MSC/M/58/2018

Adopted at MSC-59

Minutes

of the 58th Meeting of the Member State Committee (MSC-58)

6-9 February 2018

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 58th 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 modified by the MSC Secretariat with addition of an information item to AOB where Secretariat presented slides on work and results from the previous year (final Agenda is attached to these minutes as Section III).

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-58.

Item 4 - Administrative issues

The Chairman reminded MSC that plenary meetings may be followed through Secure WebEX and the remote participants should register well in advance. Late registrations are accepted only in exceptional and reasoned circumstances, and depending on availability of the participant's declaration of confidentiality.

- **Outlook for MSC-59**

The Chairman presented an estimation on the potential length of the next meeting which is expected to require approximately four and a half plenary days. The Chairman also presented an early stage estimation for the length of the MSC-60 meeting in June highlighting that the meeting could require approximately seven and a half days. Secretariat will update MSC on this topic at the next plenary meeting in April. In addition, the Chairman informed MSC of tentative meeting dates for 2019.

As one follow-up action from MSC-57 the Chairman informed MSC that the update on the discussions regarding the somatic and germ cell sampling time in the TGR is currently scheduled for the MSC-59.

- **Feedback from 2017 Stakeholder satisfaction survey**

SECR provided feedback from the 2017 Stakeholder survey outcome, relevant for MSC and outlined the potential further actions considered in this regard.

Item 5 – Minutes of the MSC-57 meeting

The minutes of MSC-57 were adopted as modified at the meeting.

Item 6 – Substance evaluation

1. Community Rolling Action Plan (CoRAP) & MSC opinion development

Discussion on the draft MSC opinion

The Rapporteur presented the draft opinion and its annex and explained that since the December MSC-57 meeting 16 justification documents were updated, 11 of them were updated on the request of the Working Group members. Overall, the changes made since

the referral of the draft CoRAP update 2017-2019 included 1) withdrawal of two substances already in CoRAP; 2) changes in years of evaluation and 3) notification and inclusion of two new substances.

During the discussion one industry stakeholder observer explained that the extensive shifts of years of evaluation make it very difficult for industry to plan and wished this concern would be considered in future rounds. Additionally a clarification was requested for putting antimony tri-chloride in the CoRAP when it lacked an exposure based concern and it was already part of the COLLA discussions on antimony substances. It was explained that, as described in its justification document and the opinion, due to the grouping approach with other antimony compounds it was considered an appropriate CoRAP candidate. MSC was reminded that the COLLA approach is an informal collaboration between (a) member state(s) and registrants and it has no regulatory power to require any information generation. On the other hand, if the substance that is part of COLLA is also put on the CoRAP it allows ECHA to ask for further information where needed.

Adoption of the MSC opinion

MSC adopted by consensus the opinion on the draft annual CoRAP update 2018-2020 and its annex. It was concluded that the MSC opinion together with the final update to CoRAP will be published on the ECHA website on 20 March 2018.

2. Decision making process

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

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on three substance evaluation cases (see Appendix to the final agenda in Section III for more detailed identification of the cases). WP was launched on 11 January 2018 and closed on 22 January 2018. By the closing date, unanimous agreement was reached on one draft decision (DD). For two DDs WP was terminated by the MSC Chairman on the basis of Article 20.6 of the MSC Rules of Procedure.

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-DE-013/2016 Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC No 270-128-1)

Session 1 (open)

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

The eMSCA from Germany (DE-CA) presented the SEv outcome of the above-mentioned substance. The initial grounds of concern when placed on the Community Rolling Action Plan (CoRAP) were: suspected PBT/vPvB, exposure to the environment, high aggregated tonnage and wide dispersive use.

The registered substance is a UVCB containing eleven identified constituents at well-defined concentration ranges. Besides the two starting reactants the registered substance consists of mono-, di- and tri-alkylated diphenylamine isomers. The alkyl chains, tert-butyl and/or tert-octyl, are substituted in para position (major part) or in ortho position (minor part) of the nitrogen atom of both aromatic rings. Based on estimations (regarding log Pow, ready biodegradability and long-term toxicity) from the available screening level information of all relevant (diphenylamine) constituents of the registered substance, eight

of the nine constituents have potential PBT properties. On the basis of the bioaccumulation potential (BCF values) and QSAR estimations on water solubility DE-CA considered that the constituent fraction of concern with regards to the PBT assessment are the para/ortho isomers of ditertbutyldiphenyl-amine – DTBDA- and monotertoctyldiphenyl-amine (a fraction with MW of 281,3g/mol). From this fraction, it was requested to test DTBDA to clarify if this constituent meets the P, B and T criteria and to decide whether the registered substance (if it is PBT/vPvB) needs revised risk management measures (RMMs).

The DD notified to the MSCAs and ECHA requested for following tests on DTBDA: 1) Simulation degradation test in water (OECD TG 309); 2) Simulation testing in sediment (OECD TG 308), if request 1 does not conclude on P or vP properties; 3) Bioaccumulation in aquatic species (OECD TG 305) if requests 1 and 2 allows to conclude that the registered substance is P or vP; 4) Long-term toxicity testing on *Daphnia magna* (OECD TG 211) if tests 1-3 allow to conclude that the substance is P/B or vP/B or P/vB; 5) Growth inhibition study on algae (OECD TG 201) if tests 1-3 allow to conclude that the substance is P/B or vP/B or P/vB; 6) Long-term toxicity testing on fish (FELS, OECD TG 210) if the toxicity tests 4-5 do not allow to conclude that the registered substance is T.

MSC was guided by the expert from the DE-CA through the information on the substance and through the twenty-seven proposal for amendments (PfAs) received from four MSCAs and from ECHA, the Registrants' comments on the PfAs and the eMSCA's response to them.

Regarding the choice of the fraction of concern of MW=281,3g/mol and testing DTBDA one PfA proposed to consider a testing strategy to clarify the PBT properties additionally for the fractions of concern with MW of 225,2 and 337,4 g/mol.

Regarding the simulation degradation testing and testing strategy another MSCA proposed that if after OECD TG 309 the substance is not considered as P or vP, the first follow-up test would be an OECD TG 307 (soil simulation test), before the test OECD TG 308 (sediment simulation test). Additionally some editorial clarifications in the DD were proposed, especially referring to non-extractable residues (NER), SPM concentrations and organic matter. They suggested to include an explanation for the potential necessity of prolonging the test duration due to potential NER formation. Also they proposed that, when performing OECD TG 309, the Registrant shall employ an SPM concentration between 10 and 20 mg/L, to explain and scientifically justify the extraction procedure and solvent used when reporting the NER. Another PfA proposed that if OECD TG 309 results indicates that DTBDA is not P, no other testing should be requested, instead give the opportunity to the Registrant to justify that the degradation testing in one compartment is sufficient if the results can be extrapolated to other compartments. One PfA proposed that either the OECD TG 309 or the OECD TG 308 study should be requested but not both, and disagreed that a tiered test strategy for persistence requiring two tests would be necessary. Finally, a PfA proposed to specify in the DD that the absence of any CO_2 formation during OECD TG 301B test would suggest that none of the constituents of the UVCB substance could be ultimately degraded under the conditions of the ready biodegradation test.

Regarding bioaccumulation testing few PfAs suggested editorial amendments in the DD in order to clarify the relevance of requesting to test DTBDA or requesting justification of the aqueous vs dietary exposure in B testing. One proposal suggested to not only request testing for isomers of DTBDA, but also on isomers of monotertoctyldiphenyl-amine, because based on the log Kow estimations, it cannot be quaranteed that DTBDA has a higher bioaccumulation potential. Alternatively to their proposal to consider MW fraction of 281.3, they proposed to request an OECD TG 305 dietary exposure for the three relevant fractions of (MW of 225.2, 281.3 and 337.4) of the UVCB substance.

Regarding toxicity testing in another PfA it was proposed to amend the text by including justification on the necessity to perform environmental toxicity testing T_{eco} once that tests

to assess human toxicity ($T_{mammalian}$) were conducted and the data are available. The PfA also provided editorial suggestions for clarifications of the text in the DD.

Additionally some PfAs on other aspects were submitted, such as: a proposal to request initial determination of water solubility (OECD TG 105) and log Kow (OECD TG 123 or OECD TG 117) depending on the suitability of the method). One PfA proposed multiple deadlines for the registrant to provide the information requested for each step of the sequential testing, including robust study summaries, full study reports, and, where relevant, an update of the Chemical Safety Report to allow the eMSCA to analyse the raw data and consider study details to conclude on the scientific merits of the studies and the interpretation of the results and their use in the PBT-assessment.

Nearly all the PfAs submitted were accepted and introduced in the DD prior to the meeting, whereas the remaining open issues for discussion at the meeting were focused on the simulation degradation and sequential testing strategy, and on testing only *para-para* and *ortho-para* isomers of DTBDA (pp-DTBDA or op-DTBDA) or if to test the more fractions of the UVCB substance.

The Registrants submitted written comments on the PfAs. In response to the PfA regarding the choice of the fraction of concern the Registrant/his representative confirmed both in writing and at the meeting that the composition of MW=281.3 g/mol has to match the composition of the registered material of the different Registrants.

Registrant's representative stressed that due to structural differences and differences in side chain lengths, tests on single constituents brings more relevant results for the assessment of the substituted diphenylamines compared to a complex group of constituents. It was further stated that there is a need to consider testing the same substance matching with the substance used in other tests. Registrant's representative explained that from their preliminary toxicity data some adverse effects were observed, however it was not possible to identify the active constituent responsible for a certain effect.

The Registrant's representative highlighted that the results from ecotoxicity testing would be difficult to interpret if the test material is more complex, for this reason their wish would be to test only the one constituent that is considered the worst case with regards P, B, and T. During the discussion the Registrant's representative responded to questions regarding ongoing or finalised tests. They explained that data gathering from Canadian studies on 4-nonyl-N-phenylaniline can be used for read across and/or indicate the way forward to comply with the SEv requirements.

Some members raised questions regarding the order of tests - OECD TG 309, followed by 308, then by 307 - in the sequential testing strategy, or if only one test OECD TG 309 would provide sufficient information. They also discussed on the relevance of the results if the tests will be performed on only one fraction and if the "known constituent" approach would be representative for the whole UVCB substance.

Regarding the testing strategy one MSC member considered that a first follow-up test should be an OECD TG 307, if OECD TG 309 will be the first step in the sequential testing. He argued that it is possible that the registered substance would degrade very quick in water and NER products absorbed/deposited in soil or sediment would result, so a borderline situation providing false negative P/vP results could occur if only OECD TG 309 would be requested.

The expert from the eMSCA highlighted the technical difficulties for performing the tests on the whole substance and presented scientific arguments for supporting the testing strategy with DTBDA as proposed in the DD. In their view testing only the *para/ortho* isomers of DTBDA represent the worst case of the (v)P, (v)B and T properties of all constituents of the UVCB substance, avoiding uncertainties arising from many possible degradation products of the whole substance (having different degradation half-life in water compartment).

Session 2 (closed)

MSC discussed in detail possible ways of addressing the remaining open questions: 1) the possibility to extrapolate results from one compartment to other non-tested compartments; 2) the possibility to identify an worst case compartment for P assessment; 3) challenges of one "known constituent" approach in the testing strategy; 4) choosing best sequential testing strategy in light of PBT Guidance documents[1] and on reports from ECHA's PBT expert group (PBT EG)[2].

The expert from the eMSCA shared with MSC members data on the simulation degradation testing in regards the possibility to extrapolate results from one compartment (water) to other non-tested compartments (soil, sediment). There are no REACH registered substances for which all three simulation tests are available, however, only in two out of eight found it seems possible to extrapolate from one compartment to another. One advisor queried whether all of the reported results were deg50[3] results rather than DT50s which would affect this conclusion ("deg50" and "DT50s are degradation rates or corresponding dissipation half-lives to be used in models for calculating Predicted Environmental Concentrations for ground and surface water for parent substance and metabolites, see footnote).

The expert from the eMSCA concluded that the limited data analysis does not contradict the assumption that water could be the worst case compartment for P assessment, but for a general conclusion on this matter a more comprehensive analysis would be needed. In addition, it considered that in P and B testing it is not technically possible to test simultaneously both constituents of fraction MW=281 g/mol (due to the anticipated differences in BCF values in water and in fish, and because of difficulty of assessment of the primary degradation of every single constituent).

An MSC member highlighted the importance to follow ECHA's Guidance documents and in the same time taking into account (on a case by case basis) complementary criteria or conclusions issued from the activity of PBT EG.

Based on the discussions MSC agreed unanimously to 1) amend the DD by removing the request for Simulation testing in sediment (OECD TG 308), but to add a statement that if a concern on the P/vP in some of the environmental compartments remains, ECHA can consider whether further simulation testing needs to be requested in future SEV decisions; 2) request the information using as test material either ppDTBDA or opDTBDA; 3) agree multiple deadlines depending on the information to be generated; 4) keep the requests for sequential B and T testing and the corresponding conditionalities as initially proposed by the eMSCA.

The MSC unanimously agreed on the decision as amended in the meeting as indicated above.

SEV-DE-014/2016 2,2',6,6'-Tetrabromo-4,4' isopropylidene- diphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether (TBBPA-PO-nBGE) (List No. 926-564-6)

Session 1 (open)

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

The eMSCA from Germany (DE-CA) presented the SEv outcome of the above-mentioned substance. The initial grounds for concern as placed on the Community Rolling Action Plan

[1] https://echa.europa.eu/documents/10162/13643/information_requirements_part_c_en.pdf
[2] https://echa.europa.eu/pbt-expert-group
[3] http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788

(CoRAP) were that relating to Potential endocrine disruptor, Suspected PBT/vPvB and Exposure of environment. In the course of the evaluation, the evaluating MSCA identified an additional concern regarding long-term aquatic toxicity.

TBBPA-PO-nBGE is a UVCB substance containing five identified constituents at well-defined concentration ranges. The identity of one further constituent was unknown with a share of a few percentage points in the UVCB. For the PBT assessment, one constituent (constituent No. 4) was selected for testing which, due to its potential bioaccumulation properties, was considered by the eMSCA to be the most likely candidate for a potential PBT substance, and therefore for the conclusion of the PBT assessment for the registered substance subject to evaluation.

The DD consulted with the MSCAs and ECHA requested for two long-term tests on aquatic invertebrates (OECD TG 211) - one using the UVCB substance and another using constituent 4; two long-term tests on fish (OECD TG 210; FELS) - one using the UVCB substance and another using constituent 4 and bioaccumulation in aquatic species (OECD TG 305) using constituent 4.

MSC was guided by the expert from the eMSCA through the information on the substance including thirty-four proposal for amendments (PfAs) received from four MSCAs and ECHA, the Registrants' comments on the PfAs and the eMSCA's response to them. The discussion of MSC focused on the PfAs as described below.

Regarding the choice of test material, PfAs were received from three MSCAs. PfAs expressed a diverging view or unclarity why component 4 was the main focus. In the view of one of the PfA submitters, constituent 2 was more relevant since it constituted approximately half of the substance's composition, had a Log Kow of 4.8, and water solubility of 5ug/L (most likely making aquatic testing feasible). Constituent 4 constituted approximately 20% of the substance's composition and water solubility of 0.3ug/L. Another PfA pointed out that further clarification on the choice of constituent 4 was needed, whereas a further PfA mentioned that the PBT criteria relate to all relevant constituents > 0.1% and that it should not be stated in the DD that testing for only one constituent for PBT is 'proportionate'.

Regarding the testing strategy and simulation degradation testing, PfAs were received from four MSCAs. Three of them preferred to follow the testing strategy as described in the recently updated PBT guidance of ECHA. One MSCA could accept that the available data on the substance indicated that the P criterion likely would be fulfilled, but as the data may not be sufficient to judge whether the substance also fulfilled the vP criterion, they believed it was more appropriate to follow the standard testing strategy and to investigate first whether both the P and vP criteria were fulfilled. Another PfA submitter on the other hand was not convinced that there was sufficient evidence to decide whether the substance is either P or vP. The available screening studies were performed at concentrations that were significantly above the water solubility of the different constituents, therefore bioavailability would have been limited. There was also no information on primary degradation (which may not be evident from screening studies), nor any available half-lives. Similarly, a third PfA submitter proposed to consider including a justification why for this specific case only screening tests and QSAR estimations were considered sufficient for (tentatively) concluding that the UVCB substance and the constituents fulfilled the P criteria. Normally, screening level information was not sufficient for a definitive conclusion on P/vP.

PfAs were also received on the simulation degradation test design and their testing order. They proposed to start with OECD TG 309 with a natural SPM content between 10-20 mg/L with the specification that an appropriate extraction procedure should be chosen to minimise the impact of NER formation. If not technically feasible, then to request another simulation degradation test according to OECD TG 308 or TG 307. If the simulation degradation testing result indicated the substance is P, then to proceed with bioaccumulation testing (OECD TG 305).

Regarding the request for bioaccumulation in aquatic species (OECD TG 305), PfAs were received from three MSCAs and ECHA. Two different types of proposals were received. One proposed to perform a fish bioaccumulation test via dietary exposure using the whole registered substance. P testing should then be performed to address specific constituents which meet the criteria for B or vB. Another type, proposed to perform the bioaccumulation test in aquatic species with the whole substance or all relevant constituents, and not with constituent 4 only, unless none of the constituents fufill the P/vP criteria. Other PfAs were received of editorial nature.

Regarding toxicity testing, PfAs were received from two MSCAs and ECHA. Three types of PfAs were received. One expressed doubt on the approach used to determine component 4 as the most ecotoxic component, and disagreed with requesting these tests on both the registered substance and constituent 4. Hence, these combined PfAs showed preference to perform T testing after the P and B testing, and to test only one constituent for T. Additionally, the PfAs expressed the view that without an exposure assessment a data-gap driven concern for long-term aquatic toxicity cannot be justified, and hence the concern should focus on addressing the T criterion for the PBT-assessment. Furthermore, it expressed disagreement with performing the long-term invertebrate and fish testing in parallel, since testing in fish may be unnecessary if T criterion is met based on the invertebrate testing

The second type of PfAs were against use of whole substance water accommodated fraction (WAF) based ecotoxicity testing because, even if the WAF indicated an EC10 or NOEC > 10 ug/L, some constituents of the UVCB could still be vPvB or less toxic constituents could be masking/ diluting the effects of the most toxic constituents. Hence, it was proposed to remove the request to test with the registered substance (WAF-testing) and choose only those constituents for T testing that fulfil the (v)P and (v)B criteria.

The third type of PfAs on toxicity testing were text suggestions to clarify the DD.

The expert from the eMSCA explained their reasons for deviating from the testing strategy described in the PBT guidance document and to start with testing for toxicity. In their view, the data available gave strong hints (through QSAR estimations and screening tests) that the substance meets the P criterion; it seemed relatively unlikely that the substance would fulfil the vB criterion; there were strong hints, but limited data, available that the substance may be a PBT and long term toxicity data for the aqueous environment were missing from the registration dossier. Hence with this proposed strategy, if the results showed that the registered substance was not T, they would assess the possibility of it being vPvB at a later stage.

The Registrants in their written comments to the PfAs supported the approach by the eMSCA to start testing on T. They stated that they already initiated a chronic daphnia study (OECD TG 211) on the test substance, which was in progress during the time of the meeting. They were of the view that the FELS (OECD TG 210) should not be conducted in parallel with the Daphnia study but only based on the outcome of the Daphnia study. The Registrants stated that they also consider the substance as P, hence in their view there was no need to start with the P testing. They also doubted that the substance was B and suggested to request the B test in a second SEV DD.

Regarding the test material, the Registrants were not in favour of testing on constituent No. 4, since it was not isolated in the manufacturing process and there was no synthesis method available to artificially produce it. Furthermore, it was not comprehensible why constituent No. 4 was prioritized. They recommended to request testing of the substance as registered.

Regarding P testing, the Registrants were asking for more specification on the ‘natural SPM’ requested for OECD TG 309.

Regarding the BCF calculations obtained using the model Bio Loom, the Registrants were questioning those calculations since the QSAR model used is not listed in the PBT guidance

document and the results obtained with this model by the Registrants were very different from those obtained by the eMSCA.

During the discussion much emphasis was put on the difficulty to use WAF toxicity testing for PBT assessment of UVCB substances. Since in a WAF the most water-soluble substances will dominate what is in solution, the toxicity obtained from such a test, will mostly reflect the most soluble components. The toxicity of lower solubility components expressed in a WAF may mask their true individual toxicity – i.e. it could be unclear whether or not they are "T". For this case, WAF would not inform on the toxicity of constituent 4 since it has a very low solubility. For this reason WAF is not useful in a PBT assessment of UVCB substances, unless all constituents of the substance tested are very comparable to each other and they can be considered to behave as one constituent. Furthermore, the WAF was designed for use in the classification and labelling of UVCBs as it provides results based on a loading rate, and it was stated that it should not be used for risk assessment, which requires results based on individual component concentrations.

Regarding the P testing, concern was expressed on whether screening tests and QSARs are sufficient to conclude that the substance is persistent, especially since it was not clear whether bioavailability had been considered in the interpretation of the screening test results. In this regard two views for a potential way forward were expressed. One was to request for P testing in this decision. The other was to await the outcome of the studies requested in the SEV decision on TBBPA, a structurally similar substance for which simulation test have been requested on two methylated degradation products, expected to be available in 2021, and to start with B testing instead.

Session 2 (closed)

In the closed session the eMSCA expert proposed to revise the testing strategy. Since performing a P testing in the view of the eMSCA is a confirmatory test for this case, and testing for P on the whole substance was likely to be technically difficult because of the different water solubilities of its constituents and ability to interpret degradation of multiple constituents of a UVCB in sediment/soil tests, they proposed to follow the option to start with B testing. The issue of constituents with different solubilities would be encountered if an aqueous B testing would be performed, furthermore the water solubility of many constituents were likely to be so low that aquatic testing would be technically very challenging / not feasible, hence the eMSCA proposed to test the whole substance via dietary exposure. The results of the B testing could then be considered in the follow-up decision for deciding on the need further testing on T or P. This approach received support from MSC.

The remainder of the discussion focused on strengthening the justifications for starting with B testing, since the Registrant informed that they already started long-term toxicity testing on invertebrates. MSC discussed that, since it is an Annex IX standard information requirement, a testing proposal should have been submitted and decided upon first.

The QSARs run by the eMSCA were re-run by an MSC member during the meeting which identified some deficiencies in the predictions. In case of constituents 4 and 5 these were outside the molecular weight range of the compounds in the training sets of the models BIOWIN 1, 2 and 3. Additionally, for the same models, the molecular fragments of the constituents were not completely included in the prediction. However, the member considered that despite these deficiencies they could still accept the QSAR models.

The change in testing strategy as discussed lead to a reduction of the deadline to 12 months.

The MSC unanimously agreed on the decision as amended in the meeting.

SEV-ES-019/2016 Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene (EC No. 271-867-2)

Session 1 (open)

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

The eMSCA from Spain (ES-CA) presented the SEv outcome of the above-mentioned substance. The initial grounds for concern as placed on the Community Rolling Action Plan (CoRAP) were that relating to suspected PBT/vPvB properties, wide dispersive use and exposure of environment. In the course of the evaluation, the evaluating MSCA identified an additional concern regarding sediment and soil toxicity.

The registered substance was a UVCB substance consisting of reaction products of p-cresol with dicyclopentadiene (DCPD) and isobutylene. The main constituent 2,2'-(octahydro-4,7-methano-1H-indenediyl)bis[6-tert-butyl-p-cresol] (EC No. 255-504-5) and one minor constituent, 2,6-di-tert-butyl-p-cresol (EC No. 204-881-4) of the registered substance were identified but the main part of the substance includes unidentified constituents at concentrations of individual constituent groups < 10 % w/w each but which are still relevant for the PBT assessment. Seven different constituent groups were identified in the DD as Type A to Type G. Each constituent group included different isomers due to the multiple possible positions of the phenol rings relative to the DCPD group. Furthermore, all constituent groups except one (Type G) included also different oligomers with varying number of cresol-DCPD monomers indicated with brackets and “n” (n=1, n=2, etc.). Based on the available information, the most typical constituents were of Type A, which also includes the identified main constituent.

The DD consulted with the MSCAs and ECHA requested for 1) water solubility, column elution method (OECD TG 105) to explore water solubility of specific constituents of the registered substance; 2) bioaccumulation in fish, aqueous or dietary exposure, (OECD TG 305) with a mixture of representative constituents of three constituent groups expected to have worst-case PBT properties; 3) simulation degradation test (OECD TG 309) on the constituent showing worst case in B (request 2 above); 4) long-term toxicity to aquatic invertebrates (OECD TG 211) on the constituent showing worst case in B and P (requests 2 and 3 above); 5) long-term toxicity to fish (OECD TG 210) on the constituent showing worst case in B and P (requests 2 and 3 above). Request 4 did not need to be performed if the constituent representing worst-case PBT properties met the vPvB criteria. Request 5 did not need to be performed if the constituent representing worst-case PBT properties could be concluded as T based on request 4.

MSC was guided by the expert from the eMSCA through the information on the substance including sixteen proposal for amendments (PfAs) received from five MSCAs and ECHA, the Registrants’ comments on the PfAs and the eMSCA’s response to them. Nearly all the PfAs submitted were open for discussion at the meeting since the eMSCA maintained the order of testing strategy as consulted with the MSCAs and ECHA by requesting for B, P and then T. Each PfA submitter maintained their PfAs during the discussion.

Regarding the choice of test substance, different views were expressed. The preferred approach by the eMSCA was the one presented in the DD, i.e., to identify the potentially worst case constituents and test a mixture of representative constituents of the three constituent groups. In this regards, the eMSCA was asked to consider more of the constituent groups to be tested since after running four models the PfA submitter identified other constituents where B cannot be excluded. Another approach was however also presented in a PfA. It was proposed to fraction the UVCB substance, using preparative HPLC, into a fraction with log K_{ow} below 10. This fraction could subsequently be used to perform the requested tests. The latter approach would prevent that potential PBT constituents are excluded, however, it was recognised that it might be challenging to be applied via aquatic exposure.

Regarding the testing strategy PfAs were received from three MSCAs. One type of PfAs proposed to change the order of testing to P, B and T. If specific components could be isolated for the purposes of B testing, it seemed that the same components could also be used to conduct a persistence test. The other type of PfAs proposed to add a justification on why it is likely that B-testing would be needed anyway, even if testing was started with degradation testing, and why it was thought that the reverse order did not lead to more vertebrate testing than what would be the case when starting with degradation.

Regarding the bioaccumulation testing, due to the complexity of the substance and the expected low of water solubility values of the constituents to be tested, one MSCA proposed a dietary OECD TG 305 study instead of the aqueous testing.

Regarding simulation degradation testing, PfAs were received from four MSCAs. All PfA submitters agreed to request for OECD TG 309. A text was proposed giving more detailed description of the conditions necessary for the test. If it was not technically feasible to conduct an OECD TG 309 (surface water simulation test) PfAs asked for OECD TG 307 (soil simulation test) to be conducted, instead of giving a choice between OECD TG 307 and OECD TG 308 (sediment simulation test), or for a OECD TG 308. Another PfA discussed the test item to conduct such test and proposed to either use one constituent from the Types A n=1, B n=1 and D n=0 to be tested on OECD TG 309 and leave it to the Registrants to justify the representativeness of the result to the rest of the constituents, or else test a mixture of representative constituents from the Types A n=1, B n=1 and D n=0 using either OECD TG 307 or OECD TG 308. Other PfAs proposed to consider whether simulation degradation testing in other compartments was needed if the outcome of the test is not P, and to introduce a text to align the SPM concentration of naturally occurring SPM with the PBT guidance.

Regarding toxicity testing, PfAs were received from three MSCAs and ECHA. PfAs received proposed to 1) delete the toxicity tests on invertebrates and fish and revise the deadlines accordingly; 2) delete the text in the DD stating that T_{eco} related testing would not be needed if the substance is vPvB based on the initial P and B related tests since in the view of the PfA submitter this would be needed for subsequent risk management measures e.g. to consider the substance for the Stockholm Convention; 3) include in the DD information about the potential $T_{mammalian}$-status of the registered substance or its constituents based on available information; 4) change the request for an OECD TG 210 (Fish Early Life Stage test; FELS) to an OECD TG 234 (Fish Sexual Development Test; FSDT) due to endocrine disrupting properties from the phenolic impurities.

The expert from the eMSCA explained the reasons for deviating from the testing strategy described in the PBT guidance document and to start with testing for bioaccumulation. In the view of the eMSCA, due to the high complexity of the registered substance, testing with the whole substance to clarify the PBT concern according to the standard P-B-T testing strategy was not feasible. They proposed to first test for B, then P and finally T. They used an approach where the constituents/constituent groups expected to present worst-case PBT properties were tested first for B, then only the representative constituent with worst case B properties would be tested for P and T. Based on the QSAR predictions, eMSCA identified 3 constituent groups that were most likely to have PBT properties. When using a mixture of representative isomers of the constituent groups expected to have worst–case PBT properties for testing, starting off with P assessment in a simulation study, required a thorough investigation of the extraction procedures and analytical detection limits. Hence, eMSCA proposed to start with testing for B so that the number of constituents in the mixture that would need to be tested for P could be reduced and the formation of NER could be minimised. Some MSC members argued that the same thorough investigation in extracting the constituents is needed even for testing the B in aqueous system, as proposed in the DD. In fact for the latter measurements need to be taken both in fish and in water. In this regards considering the different solubilities and hydrophobicity of the constituents of this registered UVCB substance, some members still expressed

preference to perform the necessary tests using the fractionation approach as proposed in the PfAs.

The Registrants in their written comments on the PfAs considered that their original proposal to conduct the test using an equal mixture of radiolabelled test substances was an appropriate approach in order to drive suitable results for investigation. They asked for an extension of 18 months to isolate and prepare the test items (i.e. test material) and requested a minimum of 36 - 54 months if additional constituents were requested. They explained that extraction of test items was not straightforward and requested to have a discussion with ECHA after the isolation of the test substances to discuss what has been obtained. Regarding P-testing, they had no objection to the alteration of the study order. In their view it is most likely that the outcome of further testing will show the substance's constutuents will meet the P criterion, hence by prioritising B testing it accelerates efforts on risk assessment. They also showed preference to be given to the option to choose between OECD TG 307 (soil) or OECD TG 308 (sediment) in case OECD TG 309 (surface water) is shown not to be technically possible. Furthermore, they requested to change the deadline from 51 months to 60 months to generate the required radiolabelled material.

Regarding P-testing, MSC discussed whether it is possible to extrapolate a non-persistency conclusion based on results from an OECD TG 309 to a conclusion that the substance is also not P in sediment and soil. One MSC expert argued that for a substance which does not have a specific anaerobic degradation pathway, OECD TG 309 could be considered as a worst case simulation degradation test and in such case, degradation in soil and sediment would not need to be asked for. Therefore, extrapolation of non-persistency to other compartments needs to be assessed on a case by case basis following the decision tree found in the recently updated PBT guidance document.

Regarding T testing, the Registrants in their written comments to the PfAs stated that the OECD TG 211 and OECD 210 tests were not necessary since recent OECD 211 and an OECD 210 tests using WAF of the substance are already available. They had submitted the results obtained in the recent OECD 211 test in their comments on the PfAs, stating that these would be included in the registration dossier soon. Based on these results, the whole substance was not active on Daphnia and they did not wish this test to be repeated. They did not agree to perform a FELS (OECD TG 210) test on the worst-case PBT constituent since the constituent might end up being a minor constituent in the commercial sample and based on the existing OECD 210 test the substance is not active on fish. If the test was still requested, they found the deadline of 72 months as acceptable. They also highlighted that the whole substance was already confirmed as T based on the reproduction data.

In this regards, MSC discussed whether they could agree with the Registrants to perform T testing for environment on the whole substance (water accommodated fraction (WAF) approach) and whether information on $T_{mammalian}$ and WAF testing can be extrapolated to an individual constituent. It was argued that humans are (more) directly exposed to UVCB substances than environmental species such that whole substance testing in respect to human health in many cases may be a reasonable approach. Environmental species are not directly exposed to the composition of the whole UVCB substance due to the differences in the environmental fate and behaviours of the UVCB constituents. Hence, for the latter a constituent approach is feasible whilst for humans a whole substance approach is better placed. MSC disagreed with the approach used by the Registrants to use a negative test from the WAF testing to conclude that the substance is not toxic for the environment. It was argued that the WAF approach should not be used for PBT assessment of UVCB substances (see SEV-DE-014/2016). Instead either the fractionation approach or the worst-case constituent approach should be used. For this case, one MSC expert expressed the view that based on the fact that the whole substance is classified as reprotoxic, this information could be used to fulfil the T mammalian part in the PBT assessment. However, another MSC expert considered that to reach a conclusion on T_{eco} constituent toxicity testing is still needed.

Session 2 (closed)

Following the discussion in open session, the eMSCA expert explained that as the Registrants agreed that they could produce a mixture of constituents, the best approach in the view of the eMSCA was to test for P or B with this mixture. As P testing with simulation degradation tests could result in the production of NERs due to the nature of the constituents, eMSCA expressed the preference to start with B testing. Due to the different hydrophobicity of the constituents making up the proposed mixture, the eMSCA expert agreed to request for OECD TG 305 via dietary exposure.

MSC agreed with the suggestion to start testing for B using OECD TG 305 via dietary exposure, however, there were still two main views with regards to the test substance. One view (eMSCA's view), was to use the worst-case constituent mixture and measure the individual constituent BMFs. This would allow the determination of the constituent with the highest BMF value to continue testing for P. T testing would then be performed with the worst-case P and B constituent. The second view was to use the HPLC fractionation approach for both B and P testing. This would make it possible to compare the peaks in the chromatograms and identify which constituents in the (HPLC-) fraction are both P and B. However, since T testing needs to be performed on one constituent only and not a fraction, the test item for this purpose would be the constituent with the highest BMF value. Whilst the constituent mixture approach could be regarded as a simpler approach, yet the fractionation approach investigates more constituents thus eliminating the uncertainty whether the selected three constituents making up the mixture in the first approach, are truly the worst case.

One proposed way forward was to give the Registrants the option to choose from amongst the two approaches and to justify why the fractionation approach was not chosen in case the Registrants still chooses the constituent mixture approach, as already indicated in their written comments to the PfAs. MSC expressed preference to the constituent mixture approach, however, due to the complex composition of the substance, some were reluctant to keep testing for P in the same decision once results from B testing are obtained. They preferred to have the eMSCA assess the outcome of the B assessment by the Registrant and then decide the next steps for P and T assessment in a follow up decision. Because this would lengthen the PBT assessment, an option was presented to introduce several deadlines after each set of results are obtained and allow the Registrants to discuss with the eMSCA on the best way forward for further testing. However, when this suggestion was further explored, it was recognised that the review periods after each test would still need to be generous enough to provide for a quality assessment, hence the overall timelines of this option would not differ much from having a decision requesting for only B assessment with further testing requested in a follow-up decision. Furthermore, it would shift the responsibility for the PBT-assessment within the context of the decision towards the eMSCA instead of keeping this with the Registrants.

Hence in order to ensure transparency in the testing strategy, eMSCA expert proposed to revise the testing strategy by requesting only for OECD TG 305 via dietary exposure route using an equal mixture of the representative constituents of Type A n=1, B n=1, C n=0, D n=0, E n=0 and F n=0. Three constituent types (C, E and F with n=0) were added based on a PfA and should be tested in the OECD 305 test unless the Registrants can justify that they are not present in the substance at concentrations relevant for the PBT assessment. Since the dietary route was chosen, the request for the water solubility testing on the constituents was no longer required. The requests for P and T testing were removed from the decision and will be re-assessed during the follow-up stage. The deadline of the decision was revised accordingly.

The MSC unanimously agreed on the decision as amended in the meeting as indicated above.

SEV-ES-020/2016 A mixture of: 4-(2,2,3-trimethylcyclopent-3-en-1-yl)-1-methyl-2-oxabicyclo[2.2.2]octane; 1-(2,2,3-trimethylcyclopent-3-en-1-yl)-5-methyl-6-oxabicyclo[3.2.1]octane; spiro[cyclohex-3-en-1-yl-[(4,5,6,6a-tetrahydro-3,6',6',6'a-tetramethyl)-1,3'(3'aH)-[2H]cyclo-penta[b]furan]; spiro[cyclohex-3-en-1-yl-[4,5,6,6a-tetrahydro-4,6',6',6'a-tetramethyl)-1,3'(3'aH)-[2H]cyclopenta[b]]furan] (EC No 422-040-1)

Session 1 (open)

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

The eMSCA from Spain (ES-CA) presented the SEv outcome of the above-mentioned substance. The initial grounds for concern as placed on the Community Rolling Action Plan (CoRAP) were that relating to suspected PBT/vPvB properties, exposure of environment and high RCRs.

The registered substance is a multi-constituent substance with four main constituents and several impurities. These are all structurally similar to each other.

The DD notified to the MSCAs and ECHA for PfAs requested for: 1) Partition coefficient of constituents and impurities using OECD TG 117; 2) Bioaccumulation in fish, aqueous exposure (OECD TG 305) with the registered substance if technically feasible to determine BCF/BMF for the expected worst-case B constituent/impurity (based on request 1), otherwise with the worst-case constituent/impurity; 3) Simulation degradation test (OECD TG 309) on the constituent showing worst case in B (request 2 above); 4) Long-term toxicity to aquatic invertebrates (OECD TG 211) on the constituent showing worst case in B and P (requests 2 and 3 above); 5) Long-term toxicity to fish (OECD TG 210) on the constituent showing worst case in B and P (requests 2 and 3 above) and T (request 4 above).

MSC was guided by the expert from the eMSCA through the information on the substance including twelve PfAs received from five MSCAs and ECHA, the Registrants' comments on the PfAs and the eMSCA's response to them. Nearly all the PfAs submitted were introduced in the DD that was discussed at the MSC meeting. The amended DD requested for an OECD TG 309 with the whole substance. If the whole substance was confirmed to be either P or vP the DD requested to determine octanol-water partition coefficient of constituents and impurities using OECD TG 117 and perform an OECD TG 305 with aqueous exposure with constituent or impurity or whole substance. The BCF value must be determined for the constituent or impurity expected to represent worst-case PBT properties. If based on the result a vPvB conclusion is reached no further testing would be needed. Otherwise if P/vP and B/vB were confirmed, the DD requested to proceed with T testing as was in the DD notified to MSCAs indicated above.

Hence, only three issues were still open for discussion during the MSC meeting. One issue related to the determination of the octanol water partition coefficients (Kow). Two MSCAs proposed in their PfAs to remove this request as the log Kow range of the constituents was very small and an OECD TG 123 test with the substance was already available, which was considered accurate.

A second issue related to the toxicity request. It was proposed to delete the text which stated that T_{eco} related testing would not be needed if the substance is vPvB since toxicity related information may nevertheless be important for risk management measures e.g. to consider the substance for the Stockholm Convention.

The third issues was that, since the eMSCA updated the DD to test for P on the registered substance, some MSC members wished to make this change also for the B testing, hence removing the option to choose between constituent, impurity or whole substance and request the B testing on just the whole (registered) substance.

The representative of the Registrants stated that their expectation on the persistency of the substance was based on several screening criteria. In their view the outcome of an OECD TG 309 would either be inconclusive due to the volatility of the substance (an argument not made in the written comments to the PfAs) or it would show a potential for P. They were of the opinion that animal welfare was not a deciding factor in this case as a BCF reading would be needed anyway for to reach a conclusion on PBT or vPvB. They expected insufficient biodegradation in the OECD TG 309, and considering the technical difficulties in isolating sufficient individual radio labelled material, timing and costs associated with this, the resources needed versus the expected results the Registrants would not consider this the most cost-effective way forward to assess the overall PBT/vPvB properties of Cassiffix (the registered substance). Therefore, they strongly supported the order of performing B testing before P testing. The registrants' Representative expressed agreement with testing the whole substance, due to the close range in log Kow of the constituents, and that measuring the log Kow again will not bring more information.

During the discussion the eMSCA expert after hearing the same arguments both from the Registrants' representatives as well as from the PfA submitters, decided to remove the request for log Kow determination from the DD.

Regarding the request for T data when a substance is vPvB, opinions expressed in the meeting were that the T data would not be needed in that case anymore.

Session 2 (closed)

During the closed session, MSC discussed the difficulty raised by the Registrants' representative in testing the substance using OECD TG 309 due to its high volatility. A question was raised that if the substance was highly volatile for the OECD TG 309, then it could also be highly volatile for the OECD TG 305 via aqueous exposure. However, it was reminded that OECD TG 305 via aquatic exposure was a flow through test whilst OECD TG 309 was a static system. One MSC member still wished to follow the recommendations from the Registrants' representative and start testing for B before P in order to avoid having to face any potential technical problems when conducting the P testing first and due to cost-effectiveness reasons. However, MSC considered that the vapour pressure of the registered substance was still within the applicability domain of the OECD TG 309 test, and several substances with comparable or higher Henry's law constant have been tested successfully in the OECD TG 309. Therefore, MSC considered that there were not enough reasons to deviate from the standard testing order to clarify the PBT concern.

Based on the discussions above, MSC agreed unanimously to revise the testing strategy by removing the request for partition coefficient of constituents and impurities using OECD TG 117; requesting first for simulation degradation test (OECD TG 309) with the registered substance using a radiolabelled test substance and determining the degradation half-lives for the relevant fractions (request 1); followed by bioaccumulation testing in fish, aqueous exposure (OECD TG 305) with the registered substance and determining the BCF values for the relevant fractions, (request 2), if one or more of the relevant fractions fulfils the criteria for persistent (P) <u>or</u> very persistent (vP); followed by toxicity testing with the relevant fraction with the highest BCF value as indicated in the DD amended for the meeting if one or more of the relevant fractions fulfils the criteria for persistent (P) <u>or</u> very persistent (vP) and bioaccumulative (B) or very bioaccumulative (vB) but not vPvB. MSC also unanimously agreed to revise the text of the DD by referring to the fraction profiling (block profiling) approach, as also referred by the Registrants in their written comments to the PfAs, instead of the worst-case constituent/impurity approach, and to revise the deadlines accordingly to reflect the changes made.

The MSC unanimously agreed on the decision as amended in the meeting.

SEV-UK-025/2016 Isopentyl p-methoxycinnamate - IPMC (EC No. 275-702-5)

Session 2 (closed)

The MSC Chairman had terminated the written procedure for MSC agreement seeking on this SEv draft decision prepared by the UK CA (eMSCA) upon request from a MSC member, and the case was brought to the meeting to specifically discuss the issue raised by the member.

The DD requested for 1) Amphibian Metamorphosis Assay (AMA, OECD TG 231) or a Larval Amphibian Growth and Development Assay (LAGDA, OECD 241); 2) Fish Sexual Development Test (FSDT, OECD TG 234, using either Japanese Medaka-*Oryzias latipes* or Zebrafish-*Danio rerio*); 3) To provide information and justification for parameters in the environmental exposure assessment within the Chemical Safety Report. Split deadlines were set in the DD to allow more rapid SVHC identification. Similar requests were made for a substance structurally similar to IPMC: 2-ethylhexyl trans-4-methoxycinnamate (OMC) (see SEV-UK-027/2016 below), which the Registrants propose to use as read across substance once the comparability of bioavailability is confirmed (after performing new water solubility and octanol-water partition coefficient tests).

The eMSCA expert introduced to MSC a summary of both cases, IPMC and OMC, highlighting the similarities and background of updates in the DD during the decision making process. A MSC member requested stopping the written procedure to allow a discussion on the editorial updates introduced in the DD after the PfA stage, specifically on the text referring to the definition of “significant” endocrine disrupting effects occurring at measured concentrations and their threshold value set at or below 0.01 mg/l for aquatic chronic toxicity studies for a rapidly degradable substance.

A rewording of the text was proposed for bringing clarity to the Registrants that if the FSDT test will show effects of IPMC that would warrant classification for aquatic life, he will be required to update the environmental exposure assessment. The MSC member requesting MSC discussion disagreed with the threshold value set in the DD of 0.01 mg/l (IPMC in water) as arbitrary and unnecessary.

Several MSC members supported this view and the suggested use of a conditional threshold value (for effects towards aquatic organisms) the one needed for the substance to be classified (1 mg/L) as this would be in accordance with REACH standard information requirements. It was highlighted that AMA and FSDT are ED tests, which may provide effects related to endocrine mode of action and to apical effects, and that the apical effects actually recorded in such studies can be used as basis for classification. This was generally acknowledged. The eMSCA considered the limit of 0.01 mg/l (i.e. the threshold for chronic cat. 1 for hazards to aquatic life) as relevant for SVHC identification and that it would be relevant in that case to have an environmental exposure assessment. A MSC member stated in contrast that the REACH standard information requirement is to conduct an exposure assessment when hazard classification of the substance is warranted. Discussion of this substance and OMC occurred together, so the above points were also relevant to OMC.

The eMSCA expert explained that the text regarding the requirement for environmental exposure assessment was copied (for alignment with the similar text for OMC) from the DD of OMC (SEV-027/2016) as response to a PfA proposing to split the decision. Initially eMSCA agreed to this addition, but on reflection realised it is incorrect as the update of the exposure assessment is required regardless of the outcome of the ED tests, therefore the eMSCA proposed not to include the latest revised text, and proposed to delete it again. The eMSCA introduced to MSC members the editorial clarifications regarding the (positive) outcome in the AMA test indicating a thyroid mode of action (MoA) which draws the need to further address this concern using a LAGDA study. MSC accepted the revisions further suggested by the eMSCA during the meeting.

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

SEV-UK-027/2016 2-Ethylhexyl trans-4-methoxycinnamate - OMC (List No. 629-661-9)

The MSC Chairman had terminated the written procedure for MSC agreement seeking on this SEv draft decision prepared by the UK CA (eMSCA) upon request from a MSC member and the case was brought to the meeting to specifically discuss the issue raised by the member.

The DD requested for 1) Amphibian Metamorphosis Assay (AMA, OECD TG 231) or a Larval Amphibian Growth and Development Assay (LAGDA, OECD 241); 2) Fish Sexual Development Test (FSDT, OECD TG 234, using either Japanese Medaka-Oryzias latipes or Zebrafish-Danio rerio); 3) *Daphnia magna* Reproduction Test (OECD TG 211); 4) Alga Growth Inhibition Test (OECD TG 201) or Lemna Growth Inhibition Test (OECD TG 221); 5) Environmental exposure assessment. The Registrants were requested to perform sequential testing with corresponding deadlines and to provide an update of the registration dossier(s) containing the information requests of 1 and 2, and subsequently the information requests of 3, 4 and 5 (if needed), including robust study summaries.

This substance, OMC, is structurally similar to IPMC: Isopentyl p-methoxycinnamate (IPMC) (see SEV-UK-025/2016 above). As stated above, the Registrants proposed to use a read across approach once the comparability of bioavailability is confirmed (after performing a new water solubility and octanol-water partition coefficient tests).

In the closed session, the eMSCA expert introduced to MSC a summary of both cases, IPMC and OMC, highlighting the similarities and background of updates in the DD during the decision making process. The MSC member requested stopping the written procedure to allow a discussion on the text referring to the definition of “significant” endocrine disrupting effects occurring at measured concentrations and their threshold value set at or below 0.01 mg/l for aquatic chronic toxicity studies for a rapidly degradable substance.

The eMSCA expert highlighted that the text in the DD referred to at the stage of request for termination of WP was available to all MSCAs for consultation and no PfAs were received on it, therefore questioned whether it was possible from a procedural point of view to introduce any further changes at this stage of the decision making process. Furthermore he noted that the Decision did not indicate how SVHC would be assessed in the descriptions of the FSDT or AMA/LAGDA tests in this or the IPMC case. He explained that the tiered structure of the Decision required a threshold to be clear to the registrant when additional data were required following the FSDT and AMA. The value of 0.01 mg/L had been considered a reasonable and proportionate trigger for this.

The MSC member who requested termination of written procedure recognised that submission of a PfA on the DD regarding the explanatory text with conditional requests for environmental exposure assessment could have been appropriate. He presented the rationale as discussed for IPMC for considering in the DD the a cut-off value of 1 mg/l OMC or water solubility of the substance, whatever is lower, to trigger an exposure assessment. Several MSC members supported to use as the conditional threshold value the one needed for the substance to be classified (1 mg/L). Regarding the eMSCA proposal in the DD to use the cut-off value of 0.01 mg/l for potential waiving of request 3 and 4, it was instead suggested to require these tests if apical NOEC results from request 1 or 2 would be above 1 mg/l. In consideration of whether this change could deprive the registrant of his right of being heard, it was noted that this would be 100 times more beneficial for the Registrants than to maintain the threshold value of 0.01 mg/L. He also proposed some editorial changes in DD for removing redundant text. Some further rephrasing of the DD text were also suggested to make clear to the Registrants that if requests 3 and 4 are not triggered in the present decision, it is not precluded that these tests might be required at a later stage on the basis of new information, or that the Registrants can perform those tests voluntarily if as a consequence of the exposure assessment in request 5 (environmental exposure assessment) they would consider it necessary.

MSC supported that the changes regarding the threshold value as proposed during the

meeting were clearly beneficial and not detrimental to the Registrants and therefore did not require a PfA that could be commented on by the Registrants.

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

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 nine dossier evaluation cases (see Section III Final agenda "Appendix to the MSC-58 agenda" for more detailed identification of the cases). WP was launched on 11 January 2018. By the closing date 22 January 2018, MSC reached unanimous agreement on all DDs.

b. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals when amendments were proposed by MS-CA's (Session 1, open session)

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

CCH-127/2017 Triclocarban (EC No. 202-924-1)

Session 1 (open)

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

SECR presented the DD and noted that triclocarban has been recently listed in the CoRAP list for substance evaluation by FR CA in 2020. Further, the SECR explained that 7 PfAs to ECHA's DD had been submitted by 4 MSCAs. A PfA noted that there is no request for a sub-chronic toxicity study in this DD and asked the DD text to be corrected accordingly. All the other PfAs referred to the EOGRTS information request. Two PfAs suggested to include cohorts 2A, 2B (DNT) and 3 (DIT) in the EOGRTS request. In an alternative PfA, these two MSCAs proposed to transfer the EOGRTS request, from the CCH DD to the forthcoming SEv process for this substance to give the eMSCA the opportunity to propose a suitable design for the study to cover both the standard information gap and to clarify the potential endocrine disruptive (ED) concerns in respect to mammalian species (including humans), while optimising the resources (e.g. time and animal-welfare). In addition, two other PfAs on this endpoint were submitted, one providing a QSAR prediction on thyroid toxicity of triclocarban with two models (in support of the inclusion of the cohorts) and another one suggesting editorial modifications to be made in the DD.

SECR had modified the DD according to the PfA referring to the sub-chronic toxicity study and to the one proposing editorial modification in the EOGRTS part of the DD. However, in advance of the meeting SECR had neither included the DNT and DIT cohorts in the request for EOGRTS, nor removed the request from this CCH DD for further consideration under SEv.

The Registrant had provided written comments on the two PfAs only: (i) agreeing with the PfA referring to the sub-chronic toxicity study, and (ii) agreeing to the first part of the PfA proposing to remove the EOGRTS request from this DD. SECR noted that the Registrant remained silent on the second part of the PfA (suggesting to move the EOGRTS to the future SEv process and specify better the study design there). In addition, the Registrant provided comments on the DD, indicating an intention to downgrade the tonnage level, but without a subsequent update of its registration dossier or of the joint submission tonnage. The latter has been noted, but not reflected in the DD, since other registrant(s) have registered Annex IX related tonnage.

In the following discussion, the MSC members from the EOGRTS-related PfA-submitting MSs expressed their disagreement with ECHA's view that the available information is not found sufficient to trigger DNT and DIT cohorts and provided further clarification on their rationale. Furthermore, another MSC member indicated that four other studies, not included in the registration dossier or in the PfAs (but provided before the meeting for MSC's consideration), provided additional evidence to support the reasoning of the PfA.

Several other members and experts shared their views on the submitted PfAs and on the possible way forward with the DD agreement seeking, including links to the SEv process and enforcement.

An ASO observer noted that this substance has been used in cosmetic products for a long time, and that therefore a lot of information, generated under the Cosmetics legislation, regarding its effects is available. The ASO observer questioned the current information needs. Another observer highlighted that this DD is a good example illustrating the need to integrate CCH and SEv processes to increase the efficiency and integrate the assessments.

SECR responded to the questions raised and noted that: (i) the information provided in the registration dossier did not indicate developmental neurotoxic or immunotoxic effects; (ii) the latest references provided to MSC should be considered as late information that could not be commented by the Registrant; (iii) the identified information data gap for the reproductive toxicity endpoint remains and should be filled in; (iv) a concern-driven assessment on DNT and DIT should be done under SEv or at a follow-up DEv stage.

The observer from the Commission expressed the Commission's understanding that triggers for additional cohorts are the same for both SEv and CCH processes.

Session 2 (closed)

In the following discussions, MSC carefully considered the way forward and reviewed different options during agreement seeking.

Concerns were raised regarding potential delays in gathering information to clarify the concerns detailed in the DD when addressing the EOGRTS endpoint in the SEv process, but also regarding potential enforcement implications.

MSC was informed of the FR CA acceptance regarding the suggested move of the EOGRTS request from DEv to SEv for more targeted evaluation and subsequent EOGRTS design consideration. In the decision the option was left open to request the test in a subsequent CCH in case the endpoint is not addressed under substance evaluation.

To support the decision, SECR presented the comparative timelines for gathering the requested information (under this CCH process versus the forthcoming SEv process).

Following the notification from the eMSCA of their agreement to consider all available information and propose the most appropriate design for the EOGRTS under the SEv process, MSC unanimously agreed to remove the EOGRTS request clarifying in the DD that it is to be addressed by eMSCA under the forthcoming SEv in 2020. SECR modified the DD accordingly.

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

TPE-041/2017 Chloroethane (EC No. 200-830-5)

Session 1 (open)

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

SECR first informed that ECHA had initially submitted the case for the MSC-57 round, from which ECHA withdrew it and brought it anew for agreement seeking for MSCA consultation,

with previous PfAs considered void. SECR then explained the new PfA that was received to this DD. The PfA on extended one-generation reproductive toxicity study (EOGRTS) in rats, inhalation route, suggested firstly including cohorts 2A and 2B (developmental neurotoxicity, DNT), and secondly reminding the Registrant of the possibility to include behavioural cognitive tests, which are not investigated by default but associate to anaesthesia.

SECR had modified the DD in advance of the meeting based on the PfA to include DNT.

The Registrant had provided written comments prior to the meeting and disagreed with the PfA.

The MSC member from the PfA submitting country appreciated that the PfA had been taken on board. He maintained its reasoning that the substance has a historical use as an anaesthetic agent associated with abnormal brain cell death when administered during periods of rapid brain growth. Further argumentation included that isoflurane (with similar anaesthetic potency and physico-chemical properties) had been reported to cause neuroapoptosis in the developing brain below anaesthetic concentrations. He additionally emphasized that the registered substance is a gas and thus the suggested route is inhalation. He continued that gases would normally require a whole body design including pups, which for solid substances would not be exposed *post natal*; thus further guidance to the Registrant might be needed. An MSC member and an expert further supported the PfA as the substance appeared to cross the blood-brain barrier and due to its anaesthetic properties and data from the isoflurane would lead to a concern.

Two MSC members expressed reservations on including DNT, arguing that a trigger was not fulfilled considering an unclear structural analogue with isoflurane, which was a liquid; the differences between human minimum alveolar concentration (MACh) values were deemed large and the registered substance could not be linked to any of the modes of action of eleven anaesthetics, which were identified for concern and investigated by the United States Food and Drug Administration (FDA).

SECR acknowledged some uncertainties and emphasized the link between the two substances based on MACh and blood/gas partition coefficient, both of which are relevant for anaesthetic properties rather than a mode of action.

Session 2 (closed)

A MSC member questioned why, following withdrawal after the MSCA consultation in the MSC-57 round, the DD had not been revised and sent back to the start of the process, i.e. sent to the Registrant. SECR confirmed that ECHA had decided to withdraw the DD before MSC referral and notified again to the MSCAs for the MSC-58 round. It acknowledged that in this specific case sending the case back to the start of the process might have been more appropriate to allow MSCA consultation on justification for inclusion of the cohort.

SECR reasoned that a concern was raised because neuroapoptosis in developing brains of test animals was detected with isoflurane at levels lower than anaesthetic levels or doses.

Several MSC members argued that there was not enough information on a mode of action and no evidence of neuroapoptosis on the registered substance. Some MSC members still considered the similar properties with isoflurane sufficient for this case to include DNT, and regretted to lack the opportunity to discuss additional data on the registered substance related to effects on central nervous system that were not mentioned in the new PfA.

As a result of the discussion during the meeting, MSC concluded not to include the request for DNT and concluded to revise the DD accordingly.

MSC agreed unanimously to the DD as amended at the meeting. Five MSC members abstained from voting, including the MSC members from Austria, Finland, the Netherlands, Norway and Sweden.

d. Decision making process - general topics

- Update to working procedures for MSC to process draft decisions under dossier evaluation

SECR presented a proposal for a change to the MSC working procedures for processing draft decisions under dossier evaluation. This update concerned a small practical change on how MSC receives the agreed decisions, and at the same time it brings an alignment with the MSC working procedures established for substance evaluation. SECR also clarified that for an easy finding of the files, case specific folders in MSC S-Circabc will be used for that purpose. MSC adopted the working procedures with this change without further discussion.

Item 8 – Any other business

a. Feedback from ED EG on issues raised by MSC

A member of the ECHA's Endocrine Disruptor Expert group (ED EG) introduced to MSC the conclusions of the ED EG on issues raised by MSC during previous ED-related DEv and SEv case-specific discussions in 2016-2017. These issues were mainly related to fish test choice and sensitivity of different species for testing of certain parameters relevant for ED assessment. MSC discussed possible ways to take up these relevant issues (e.g. use of human health ED data in the context of environment-related ED concerns) into further OECD Test Guideline development and in relation to the EU Horizon 2020 research programme.

In conclusion, the MSC Chairman thanked the ED EG's presenters. Furthermore, he informed the committee that the general questions MSC had raised at the MSC-57 meeting have been sent to the ED EG's secretariat with a request for a scientific advice from the expert group by end of 2018.

b. Update on appeals and court cases *(open session)*

SECR gave an overview of litigation in 2017, the status of recent appeals on evaluation submitted to the Board of Appeal of ECHA and pending cases submitted to the European Court of Justice relating to the authorisation process. MSC took note of the information received.

c. Report on MSC work in 2017

SECR presented to MSC a brief report regarding MSC work and results from the previous year (2017). The slides had been shared in advance as part of the information documents.

SECR also warmly congratulated MSC for its achievement during the meeting of exceeding 1001 agreements and opinions during its existence from 2008 onwards.

d. Suggestions from members

No suggestions were received by members under this agenda item.

Item 9– Adoption of conclusions and action points

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

II. List of attendees

Members/Alternate members
ANDRIJEWSKI, Michal (PL)
ATTIAS, Leonello (IT)
COCKSHOTT, Amanda (UK)
CONWAY, Louise (IE)
DE KNECHT, Joop (NL)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
HORSKA, Alexandra (SK)
HUMAR-JURIC, Tatjana (SI)
JANTONE, Anta (LV)
KOUTSODIMOU, Aglaia (EL)
KREKOVIĆ, Dubravka (HR)
KULHANKOVA, Pavlína(CZ)
LE, Elisa (FR)
LUNDBERGH, Ivar (SE)
MARTÍN, Esther (ES)
MENDONÇA, Elsa (PT)
MIHALCEA UDREA, Mariana (RO)
NYITRAI, Viktor (HU)
REIERSON, Linda (NO)
RISSANEN, Eeva (FI)
STESSEL, Helmut (AT)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
WAGENER, Alex (LU)
Representatives of the Commission:
SCHUTTE, Katrin (DG ENV)
Observers
ANNYS, Erwin (Cefic)
BERNARD, Alice (ClientEarth)
FAßBENDER, Christopher (PETA)
HÖK, Frida (ChemSec)
KERÄNEN, Hannu (CONCAWE)
LEROY, Didier (CEPE)
LOONEN, Helene (EEB)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
BERCARU, Ofelia
BICHLMAIER, Ingo
BROERE, William
CALEY, Jane
DE WOLF, Watze
DREVE, Simina
HANSEN, Bjorn
HERBATSCHEK, Nicolas
HOFFSTADT, Laurence
HUUSKONEN, Hannele
JOHANSSON, Matti
KOVARI, Agnes
LEPPÄRANTA, Outi
NAUR, Liina
PELLIZZATO, Francesca
RÖNTY, Kaisu
SCHULTHEISS, Christian
TRNKA, Jan-Peter
VAHTERISTO, Liisa
VASILEVA, Katya
WALKER, Lee
WOLLENBERGER, Leah

Proxies

- ATTIAS, Leonello (IT) also acting as proxy of BORG, Ingrid (MT)
- KOUTSODIMOU, Aglaia (EL) also acting as proxy of PALEOMILITOU, Maria (CY)
- NYITRAI, Viktor (HU) also acting as proxy of DIMITROVA, Rada (BG)
- HUMAR-JURIC, Tatjana (SI) also acting as proxy of MIHALCEA UDREA, Mariana (RO) on 9 February from 11:00 onwards
- TYLE, Henrik (DK) also acting as proxy of DUNAUSKIENE, Lina (LT) for short periods during the meeting.

Experts and advisers to MSC members

BARTHELEMY-BERNERON, Johanna (FR) (expert to LE, Elisa)
CIESLA; Jacek (PL) (expert to ANDRIJEWSKI, Michal)
COPOIU, Oana (RO) (expert to MIHALCEA UDREA, Mariana)
DOBRAK-VAN BERLO, Agnieszka (BE) (expert to VANDERSTEEN, Kelly)
DOYLE, Ian (UK) (expert to COCKSHOTT, Amanda)
EINOLA, Juha (FI) (adviser to RISSANEN, Eeva)

GRINCEVICIUTE, Otilija (LT) (expert to DUNAUSKIENE, Lina)
HOLMBERG, Rikke (DK) (expert to TYLE, Henrik)
INDANS, Ian (UK) (adviser to COCKSHOTT, Amanda)
JÖHNCKE, Ulrich (DE) (adviser to FINDENEGG, Helene)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
KUROVA, Martina (SK) (expert to HORSKA, Alexandra)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBERGH, Ivar)
NYGREEN, Beryl C. (NO) (expert to REIERSON, Linda)
ROSENTHAL, Esther (DE) (adviser to FINDENEGG, Helene)
TARNOCZAI, Timea (HU) (expert to NYITRAI, Viktor)
UNKELBACH, Christian (DE) (expert to FINDENEGG, Helene)
VERBRUGGEN, Eric (NL) (expert to DE KNECHT, Joop)
WASSENAAR, Pim (NL) (adviser to DE KNECHT, Joop)
ZELJEZIC, Davor (HR) (expert to KREKOVIC, Dubravka)

MSCA experts for SEv cases:
CLAßEN, Daniela (DE)
TIETJEN, Lars (DE)
UOTILA, Elina (ES)
VEGA, Milagros (ES)

By WEBEX / phone connection:

During the whole meeting:
FRANZ, Michel (FR)
MALKIEWICZ, Katarzyna (SE) on 6 February

During the Agenda Item 6:
MRUKWA, Patrice (DE)
SAKSA, Jana (EE)
GONZALEZ SANCHEZ, Oscar (ES)

During the Agenda item 7:
SAKSA, Jana (EE)
SCHMEISSER, Sebastian (DE) for CCH-127/2017

During the Agenda item 8:
HOLBECH, Henrik (DK)
JOMINI, Stephane (FR)
ROHL, Martine (BE)
SAKSA, Jana (EE)

Case owners:
Representatives of the Registrants were attending under the Agenda Item 6.2 b for SEV-ES-020/2016 and SEV-DE-013/2016.

Apologies:
ALMEIDA, Inês (PT)
BORG, Ingrid (MT)
DEIM, Szilvia (HU)
DIMITROVA, Rada (BG)
FRANZ, Michel (FR)
PALEOMILITOU, Maria (CY)
PISTOLESE, Pietro (IT)
WIJMENGA, Jan (NL)

III. Final Agenda

MSC/A/058/2018

Agenda

58th meeting of the Member State Committee

6-9 February 2018
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

6 February: starts at 9 am
9 February: ends at 1 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/058/2018
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-57

- Draft minutes of MSC-57

MSC/M/57/2017
For adoption

Item 6 – Substance evaluation

Start of item 6.2b is Day 1
Closed session for 6.2c

3. Community Rolling Action Plan (CoRAP) & MSC opinion development

MSC opinion on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2018-2020)

- Discussion on the draft MSC opinion
- Adoption of the opinion

4. Decision making process

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

ECHA/MSC-58/2018/008
For information

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

ECHA/MSC-58/2018/009

For discussion followed by agreement seeking under 6c:

MSC code	Substance name	EC No. / Doc. Number
SEV-DE-013/2016	Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene	270-128-1
		ECHA/MSC-58/2018/010-011
SEV-DE-014/2016	2,2',6,6'-Tetrabromo-4,4' isopropylidene-diphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether	926-564-6
		ECHA/MSC-58/2018/012-013
SEV-ES-019/2016	Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene	271-867-2
		ECHA/MSC-58/2018/014-015
SEV-ES-020/2016	A mixture of: 4-(2,2,3-trimethylcyclopent -3-en-1-yl)-1-methyl-2-oxabicyclo[2.2.2] octane; 1-(2,2,3-trimethylcyclopent-3-en-1-yl)-5-methyl-6-oxabicyclo[3.2.1]octane; spiro[cyclohex-3-en-1-yl-[(4,5,6,6a-tetrahydro-3,6',6',6'a-tetramethyl)-1,3'(3'aH)-[2H]cyclo-penta[b]furan]; spiro[cyclohex-3-en-1-yl-[4,5,6,6a-tetrahydro-4,6',6',6'a-tetramethyl)-1,3'(3'aH)-[2H]cyclopenta[b]]furan]	422-040-1
		ECHA/MSC-58/2018/016-017

For discussion

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

Cases as listed above under **6.2b** and the cases returned from written procedure agreement seeking at the meeting:

SEV-UK-025/2016 Isopentyl p-methoxycinnamate (EC No. 275-702-5)

SEV-UK-027/2016 2-Ethylhexyl trans-4-methoxycinnamate (List No. 629-661-9)

For agreement

Item 7 – Dossier evaluation

Start of item 7b is on Day 2
Closed session for 7c

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

ECHA/MSC-58/2018/001
For information

b. **Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals when amendments were proposed by MS-CA's *(Session 1, open session)***

ECHA/MSC-58/2018/002

For discussion followed by agreement seeking under 7c:

Compliance checks

MSC code	Substance name	EC/List No.	Documents
CCH-127/2017	Triclocarban	202-924-1	ECHA/MSC-58/2018/003-4

Testing proposal examinations

MSC code	Substance name	EC/List No.	
TPE-041/2017	Chloroethane	200-830-5	ECHA/MSC-58/2018/005-6

For discussion

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

Cases as listed above under **7b**

For agreement

d. Decision making process general topics

- Update to working procedures for MSC to process draft decisions under dossier evaluation

ECHA/MSC-58/2018/007
For adoption

Item 8 – Any other business

a. Feedback from ED EG on issues raised by MSC

ECHA/MSC-58/2018/18-20
For information and discussion

b. Update on appeals and court cases
c. Report on MSC work in 2017
d. Suggestions from members

For information

Item 9 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-58

For adoption

Information documents

- Status report on on-going substance evaluation work
- Status report on on-going dossier evaluation work

APPENDIX to the MSC-58 agenda:

List of evaluation cases agreed by MSC in written procedure in advance of the MSC-58 meeting:

Substance evaluation

SEV-SI-018/2016	Ethyl 3,5-dichloro-4-hexadecyloxycarbonyl oxybenzoate (EC No. 404-740-9)

Dossier evaluation

Compliance checks

CCH-130/2017	Tris(2-ethylhexyl) phosphate (EC No. 201-116-6)
CCH-131/2017	2-(2-aminoethoxy)ethanol (EC No. 213-195-4)
CCH-133/2017	Castor oil, sulfated, sodium salt (EC No. 269-123-7)
CCH-136/2017	2-[2-(dimethylamino)ethoxy]ethanol (EC No. 216-940-1)
CCH-138/2017	2-dibutylaminoethanol (EC No. 203-057-1)
CCH-139/2017	[1,3-phenylenebis(1-methylethylidene)]-bis[tert-butyl]peroxide (EC No. 218-664-7)
CCH-140/2017	Dimethyl naphthalene-2,6-dicarboxylate (EC No. 212-661-4)
CCH-141/2017	Benzenesulphonic acid, mono-C10-13-alkyl derivs., compds. with ethanolamine (EC No. 287-335-8)

Testing proposals

TPE-042/2017	[1,3-phenylenebis(1-methylethylidene)]-bis[tert-butyl] peroxide (EC No. 218-664-7)

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-58 6-9 February 2018
(adopted at the meeting on 9 February 2018)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues	
MSC took note of the planned meeting dates for 2019.	**MSC-S** to upload the tentative meeting dates to MSC S-CIRCABC by 12 February 2018.
Item 5 – Minutes of the MSC-57	
MSC adopted the draft minutes as modified at the meeting.	**MSC-S** to upload final version of the minutes on MSC S-CIRCABC by 12 February 2018 and on ECHA website without undue delay.
Item 6.1 – Community Rolling Action Plan (CoRAP) & MSC opinion development MSC opinion on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2018-2020) • Discussion on the draft MSC opinion • Adoption of the opinion	
MSC adopted by consensus the draft opinion and its Annex on the draft CoRAP update 2018-2020.	**MSC-S** to upload the MSC CoRAP Opinion including its Annex on MSC S-CIRCABC by 16 February 2018. **SECR** to publish the opinion on the ECHA website together with the annual CoRAP update on 20 March 2018.
Item 6.2 – Substance evaluation - Decision making process **a. Written procedure report on seeking agreement on draft decisions on substance evaluation**	
MSC took note of the written procedure outcome.	**MSC** to consider the decisions uploaded on MSC S-CIRCABC for the written procedure as agreed ones. Final ECHA decisions will become available at ECHA website in due course.
Item 6.2 – Substance evaluation - Decision making process **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 a draft decision 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-DE-013/2016** Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene (EC No. 270-128-1) MSC gave a mandate to eMSCA from DE detailing the editorial	**MSC-S** to upload on MSC S-CIRCABC the agreed decisions **in the respective case folders.** **eMSCA from DE** to submit to MSC-S via the Evaluation S-CIRCABC, the agreed decision updated based on

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
changes that need to be done on SEV-DE-013/2016, after the meeting. **SEV-DE-014/2016** 2,2',6,6'-Tetrabromo-4,4' isopropylidene-diphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether (EC No. 926-564-6) **SEV-ES-019/2016** Phenol, 4-methyl-, reaction products with dicyclopentadiene and isobutylene (EC No. 271-867-2) **SEV-ES-020/2016** A mixture of: 4-(2,2,3-rimethylcyclopent-3-en-1-yl)-1-methyl-2-oxabicyclo[2.2.2]octane; 1-(2,2,3-trimethylcyclopent-3-en-1-yl)-5-methyl-6-oxabicyclo[3.2.1]octane; spiro[cyclohex-3-en-1-yl-[(4,5,6,6a-tetrahydro-3,6',6',6'a-tetramethyl)-1,3'(3'aH)-[2H]cyclo-penta[b]furan]; spiro[cyclohex-3-en-1-yl-[4,5,6,6a-tetrahydro-4,6',6',6'a-tetramethyl)-1,3'(3'aH)-[2H]cyclopenta[b]]furan] (EC No. 422-040-1) **SEV-UK-025/2016** Isopentyl p-methoxycinnamate (EC No. 275-702-5) **SEV-UK-027/2016** 2-Ethylhexyl trans-4-methoxycinnamate (List No. 629-661-9)	the mandate given by MSC not later than 16 February 2018. **MSC Chairman** to review with ECHA SECR the inputs received on the testing strategies for these substances through the PBT EG and considerations for the changes introduced.
Item 7 – Dossier evaluation **a. Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the report.	**MSC** to consider the decisions uploaded on MSC S-CIRCABC for the written procedure as agreed ones. Final ECHA decisions will become available at ECHA website in due course.
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, open session)*** **c. Seeking agreement on draft decisions on compliance checks and testing proposal examinations when amendments were proposed by MS-CA's *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions (as modified in the meeting): **<u>Compliance check</u>** CCH-127/2017 Triclocarban (EC No. 202-924-1) **<u>Testing proposal examination</u>** TPE-041/2017 Chloroethane (EC No. 200-830-5)	**MSC-S** to upload on MSC S-CIRCABC the agreed decisions in the respective case folders.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 7d. Dossier evaluation decision making process -General topics Update to working procedures for MSC to process draft decisions under dossier evaluation	
MSC adopted the update to its working procedure.	**MSC-S** to upload the updated working procedure to the ECHA website and to MSC S-CIRCABC after the meeting.
Item 9 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-58 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC S-CIRCABC by 9 February 2018.

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