiolabel in the molecule, in order to further reflect on the Registrant's initial comments and to address the PfAs.

The PfAs that required further discussion at the meeting were related to: (a) persistence assessment of BENPAT in water, sediment and/or soil compartment, (b) mechanisms of adsorption, degradation or mineralisation occurring during hydrolysis, variability with temperature and interpretation of data, (c) options for parallel or sequential biodegradation simulation testing in sediment and/or water compartment, in relation with non-extractable residues (NER) and (d) deadlines and other alternative methods for addressing the grounds of concern for BENPAT.

The representatives of the Registrants provided written comments on the PfAs prior to the meeting and clarified them at the meeting. The representatives of the Registrants argued against BENPAT being PBT/vPvB as based on its antioxidant property it could not be PBT nor vPvB

The Registrants' representatives expressed their concern on parallel/combined biodegradation simulation testing (OECD 308 in sediment and OECD 309 in surface water) stating that a combined test protocol is complex and experimental in nature without being validated. They argued that there is no criterion for pass or fail. It was confirmed by the eMSCA that there are currently no established pass criteria for the simulation testing. Also, Type 2 NER formation is highly likely and the registrants representatives stated that they will not be able to show this in the test proposed. In the view of the Registrant's representatives, Type 2 NER formation is according to the guidelines considered biodegradation. Furthermore, they considered soil simulation testing (OECD 307) with appropriate analytical extraction techniques to assess NERs as the better approach. The representatives of the Registrants stated that their combined OECD 301B and OECD 302C tests already indicated that there is biodegradation in water, hence they are not in favour of performing an OECD 309 (water simulation testing).

If required to perform simulation testing, the Registrants agreed to perform the test at 20°C. However, the Registrants' representatives questioned the correction of the results to 12°C (using the Arrhenius equation) as in their view this results *de facto* in a change to the Annex XIII criteria.

The Registrants provided explanation on the apparent concern arising on human health and proposed to perform a repeat Ames test before comet assay test, or an OECD 489 to avoid unnecessary animal testing.

The representative of the Registrant addressed some clarifying questions from eMSCA and from MSC members. During this exchange of information it became clear that there was a different interpretation of the pass level in the degradation studies between the eMSCA and the representatives of the Registrants. The Chairman thanked the representatives of the Registrant and explained that the comments would be further considered during the closed session deliberations of MSC.

Session 2 (closed)

MSC discussed on the persistence (P) assessment in the PBT assessment. The Committee confirmed that only the mineralisation percentage should be accounted for relative to the pass level of enhanced ready biodegradability studies. Furthermore, it was reminded that the Registrants have not provided information on the identity of the degradation products, and whether these transformation products of BENPAT are or are not PBTs themselves.

An exchange of views on the standard simulation studies available and on the options for sequential or parallel biodegradation simulation testing in relation to NER formation took place. Possible scenarios for the representative degradation compartment (sediment

and/or water) in relation with NER were discussed. In this discussion, MSC also considered that the initial request for parallel water and sediment simulation testing had been inadvertently interpreted by the Registrant as a request to combine these two protocols into one. MSC further discussed on the relevance of pelagic testing in relation to an OECD 307 test combined with analytical extraction approaches for the assessment of BENPAT.

It was agreed that although water may not be the main receiving compartment after release to the environment, it is still needed to give a more correct representation of biodegradation with data least confounded by NER formation.

In conclusion, MSC agreed to request simulation testing on ultimate degradation in surface water. In case the simulation testing on ultimate degradation in surface water does not allow a conclusion that BENPAT is persistent (P) or very persistent (vP), additional sediment simulation testing is requested. MSC further agreed the deadline for submission of the information of 30 months from the date of the final decision taken by ECHA.

The DD was amended in Section II and in Section III accordingly. No other major modifications were made to the draft decision at the MSC meeting.

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

SEV-SK-026/2013 Mixture of two components: 1. N-(1,3- dimethylbutyl)-N´- phenyl-p-phenylenediamine 2. N1-(1,3-dimethylbutyl)- N4-(4-(1-methyl-1- phenylethyl)phenyl)ben zene-1,4-diamine (EC No. 448-020-2)

Session 2 (closed)

An eMSCA's expert from the Slovak CA explained that this SEv case was returned from the written procedure due to a need for MSC discussion on whether a PfA requesting a PNDT in a second species should be addressed in the DD. The additional information request is based on findings from the available PNDT study in rat indicating some effects on maternal and developmental toxicity and the potential data gap identified for this endpoint. The eMSCA agreed in principle with the arguments of the PfA's submitter, however, as the only Registrant currently self-classifies the substance as toxic for reproduction 1B (Repr. 1B), the eMSCA concluded at this point of the evaluation process that there is no need for requesting a further PNDT testing in a second species as appropriate risk management measures have already been put in place with this self-classification.

In the following discussion, members agreed with the eMSCA that the available dataset does not allow drawing a clear conclusion whether the substance should be classified as Repr 1B or Repr 2. However, the current Registrant's self-classification covers the possible concerns and ensures the appropriate risk management measures are in place; thus, MSC agreed with the eMSCA that further PNDT testing may not be fully justified at this point in time and under these circumstances also for animal welfare reasons.

The eMSCA expert further clarified that his CA intends to carefully examine the situation in the follow-up evaluation stage and if changes in the current circumstances occur (such as e.g. new Registrants appear with different self-classifications of this substance than Repr. 1B), the PNDT study in a second species (rabbit) may be required for possible clarification of the remaining unclear concerns and possible preparation of an Annex VI dossier for harmonised classification and labelling either by a MSCA, or by the Registrant according to the CLP Regulation.

MSC agreed with the outlined approach and concluded that the suspected concern for this endpoint is currently properly managed with this self-classification and unanimously agreed on the DD as modified at the meeting based on the above considerations.

d. General topics

- **Appeals update**

See under Item 7d below.

- **Status report on substance evaluation**

The Chairman introduced a proposal of not referring any evaluation cases to the September 2016 due to the associated legal deadlines that then expire in the summer period possibly leading to human resource issues for MSCAs, ECHA and/or Registrants, and to keep the September 2016 for other MSC processes without such deadlines. MSC was asked to send in their feedback on this proposal by 18 June 2015.

SECR gave an overview of the issues discussed at the CCH workshop, next steps in the CoRAP process and SEV workshop. It was mentioned that after publication of the draft CoRAP on the ECHA website industry are updating the registration dossiers of those substances. Hence CAs were asked to consider these updates, update the justification document and consider whether the concern is still there or not before the finalisation of the CoRAP.

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 eleven dossier evaluation cases (see Section VII for more detailed identification of the cases). WP was launched on 13 May 2015 and closed on 26 May 2015. By the closing date, unanimous agreement was reached on 10 DDs. 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 a discussion of the case at the MSC-42 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)*

TPE-052/2015 Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs. (EC No. 308-208-6)

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 four MSC members requesting a MSC meeting discussion.

SECR introduced the PfA which was submitted for this ECHA's DD. The PfA requested the deletion of the pre-natal developmental toxicity study (PNDT) in rabbits, oral route, (a PNDT study in a second species for this substance). It argued – considering the severity and dose-dependency of the developmental effects observed in the first study in rats – that the available data from the first study indicated sufficient evidence for classification. Even if the rabbit study would be negative, the effects seen in rats could not be disregarded. In the opinion of the MSCA there was sufficient evidence to classify this substance as category 1B for reproductive toxicity.

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

The Registrant provided written comments on the PfA. He considered making reference to some literature sources that insufficient information had been established through the earlier conducted testing on rats to properly establish the types and extent of toxicological effects of the registered substance He further considered the PfA not providing adequate details to justify the classification of the substance as category 1B for reproductive toxicity

based on a single animal gavage study. He argued that, in such studies, gavage would not be a suitable method for administration to model exposure patterns in man or properties and effects of certain substances, including corrosive ones, such as the registered substance. In addition, according to the Registrant a number of recent scientific papers have called into question the use of gavage in developmental studies. In conclusion, he considered the parameters of the proposed testing appropriate. The requirements of column 2 of paragraph 8.7 have, in his view, not been fulfilled at this stage.

Four MSC members and their experts presented their arguments for stopping the written procedure noting that the data available observed in the first study in rats indicated sufficient evidence for classification and at this stage there was no necessity to conduct a second species PNDT. SECR noted that the Registrant is responsible for ensuring the safe use of the substance and that risk management measures should be in place. One member informed that their MSCA had submitted to ECHA's registry of intent that they will prepare a dossier with a proposal for harmonised classification and labelling of the registered substance.

Based on the justifications outlined in the discussion, the MSC concluded that considering the severity and dose-dependency of the developmental effects observed in the first study in rats, there was no need at this stage for further testing for developmental toxicity and rejected the proposed test accordingly. The DD was subsequently amended to reflect this.

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

d. General topics

1) Report on CCH workshop (19-20 May 2015)

SECR presented the results from the Workshop on compliance checks (CCH) held on 19 and 20 May 2015 in ECHA. The key outcome included, inter alia, scoping of CCH, sharing practical experience with MSCAs, interplay between CoRAP CCH and SEv, and training needs for National Helpdesks on new information requirements.

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

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

3) Status report on on-going evaluation work

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

Item 8 – SVHC identification

1) Seeking agreement on Annex XV proposals for identification of SVHC

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 two substances, as follows: *1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5)* proposed to be identified as SVHC based on Article 57 (c) as toxic for reproduction and *5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]*proposed to be identified as SVHC based on Article 57(e) as vPvB substance. MSC agreed unanimously on identification of these substances as SVHCs in the written procedure launched on 19 May 2015 and closed on 29 May 2015. 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.

2) Legal procedures related to Candidate List substances

SECR presented an overview of judgements of the General Court of the European Union in recently concluded cases on the substances HHPA and MHHPA (T-134/13 and T-135/13) that have been identified as SVHCs under Article 57 (f) of the REACH Regulation due to their respiratory sensitiser properties and listed in the Candidate list in December 2012. MSC was informed that the Court confirmed ECHA's decision and confirmed that ECHA did not err either procedurally or in its assessment of the SVHC proposals for the inclusion of these substances in the Candidate List in its decision.

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

1) Responses of ECHA to the comments received in the public consultation on ECHA's 6th draft recommendation – update since last MSC

The Chairman opened this item by informing the Committee that some members have been approached via email by an industry association asking the recipient to consider their comments again, although the public consultation had ended long ago. He asked all members to inform SECR if they had received a similar message so that a response from SECR could be prepared in which it would be clearly stated that such an attempt to influence any Committee members and interfere with the basic obligation of the Committee to remain independent in its opinion forming process is not acceptable and against the General Principles and Guidance for Committees' members of ECHA. SECR then explained the changes introduced in the documentation regarding the process information, responses to the comments received and background documents since the previous plenary. SECR reconfirmed its view expressed in MSC-41 that following the assessment of the comments from the public consultation including their impact on the priority score, the grouping approach applied for the three lower scoring lead substances seemed no longer justified whereas the priority for all remaining substances remained high. SECR also reminded MSC that at the start of the public consultation it was clarified that not all substances on the draft recommendation would finally be included in ECHA's recommendation. SECR shared with MSC its current considerations of not progressing further with the group of lead substances based on workload considerations. However, SECR reminded of its earlier clarification that the final decision about which substances to include in the 6th recommendation will only be taken after the MSC discussions and after receiving the opinion.

2) Updated time plan for ECHA's seventh draft recommendation

SECR provided an update as regards the planning of the work for ECHA's 7th draft recommendation of substances for inclusion in the authorisation list, and in particular as regards the related timings and MSC involvement. A time-plan was presented according to which the prioritisation results of all Candidate List substances (not yet recommended) will be discussed in September MSC meeting and the 7th draft recommendation in the October meeting. The next public consultation would start in November 2015 and, following the discussion schedule established in previous recommendation rounds, adoption of MSC opinion would take place in September 2016. It was noted that the updated time plan would mean that the recommendation round would actually take longer than a year, and consequently the start of future rounds would move each year. However, with this plan the discussions on different recommendations in MSC would not take place in parallel.

Responding to a question SECR explained that any substances that will not be included in the 6th recommendation will again be considered for 7th prioritisation and recommendation round. In concluding, the Chairman reminded the members about the invitation for volunteers for the rapporteurship and membership in the possible working group that MSC would need for this next recommendation round.

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

a) Discussion on the draft MSC opinion

b) Adoption of MSC opinion

The Rapporteur presented the second draft MSC opinion on the draft 6th recommendation of ECHA for inclusion of substances in Annex XIV. To start with, MSC discussed the scope of the opinion as it was questioned whether it is useful to make a general remark on substances not included in the draft recommendation. Similarly, some members did not see a need for MSC to make statements in the opinion that were considered to fall outside the remit of the Committee, such as on appropriate length of review periods to be set out in the authorisation decisions based on authorisation applications and RAC/SEC opinions. After some discussion carefully crafted wordings to be included in the opinion were agreed upon. Regarding priority scoring MSC followed the re-assessment of SECR based on the comments from the public consultation regarding the assessment that the grouping approach applied for the three lower scoring lead substances seemed no longer justified. Hence, MSC advised ECHA to reconsider the priority of these substances.

Regarding transitional arrangements the discussion focused on how to define or assess complexity of a supply chain and how to substantiate any deviations, up or downwards, from latest application dates (LADs) as set in the recommendations so far. An industry observer provided further elaboration on the experiences until now from industry, and on the main factors having an impact on supply chain complexity. SECR welcomed further discussions on assessment criteria to develop a generic approach for setting LADs. As regards exemptions in light of Article 58(2) of REACH MSC discussed those in particularly in the context of the lead substances. As regards RoHS and ELV legislation and possible exemptions a member raised the issue of MSC giving an opinion on those when there is insufficient knowledge about whether risks may or may not have been assessed in the context of those legislations, what methods for assessment may have been used and how they would compare to risk assessments under the authorisation process. SECR shared how they had assessed the existing legislation in this context, including all life-cycle stages and all endpoints, and stressed that currently no legislation seems to cover all protection targets. MSC in general supported that for the uses of the four high scoring lead compounds that are regulated under RoHS and ELV legislation there may be grounds for exemptions, based on the information provided in the public consultation.

MSC unanimously supported ECHA's draft recommendation for 15 of the 22 substances, comprising of the group of seven phatalates, 1-bromopropane, 4-nonylphenol, branched and linear, ethoxylated, two coal stream substances and four lead compounds. For four borates a majority of MSC supported ECHA's draft recommendation. The suggestion by the Rapporteur and Working Group to remove three lead substances from the draft recommendation, because there appears not to be reasons to group these three substances with the other lead compounds, was supported by MSC. For the boron and the four lead compounds, it was considered that longer transitional arrangements could be appropriate due to indications of complex supply chains. As regards the coal stream substances one member indicated that while they can agree with the prioritisation, it is a disappointment that these substances are now recommended while not all similar substances have yet been included on the candidate list.

MSC adopted its opinion by consensus, except as regards the prioritisation of the four boron compounds. The latter was adopted by majority, as six members of MSC had a diverging opinion. This minority opinion will be attached to the MSC opinion.

One member, also on behalf of five other members, indicated that they wished to include a statement to the minutes that while the prioritisation criteria seemed to be fulfilled for the remaining four lead substances the benefits of inclusion needed to be further discussed, as

well as the appropriateness of authorization of the use in batteries (see Section VIII). After adoption of the MSC opinion another member, also on behalf of two other members, indicated that they wished to include a statement to the minutes indicating that if ECHA would have to make a choice in the final recommendation, their MSCAs would prefer to include lead substances over the inclusion of boron compounds (see Section VIII).

Item 11 – MSC Manual of Decisions and Opinions

The Chairman first reminded the members that SECR had asked for feedback by 27 May 2015 on the intent to grant access to the MSC Manual of Decisions and Opinions (MoD) to ASO observers. No (negative) feedback was received, and SECR had made the document available for ASOs.

SECR presented proposals for entries for inclusion in MoD. The two new entries comprised test temperature for soil simulation test and personal protective equipment. The two existing items for potential revision covered the CLP classification in Annex XV dossiers for SVHC identification and the withdrawal of substances from the Candidate list.

Regarding the proposal for a substance evaluation (SEv) process entry concerning the test temperature for soil simulation test, one member requested to reword the entry so as not to restrict the test temperature to only 12°C since there were situations where simulation tests were requested for a temperature of 20°C in order to be able to identify the metabolites. However, since the discussion on this matter is still developing and possibly will involve the PBT EG, MSC agreed to restrict the current entry to the conclusion made in MSC-32 and keep the text as proposed. This entry can be revised once the discussion at PBT EG has matured and the outcome applied in SEv DDs. Temperature conditions for other simulation tests from different compartments could also be included in the revision.

Regarding the personal protective equipment, MSC agreed with the proposal with only an editorial change. As for the decision on the test temperature for soil simulation test, it will also apply to Dossier Evaluation.

Regarding the proposal for revision of two entries concerning SVHC process, MSC concluded that some further elaboration of the revised 1.1.5 entry was needed and agreed on the revised 1.1.8 entry as modified at the meeting. The Chairman thanked members for good suggestions provided.

In conclusion, MSC agreed to include three items in MoD, comprising two new entries (4.1.1 and 3.1.6) and one existing (1.1.8) as revised at the meeting. Further, MSC agreed to consider the SECR's proposals for potential revision of one existing entry (1.1.5) at the next meeting, for which MSC members were invited to send their suggestions for modification to SECR by 30 of June 2015. MSC-S will take them into account when preparing the revised MoD entry's proposal for MSC consideration and decision at MSC-43 in September 2015.

Item 12 – Any other business

The Chairman informed that a member had requested to clarify the role of the comet assay in ECHA's Risk Assessment Committee (RAC) when handling the classification and labelling proposals. He reported that the test has been used by RAC in the overall assessment. In several cases the *in vivo* comet assay has been part of the weight of evidence approach, also in the absence of *in vivo* mutagenicity studies.

Item 13 – Adoption of conclusions and action points

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

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ANDRIJEWSKI, Michal (PL)
BASTIJANCIC-KOKIC, Biserka (HR)
COCKSHOTT, Amanda (UK)
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
DIMCHEVA, Tsvetanka (BG)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
GAIDUKOVS, Sergejs (LV)
HUMAR-JURIC, Tatjana (SI)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina(CZ)
LONDESBOROUGH, Susan (FI)
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
BERTATO, Valentina (DG GROW)
KOBE, Andrej (DG ENV)
Observers
ANNYS, Erwin (Cefic)
BÖNIGK, Winfried (RUETGERS Group)
DOOME, Roger (IMA-Europe)
DROHMANN, Dieter (ORO)
KERÄNEN, Hannu (Concawe)
MUSU, Tony (ETUC)
STODDART, Gilly (PISC)
VAN VLIET, Lisette (HEAL)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
BERCARU, Ofelia
BRAUNSCHWEILER, Hannu
CALEY, Jane
CARLON, Claudio
DELOFF-BIALEK, Anna
DE WOLF, Watze
DEYDIER, Laurence
DREVE, Simina
HAUTAMÄKI, Anne
HUUSKONEN, Hannele
JOHANSSON, Matti
KAPANEN, Anu
KARHU, Elina
KORJUS, Pia
KREUZER, Paul
MÜLLER, Birgit
NAUR, Liina
PELLIZZATO, Francesca
PELTOLA-THIES, Johanna
RODRIGUEZ IGLESIAS, Pilar
RÖCKE, Timo
RÖNTY, Kaisu
SCHOENING, Gabriele
SOBANSKA, Marta
UOTILA, Elina
VAHTERISTO, Liisa
VASILEVA, Katya
ZBIHLEJ Tomas

Proxies

- MARTÍN, Esther (ES) also acting as proxy of DRUGEON, Sylvie (FR)
- PISTOLESE, Pietro (IT) also acting as proxy of BUSUTTIL, Ingrid (MT)
- WIJMENGA, Jan (NL) also acting as proxy of TYLE, Henrik (DK) on Wednesday and Thursday
- WIJMENGA, Jan (NL) also acting as proxy of DUNAUSKIENE, Lina during short periods on Thursday

Experts and advisers to MSC members

ALI MOHAMMED, Ifthekhar (SE) (adviser to LUNDBERGH, Ivar)
ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BALEJIKOVA, Jana (SK) (expert to RUSNAK, Peter)
BALCIUNIENE, Jurgita (LT) (expert to DUNAUSKIENE, Lina)

DOYLE, Ian (UK) (expert to COCKSHOTT, Amanda)
HERMES, Joe (LU) (expert to WAGENER, Alex)
INDANS, Ian (UK) (adviser to COCKSHOTT, Amanda)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
KJUUS, Berit Eyde (NO) (adviser to REIERSON, Linda)
LULEVA, Parvoleta (BG) (expert to DIMCHEVA, Tsvetanka)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBRGH, Ivar)
MENDONÇA, Elsa (PT) (expert to ALMEIDA, Inês)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
PEDERSEN, Finn (DK) (expert to TYLE, Henrik)
RISSANEN, Eeva (FI) (adviser to LONDESBOROUGH, Susan)
TRAAS, Theo (NL) (expert to WIJMENGA, Jan)
ZELJEZIC, Davor (HR) (expert to BASTIJANCIC-KOKIC, Biserka)
WODLI, Jordane (FR) (expert to DRUGEON, Sylvie)

MSCA Experts for SEV cases
ANDERSSON, Lars (SE)
JÖHNCKE, Ulrich (DE)
POLAKOVICOVA, Helena (SK)
VEGA, Milagrosa (PT)

By WEBEX-phone connection:
During the agenda item 6 for SEV-DE-018/2013: Ulrike BERNAUER (DE) and Uta HERBST (DE)
During the agenda items 8, 9, 10 and 11: Enrique GARCÍA-JOHN (DG GROW) and Giuseppina LUVARA (DG GROW)
During the agenda items 9 and 10: Cécile MICHEL (FR)

Case owners:
Representatives of the Registrants were attending under the agenda item 6b for SEV-PT-025/2013, SEV-SE-032/2013 and SEV-DE-018/2013.

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

III. Final Agenda

MSC/A/042/2015 Agenda

Final Agenda
42nd meeting of the Member State Committee

8-11 June 2015
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

8 June: **starts at 9 am**
11 June: **ends at 6 pm**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/042/2015
For adoption

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

Item 4 – Administrative issues

For information

Item 5 – Minutes of the MSC-41

- Draft minutes of MSC-41

MSC/M/41/2014
For adoption

Item 6 – Substance evaluation

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

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

ECHA/MSC-42/2015/002
(Room document)

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-42/2015/001

MSC code	Substance name	EC number	Document
SEV-PT-025/2013	Biphenyl	202-163-5	ECHA/MSC-42/2015/008-009
SEV-SE-032/2013	Bis(isopropyl)naphthalene	254-052-6	ECHA/MSC-42 /2015/004-005
SEV-DE-018/2013	1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivs.	273-227-8	ECHA/MSC-42 /2015/006-007

For discussion

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

Cases as listed above under **6b** and any cases returned from written procedure[1] for agreement seeking in the meeting

MSC code	Substance name	EC number
SEV-IT-021/2013	Tert-butyl perbenzoate	210-382-2
SEV-IT-023/2013	Diisodecyl azelate	249-044-4
SEV-BE-002/2013	Ammonium salts of mono- and bis[3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl and/or poly (substituted alkene)] phosphate	700-403-8
SEV-SK-026/2013	Mixture of two components: 1. N-(1,3-dimethylbutyl)-N´- phenyl-p-phenylenediamine 2. N1-(1,3-dimethylbutyl)- N4-(4-(1-methyl-1-phenylethyl)phenyl)ben zene-1,4-diamine	448-020-2
SEV-NL-034/2013	Reaction mass of mixed (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) phosphates, ammonium salt	700-161-3

For agreement

d. General topics

- Appeals update[2]

For information

[1] Any case listed below will be removed from the agenda if agreed in written procedure in advance of the meeting. Should the case be addressed in the meeting, the documentation is available in MSC CIRCABC in substance specific folders.
[2] A combination of Appeal updates for Substance and Dossier Evaluation may be introduced, if appropriate.

Item 7 – Dossier evaluation

Closed session for 7c
Indicative time plan is Day 2

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

ECHA/MSC-42/2015/011
For information

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

For discussion followed by agreement seeking under 7c:

- *No cases*

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

A case returned from written procedure for agreement seeking in the meeting:

Testing proposal examination

MSC code	Substance name	EC No.
TPE-052/2015[3]	Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs.	308-208-6

For agreement

d. General topics

- Status report on on-going evaluation work:
  Report on CCH Workshop 2015 (May 19-20)
- Appeals update[2]

For information

Item 8 – SVHC identification

Indicative time plan is Day 3

1) Seeking agreement on Annex XV proposals for identification of SVHC[3]

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

Room document
For information

b. Agreement seeking *(if any cases as listed below are returned from written procedure for agreement seeking in the meeting)*

- 1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC No. 201-559-5), EC No. 271-094-0 and 272-013-1
- 5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual isomers of [1] and [2] or any combination thereof]

For agreement

2) Legal procedures related to Candidate List substances

For information

[3] Documents are available in substance specific folder in MSC CIRCABC

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

Indicative time plan is Day 3 & 4

1) Responses of ECHA to the comments received in the public consultation on ECHA's 6th draft recommendation – update since last MSC

ECHA/MSC-42/2015/03,
ECHA/MSC-42/2015/012-062,065
For information

2) Updated time plan for ECHA's 7th draft recommendation

ECHA/MSC-42/2015/063
For discussion

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

Indicative time plan is Day 3 & 4

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

a) Discussion on the draft MSC opinion

ECHA/MSC-42/2015/064
For discussion

b) Adoption of MSC opinion

(ECHA/MSC-42/2015/064)
For adoption

Item 11 – MSC Manual of Decisions and Opinions (MoD)

- Proposal for new entries and review of existing ones

ECHA/MSC-42/2015/010
For decision

Item 12 – Any other business

- Suggestions from members

For information

Item 13– Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-42

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

- *Substance evaluation status report (presentation slides)*
- *Dossier evaluation status report (presentation slides)*
- *Update on implementing the EOGRTS information requirement by ECHA (presentation slides)*

Outside plenary activities (tentatively lunch hour of Day 4):

- **Presentation by ECHA entitled: The "Assessment Entity": An approach to support the transparency of Chemical Safety Assessments under REACH**

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

AP/Dossier	MSC Chairman	Reason for potential CoI/ mitigating measures
AP 6 a: SEV-BE-002/2013, SEV-NL-034/2013	Watze de Wolf	Declaration of potential conflict of interests prior to preparation of written procedure / Appointed Acting Chair: Pilar Rodriguez Iglesias

V. Main Conclusions and Action Points

Main conclusions and action points
MSC-42, 8-11 June 2015
(adopted at MSC-42)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues	
	SECR to archive outdated/old files from MSC CIRCABC prior to migration to S-CIRCABC
Item 5 – Adoption of minutes of the MSC-41	
MSC adopted the draft minutes as provided for the meeting and further modified during the meeting.	**MSC-S** to upload final version of the minutes on MSC CIRCABC by 15 June 2015 and on ECHA website without undue delay.
Item 6 - Substance evaluation **a. Written procedure report on seeking agreement on a draft decision on substance evaluation**	
MSC took note of the report as presented in document ECHA/MSC-42/2015/002.	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions agreed in written procedure, as indicated in document ECHA/MSC-42/2015/002.
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-PT-025/2013 Biphenyl (EC Nr. 202-163-5) SEV-SE-032/2013 Bis(isopropyl)naphthalene (EC Nr.254-052-6) SEV-DE-018/2013 1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivs. (EC Nr. 273-227-8) SEV-SK-026/2013 Mixture of two components: 1. N-(1,3-dimethylbutyl)-N´- phenyl-p-phenylenediamine 2. N1-(1,3-dimethylbutyl)- N4-(4-(1-methyl-1- phenylethyl)phenyl) benzene-1,4-diamine (EC Nr. 448-020-2).	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases.
d. General topics	
	SECR to upload the planned MSC meeting dates for 2016 in CIRCABC after the meeting. **MSC** to provide to MSC-S by 18 June 2015: • Feedback on the proposal of not referring DEV and SEV cases to MSC-49 (September 2016). • Suggestions for questions for the survey to be sent to the eMSCAs, MSC members, StOs on the efficiency of the SEV/CoRAP process to be presented at the workshop on Substance Evaluation to be held on 19-20 November 2015.
Item 7 – Dossier evaluation **a. Written procedure report on seeking agreement on draft decisions on dossier**	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
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-42/2015/011.
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)*** **c. Seeking agreement on draft decisions on testing proposal examinations when amendments were proposed by MS-CA's (Session 2, closed)**	
MSC reached unanimous agreement on the following ECHA draft decision (as modified in the meeting): TPE-052/2015 Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs. (EC Nr. 308-208-6)	**MSC-S** to upload on MSC CIRCABC the final ECHA decision of the agreed case.
Item 9 – ECHA's draft recommendation of priority substances to be included in Annex XIV 1) Responses of ECHA to the comments received in the public consultation on ECHA's 6th draft recommendation – update since last MSC 2) Updated time plan for ECHA's 7th draft recommendation	
MSC took note of the update on the responses of ECHA and the background documentation concerning the 6th recommendation. MSC took note of the timeplan for the 7th draft recommendation for inclusion of priority substances to Annex XIV.	**MSC members** to consider volunteering as a Rapporteur or as a Working Group member for the opinion development for the 7th draft recommendation, and to indicate such interest to the MSC Chairman by 1st September 2015.
Item 10 – Opinion of MSC on the draft 6th recommendation of priority substances to be included in Annex XIV MSC opinion on ECHA's Draft 6th recommendation of priority substances to be included in Annex XIV a) Discussion on the draft MSC opinion b) Adoption of MSC opinion	
MSC discussed the 6th ECHA's draft recommendation for inclusion of priority substances in Annex XIV. Majority of MSC supported recommending 19 substances for inclusion in Annex XIV out of the 22 initially proposed. Some members did not consider the prioritisation of group of borates as appropriate and provided minority view to the opinion for these substances. Some members provided a statement to be included in the minutes as regards the inclusion of any of the four lead substances in ECHA's recommendation in the current round. **MSC** adopted the opinion on ECHA's 6th draft recommendation.	**Members** with a minority view or statements to the minutes to submit that to SECR in writing by 15 June in this finalised form (if not yet done). **SECR** to take into account the MSC opinion and discussion at MSC-42 when finalising the 6th ECHA's recommendation for inclusion of substances in Annex XIV and to submit it to the Commission. **MSC-S** to publish the final MSC opinion on MSC CIRCABC and on ECHA website after the meeting.
Item 11 – MSC Manual of Decisions and Opinions (MoD) Proposal for new entries and review of existing ones	
MSC agreed to include three items, two new entries (4.1.1 and 3.1.6) and one existing (1.1.8), in the MSC Manual of Decisions and Opinions (MoD), as revised at the meeting. Further, MSC agreed to consider the SECR's proposals for potential revision of one existing entry at the next meeting.	**MSC-S** to update on MSC CIRCABC the MoD as revised by 17 June 2015 **MSC** to send their suggestions for modification of MoD entry 1.1.5 to the Secretariat by 30 of June.
Item 13– Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-42 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC CIRCABC by 12 June 2015.

VI. Dossier evaluation cases addressed for MSC agreement seeking in written procedure (WP).

Draft decisions unanimously agreed by MSC in WP:

Testing proposal examinations

MSC ID number	Substance name used in draft decision	EC number
TPE-068/2015	2-Butenedioic acid (Z)-, ester with 1,2-propanediol, compd. with 2-(dibutylamino) ethanol	286-304-6
TPE-073/2015	1,6-hexanediyl-bis(2-(2-(1-ethylpentyl)-3-oxazolidinyl)ethyl)carbamate	925-259-5

Compliance checks

MSC ID number	Substance name used in draft decision	EC number
CCH-016/2015	Slags, ferromanganese-manufg	273-728-1
CCH-019/2015	Sodium prop-2-enesulphonate	219-676-5
CCH-029/2015	Diisotridecyl 3,3'-[(dibutylstannylene) bis(thio)]dipropionate	284-461-5
CCH-030/2015	2-phenoxyethanol	204-589-7
CCH-034/2015	Potassium thiocyanate	206-370-1
CCH-035/2015	Sodium thiocyanate	208-754-4
CCH-039/2015	Hexahydro-1,3,5-trimethyl-1,3,5-triazine	203-612-8
CCH-040/2015	Dimethyl carbonate	210-478-4

VII. Substance evaluation cases addressed for MSC agreement seeking in written procedure (WP).

Draft decisions unanimously agreed by MSC in WP:

MSC ID number	Substance name used in draft decision	EC number
SEV-BE-02/2013	Ammonium salts of mono- and bis[3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl and/or poly (substituted alkene)] phosphate	700-403-8
SEV-IT-21/2013	Tert-butyl perbenzoate	210-382-2
SEV-IT-23/2013	Diisodecyl azelate	249-044-4
SEV-NL-34/2013	Reaction mass of mixed (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) phosphates, ammonium salt	700-161-3

Draft decision for which the written procedure for agreement seeking was terminated by the Chairman of the Member State Committee:

MSC ID number	Substance name used in draft decision	EC number
SEV-SK-26/2013	Mixture of two components: 1. N-(1,3- dimethylbutyl)-N´- phenyl-p-phenylenediamine 2. N1-(1,3-dimethylbutyl)- N4-(4-(1-methyl-1-phenylethyl) phenyl)benzene-1,4-diamine	448-020-2

VIII. Statements to the minutes as regards agenda item 10 'Opinion of MSC on ECHA's draft 6th recommendation of priority substances to be included in Annex XIV'

MSC-42

Statement to the minutes of Germany, Italy, Czech Republic, Spain, Poland and Austria on the inclusion of four lead substances into the 6th ECHA recommendation

The representatives on the MSC for the countries named above do not support the inclusion of the substances Orange lead (lead tetroxide), Lead monoxide (lead oxide), Tetralead trioxide sulphate and Pentalead tetroxide sulphate into Annex XIV.

We doubt about the proportionality and the regulatory effectiveness of inclusion of these lead substances into Annex XIV. Lead substances are already highly regulated in various legislative acts (e.g. Battery Directive (2006/66/EG), End of Life Vehicle (ELV) Directive (2000/53/EC), RoHS Directive (2011/65/EU)). Further regulation of the lead substances by listing them in Annex XIV should be reflected in the light of climate protection efforts: promoting of batteries for storing renewable energy.

Regarding this we request ECHA to further analyse the benefits of prioritising these already regulated substances for Annex XIV inclusion at the current stage. Based on the results of this analysis the best way forward should be discussed.

Statement on the adoption of the MSC opinion on the 6th recommendation

The Netherlands, Norway and Lithuania supported the MSC opinion mentioned above.

These countries are of the opinion that in the case ECHA – for reasons associated with the expected workload - would need to recommend a lower number of substances for inclusion in Annex XIV, it should give priority to the lead substances over the boron substances.

Although the risks associated with the use of both groups of substances are to be regulated ultimately through a placement on Annex XIV, for these countries the regulation of the use of lead containing substances is nationally of a higher priority due to the expected higher risks for the general public and the environment associated with the use of lead.