MSC/M/62/2018
Adopted at MSC-63

Minutes

of the 62nd Meeting of the Member State Committee (MSC-62)

10-14 December 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 62nd meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Section 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 as Section III).

Item 3 - Declaration of specific interests to items on the Agenda

The Chairman informed MSC that some Member State Component Authorities (MSCAs) were contacted by an EU government relations law firm on behalf of a company with a request to meet and discuss their comments on the proposed identification of perfluorohexanoic acid (PFHxA) as a substance of very high concern (SVHC). Many Permanent Representatives to the EU, MSCAs and individuals were approached by the law firm but only one alternate member was contacted directly. The alternate member in question declined the meeting and therefore the Chairman considered that no specific or potential conflict of interest for the case had been created by these actions of that law firm and therefore no mitigating action was required. The Chairman also informed MSC that he sent a letter expressing his concerns to the law firm and in their response they acknowledged that they had been active in communicating with the EU institutions, however they stated to have refrained from contacting the members of the ECHA MSC and wished to ensure that it was not and it will never be their intention to affect the independence of the institution. Unfortunately they missed that also alternate members should not have been approached. The law firm recently also contacted the Secretariat with a request to share with MSC a document with their arguments against identification of PFHxA as an SVHC. The Chairman informed MSC that he decided to decline the request of the company to share this document as neither the law firm nor its client had provided any comments during the public consultation and the Chairman did not wish to create any privileged situation for them by sharing the document with MSC.

The Chairman informed MSC that he has a specific interest to declare in respect to one item on the agenda for MSC-62, on the substance evaluation case SEV-DE-011/2017, due to his prior employment. He also informed MSC that he had declined any involvement or preparatory action on this case since its referral to MSC. The case is to be chaired by the Chairman of RAC, Mr Tim Bowmer, who was involved in the MSC preparatory activities and who will review the final decision.

No other potential specific interests were declared by any other members, experts or advisers with any other item on the agenda of MSC-62.

Item 4 - Administrative issues

Outlook for MSC-63

The Chairman presented an outlook on the potential length of the next meeting which is expected to require approximately 3-4 days. He requested informal inputs from MSC members by 3rd January 2019 to allow him to increase number of cases that potentially could be agreed in written procedure, thereby decreasing the length of the plenary meeting.

MSC-RAC Workshop

The Chairman gave a short update to MSC on MSC-RAC joint workshop which took place on 11-12 October 2018. He informed MSC that a draft report from the workshop is currently being finalised in order to be shared for comments with the participants. The final version will be published on the ECHA website.

Workshop on EOGRTS

The alternate member of NL provided a brief update to MSC on the planning of the upcoming Workshop on EOGRTS which tentatively will take place on 2-3 May 2019 in Helsinki. He encouraged those members who are part of the organising committee to start discussing the plans in order to finalise the agenda before the next MSC meeting.

Update on ED EG response to MSC-57 issues

The MSC Chairman informed MSC that ECHA's Endocrine Disruptor Expert group (ED EG) still works on its recommendation in response to the MSC questions, sent after MSC-57, regarding some outstanding scientific issues when requesting a Fish sexual developmental toxicity test (FSDT, OECD TG 234) in dossier evaluation. Finalised ED EG's recommendation will be provided to MSC at one of the forthcoming plenary meetings.

Voting sheets

After feedback received from members MSC-S agreed to update the written procedure voting sheets to more clearly distinguish between justifications requested to be included in a written procedure report and comments (not to be included).

Item 5 – Minutes of the MSC-61 meeting

SECR gave a brief procedural report on the adoption of the minutes of MSC-61, done in written procedure (WP), that had been suspended for responding to a member's additional comments and subsequently continued (in line with Article 19 (6) of the MSC Rules of procedure). The Committee was informed that the final MSC-61 minutes have been published in MSC S-CIRCABC and on ECHA's website.

The MSC Chairman further explained to MSC the reasons for the WP suspension, noting the learning that there is a need to reinforce the agreed rules that the MSC plenary minutes should focus on decisions taken and conclusions made, and avoid referring to the individual statements, as discussion minutes could lead to misunderstanding/misinterpretation, if not all substance-specific details and views expressed are sufficiently covered.

Item 6 – Substance evaluation

1. 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 (SEv) cases (see Appendix to the final agenda in Section III for more detailed identification of the cases). WP was launched on 15 November 2018. By the closing date 26 November 2018, MSC reached unanimous agreement on these three SEv cases.

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

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

SEV-AT-001/2015 6,6'-di-tert-butyl-4,4'-thiodi-m-cresol EC No 202-525-2

Session 1 (open)

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

The evaluating Member State Competent Authority (eMSCA) from Austria (AT-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 CMR

(reproductive toxicity), suspected sensitiser, immunotoxicity, suspected PBT, suspected endocrine disruptor (ED), wide dispersive use, and consumer exposure. In the course of the evaluation, the eMSCA identified additional concerns regarding neurodevelopmental toxicity.

MSC was guided by the expert from the AT-CA through the information on the substance and through the proposals for amendment (PfAs) on the draft decision (DD) received from four Member State Competent Authorities (MSCAs) and from ECHA, the Registrants' comments on the PfAs and the eMSCA's response to them.

Some of the PfAs submitted were agreed by the eMSCA and led to an amendment in the DD in advance of the meeting. The MSC discussion focused on the unresolved PfAs.

The DD requested for an extended one generation reproductive toxicity study (EOGRTS; OECD TG 443) in rats, oral route, with the developmental neurotoxicity cohorts (DNT) and the developmental immunotoxicity cohort (DIT) and an extended pre-mating period of 10 weeks including parameters clarifying mode of action. The unresolved issue related to this request was whether there was sufficient evidence to justify the request for the DNT cohort. In the view of the PfA submitters 1) the results from the available *in vivo* studies did not indicate clear effects on the hypothalamus-pituitary-thyroid axis (HPT-axis); 2) no clear effect on grip strength was seen, all other neurotoxicity parameters were unaffected and no histopathological or electrophysiology measurements to indicate damage to muscle and nervous tissue were taken; 3) in most of the studies reduction in brain weight seemed to be related to reduction in bodyweight. Additionally the *in vitro* findings indicating activity at the oestrogen and androgen receptors were not considered to provide any justification to support inclusion of the DNT cohort. On the exposure analysis, in the view of a PfA submitter the reader was left unclear on what is the conclusion on exposure. If exposure was significant due to wide dispersive use by consumers and professionals, the EOGRTS design should extend to include the extension of cohort 1B to produce the F2 generation. Hence it was proposed to add some sentences to indicate why this cohort extension was not included. Furthermore it was proposed to remove the exact doses from the decision, refer only to the guideline and leave the appropriate dosing to the contract research organisation (CRO).

The DD requested also a fish sexual development test (FSDT), OECD TG 234. The unresolved PfAs for this study requested to include at least five test concentration together with controls to enable determination of a robust NOEC and/or EC10.

The Registrants submitted written comments on the PfAs which were duly considered during the discussion at MSC.

MSC members from PfA submitting countries reiterated the requested explanation for the way the Klimisch scoring of the available data was done and why they triggered a concern for DNT and therefore inclusion of the DNT cohort in the EOGRTS request. They could agree that there were rather strong indications for estrogenic MoA but questioned specific links to developmental neurotoxicity. Indications for interference with the immune system as a trigger for DNT cohort were not considered aligned with REACH text.
Furthermore, they requested to clarify the conclusion on exposure since in the basis of the assessment by the AT-CA a request for the extension of cohort 1B to produce the F2 generation seemed to be justified.

The eMSCA expert explained that all the available studies were taken in a weight of evidence and that the strong interference with the hypothalamus-pituitary-gonadal axis (HPG axis) was the basic concern that triggered the DNT cohort with the other identified effects as being supporting evidence. During the discussion it was further noted that an estrogenic and androgenic substance could impact brain development, hence, it was suggested to recommend the testing of the hypothalamus as an additional parameter in the DNT cohort request. Another good indicator of DNT effects included by default in the EOGRTS study is the motor activity. As the EOGRTS study has a long list of parameters

that can be included, some of which are part of the standard test design whilst others are optional, MSC discussed whether in SEv, when asking for a DNT cohort, the DD should specify the type of parameters, optional in the test guideline, that shall be carried out in addition.

Regarding the link to immunotoxicity, used as another trigger for the DNT request in the DD, AT-CA agreed not to include it in the justification for this request and the DD was updated accordingly.

Regarding the further clarification of the exposure to the registered substance, the AT-CA explained that from the information in the registration dossier they could not exclude 'significant exposure of consumers or professionals, taking into account, *inter alia*, consumer exposure from articles', which as specified by REACH Annex IX, 8.7.3 column 2, is a trigger for extension of cohort 1B to produce the F2 generation. The Registrants, in their written comments to the PfAs, did not comment on the exposure to the registered substance. Subsequent information from the Registrants suggested that the substance is used as an anti-oxidant in (high voltage) electricity cables so no one is expected to be in direct contact with them when in place, and that there is no consumer use.

Regarding the four dose levels of 2, 10, 50 and 200 mg/kg specified in the DD, MSC discussed whether to keep the doses or else refer to the OECD TG 443 guideline which states that two- to four-fold intervals between doses should not be exceeded and what should be the low and high doses.

Regarding the FSDT request AT-CA was asked to clarify the concern of the substance. Normally, according to the OECD TG 234, if the concern is to assess a substance's ED properties, 3 test concentrations would be sufficient whereas five test concentrations are recommended if the data are to be used for risk assessment. Some MSC members were of the view to request for five test concentrations due to the increase in statistical robustness of the NOEC, LOEC or EC_{10} derived. AT-CA agreed to request for five test concentrations since the statistically robust NOEC and/or EC_{10} could be used for further risk management considerations. AT-CA explained that their concern was mainly ED, however, in the uterotrophic assays whilst predominantly an agonistic response was observed, also an antagonistic response was elicited in one of the assays. These different responses could occur at different concentrations, which was one more reason to test a broader concentration range to cover both types of responses.

Session 2 (closed)

Regarding the parameters to be requested for the EOGRTS DNT- and DIT-cohorts, AT-CA agreed with the suggestions made by the MSC members in the open session to request the default parameter on motor activity and spatial learning and recommend histopathological investigations of the hypothalamus. The DD was updated accordingly.

Regarding the request for extension of the 1B-cohort to produce the F2 generation, MSC deliberated on whether to take the informal communication by the Registrant into account or not. However it was agreed that since this information is not reflected in the registration dossier and it is only related to consumer exposure, the Registrant still needs to provide justification of no significant exposure to professionals if they wish to successfully waive testing the F2 generation. Hence MSC agreed that based on the current information in the Registration dossier, requesting extension of the 1B-cohort to produce the F2 generation is justified.

Regarding dose selection in the EOGRTS, MSC agreed not to quantify the doses in the DD but to refer to the two- to fourfold intervals between doses as specified in OECD 443 test guideline. MSC also agreed to provide some further guidance to the Registrants on the selection of the low and high doses without quantifying them in the DD.

Regarding the FSDT request, MSC agreed to request for five test concentrations for the reasons discussed in the open session.

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

SEV-UK-022/2017 Triphenyl phosphate EC No 204-112-2

Session 1 (open)

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

The evaluating Member State Competent Authority (eMSCA) from United Kingdom (UK-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: potential endocrine disruption (including wide dispersive use, consumer use, high aggregated tonnage) and environmental risk assessment.

MSC was guided by the expert from the UK-CA through the information on the substance and through the proposal for amendments (PfAs) on the draft decision (DD) received from four Member State Competent Authorities (MSCAs) and from ECHA, the Registrants' comments on the PfAs and the eMSCA's response to them.

Some of the PfAs submitted were agreed by the eMSCA and led to an amendment in the DD in advance of the meeting. The MSC discussion focused on the unresolved PfAs.

The UK-CA requested for a Fish Early Life Stage toxicity Test (FELS; OECD TG 210) with the inclusion of liver and kidney histopathology, and a recommendation for the observation of pericardial edema. All PfA submitters agreed on the need to perform a test on fish to remove some uncertainties regarding both long term toxicity and ED concerns. However, four PfA submitters proposed to request a Fish Sexual Development Test (FSDT; OECD TG 234) instead of the FELS test.
One proposed to include as well the liver histopathology. In the view of the PfA submitters it appears that the effects observed in the different studies cannot be associated to the cytotoxicity of the registered substance due to wide differences in the considered concentration for ED effects (well below 1 mg/L) and the 96h LC50 ranging from 1 to 1.5 mg/L depending on the considered study. Furthermore, they agreed with the UK-CA that there were uncertainties regarding long-term toxicity data for fish which reinforced the need to perform a FSDT study.
Another PfA submitter proposed to request for FSDT with liver and kidney histological examinations. They proposed to test lower test concentrations for the potential endocrine mediated effects and higher concentrations to determine general ecotoxicity.
The third PfA submitter proposed to request for FSDT with liver histology and *Danio rerio* (zebrafish) as test species. In their view the variability in test results and potential difference in test conditions will make it difficult to investigate the hypothesis that endocrine related effects were secondary to liver toxicity. Furthermore, they considered this hypothesis less obvious with respect to the results of *Danio rerio*, and suggested this test species to be able to use the available data with this species for comparison.
Similarly, the fourth PfA submitter also had doubts that the hypothesis could be investigated with the test design requested in the DD. In their view:

1) while the FELS/histology in the tissues suggested might be used to determine the concentrations where systemic toxicity occur, it would not offer the opportunity to link this to the onset of an eventual endocrine disruption;
2) the endpoints of systemic toxicity had to be measured in the same experiment where relevant ED endpoints were measured in order to judge whether ED related effects occur and whether they occur at the same or different exposure concentrations as the reported systemic effects;
3) the FELS would not provide the information necessary to confirm or disprove a plausible causal link between possible systemic toxicity and 'secondary' ED effects.

Hence they proposed to combine FELS with FSDT including the histological examinations for liver, kidney and heart including 5 exposure concentrations, and relevant steroid hormone measurements.

The Registrants submitted written comments on the PfAs which were duly considered during the discussion at MSC.

The expert from UK-CA explained that their proposed request was to get a better understanding of the long-term systemic toxicity. In their view, the available data suggested that apical effects in the ED screening studies could be a consequence of other modes of toxicity rather than an ED mode of action. Liver toxicity, heart toxicity and neurotoxicity were observed in short term tests at concentrations below the acute LC50 but the significance of these effects over a long term was not known. The UK expert further explained that they considered it necessary to understand these effects before considering whether more extensive endocrine disruption testing was needed. . If the ED concern was not addressed by the proposed FELS test, the study would still act as a range finding test for a level 4 or 5 ED test. The UK expert noted that as the observed adverse effect in the ED screening studies was on fecundity, a life cycle test, such as the Medaka Extended One Generation Reproductive Toxicity Study (MEOGRTS) covering reproduction, could be more appropriate than the FSDT. The UK expert also highlighted that in their written comments the Registrants did not support the request for FSDT. In their view, the FELS should be performed first to define the range of acute toxicity and to allow an informed decision whether or not the effects reported in the available data are above or below this concentration range. The eMSCA was of the view the request for liver histopathology should be maintained, and agreed that kidney histopathology could provide additional useful information about systemic toxicity. The eMSCA expert reiterated that the database of available effects included a number of modes of action, not just liver toxicity.

The available data set shows different increasing or decreasing levels of vitellogenin between zebrafish and medaka. Whilst this was considered by the eMSCA as a further justification for requesting the FELS, due to the contrasting ED effects of the substance, some MSC members considered the differences between the two species could be due to a difference in metabolism of the test substance. The data seen in zebrafish could be explained by estrogenic effects. Hence they expressed preference for zebrafish as test species when requesting for FSDT.

Regarding the liver toxicity observed in the current data set, an MSC member was of the view that this could be due to enzyme induction, which could also impact the catabolic conversion of hormones and vitellogenin in the liver. Hence to be able in a study to conclude whether one MoA is in reality the reason for another MoA is very difficult.

One of the Stakeholder observers requested a clarification on the status of the evaluation of the human health concern, since ED concerns for human health were also reasons for putting this substance on the CoRAP. The UK MSC member explained that on the basis of the currently available human health data they had no verified concern on ED. However an EOGRTS study is being conducted on TPhP by the American National Institute of Environmental Health Sciences (NIEHS) as part of its national toxicology testing programme (NTP). The results of this study would be considered once available.

Session 2 (closed)

In the subsequent discussion MSC expressed clear preference to request for FSDT instead of a FELS. Based on this MSC view, eMSCA redrafted the DD requesting for FSDT instead of FELS, keeping in mind the Registrants' written comments stating that if an FSDT was requested, the study design should be limited to an extent which could be justified and which was proportionate.

MSC discussed whether it was possible to differentiate between liver toxicity and endocrine disruption, and it was concluded that this is difficult to be achieved since liver toxicity could be caused by some types of ED effects. However, by still including some of the histopathological determinations in the test design the eMSCA can still try to identify any

potential relationship between liver toxicity and ED effects during the follow-up phase when they are evaluating the test results.

Regarding the test species, MSC preferred zebrafish over Medaka in this specific case because the results from zebrafish were more indicative of ED effects than the results in Medaka.

Regarding the number of test concentrations, MSC agreed to request five test concentrations since in this case the test is to also investigate potential adverse effects, which based on the available dataset may occur over a broad range of concentrations. Furthermore, five test concentrations might provide more robust NOEC/LOEC/EC_{10} values, which will be important for risk management if it is necessary.

PfAs proposed to include liver, kidney and heart histopathology as well as sex hormones in the FSDT test design. MSC however agreed to preserve the right of the Registrant to be heard and, based on the lack of a clear justification for these requests in the PfAs, some of these parameters were only included in the DD as a recommendation.

MSC unanimously agreed on the DD as further amended during the meeting, requesting for FSDT (OECD TG 234), using zebrafish and five test concentrations and recommending the inclusion of liver histopathology, the measurement of sex steroid hormones and the observation of pericardial edema.

SEV-DE-011/2016 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate (EC No. 218-407-9) (6:2 FTMA) and
SEV-DE-012/2016 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate (EC No. 241-527-8) (6:2 FTA)

Session 1 (open)

Registrants agreed to an initial session combining these two cases. Three representatives of the Registrants participated in the initial discussion. In absence of specific confidentiality concerns an open session was held.

The evaluating Member State Competent Authority (eMSCA) from Germany (DE-CA) presented the SEv outcome of the above substances. The initial grounds of concern when placed on the Community Rolling Action Plan (CoRAP) were: potential endocrine disruptor, suspected PBT/vPvB, high mobility in the environment, wide dispersive use and exposure of the environment.

During the evaluation concerns for endocrine disruption had been identified for the common metabolites/transformation products of both 6:2 FTMA and 6:2 FTA, which are 1) 6:2 fluorotelomer alcohol (6:2 FTOH) and 2) perfluorohexanoic acid (PFHxA)[1].

Both draft decisions (DDs) notified to the Member State Competent Authorities (MSCAs) and ECHA requested for following tests: 1) a fish sexual development test (FSDT; OECD TG 234), using the metabolite/transformation product 6:2 FTOH, 2) a larval amphibian growth and development assay (LAGDA; OECD TG 241), using the metabolite/transformation product PFHxA, 3) further information on uses and environmental release estimations for the registered substance. Given that the Proposals for Amendment (PfAs) for both DDs were also the same, these two cases were presented and discussed together during the plenary meeting.

[1] For PFHxA a proposal to identify the substance as an SVHC according to Article 57 (f), among others based on its persistency and mobility in the environment, was also discussed at MSC-62 (see under agenda item 8).

MSC was guided by the expert from the DE-CA through the information on the substances and through the PfAs received from two MSCAs and from ECHA, the Registrants' comments on the PfAs and the eMSCA's response to them.

Some of the PfAs submitted were agreed by the eMSCA and led to an amendment in the DD in advance of the meeting. The MSC discussion focused on the unresolved PfAs.

On the request for FSDT, the unresolved PfA was the one requesting five test concentrations to be used.
On the request for the LAGDA (OECD TG 241) with PFHxA, one MSCA proposed to delete this request. They considered that there was only weak evidence demonstrating the concern for both thyroid and estrogenic endpoints which was, in their view, insufficient to justify a test at level 4 in the OECD Conceptual Framework for Testing and Assessment of Endocrine Disrupters. As an alternative request, if the concern was better defined and substantiated in the DD, they proposed to request an amphibian metamorphosis assay (AMA; OECD TG 231), and described advantages that they saw with such a testing strategy. They argued that the AMA could serve as the range-finder for a LAGDA test with PFHxA, if a follow-up decision is required. The PfA also indicated that if in the end the request for LAGDA remains, they proposed to request for five test concentrations instead of the four concentrations mentioned currently in the request. This would provide greater statistical power in terms of NOEC/LOEC values.

The Registrants had submitted written comments on the PfAs which among others agreed with the proposal to remove the request for LAGDA study for PFHxA and to conduct the AMA test, which was also reiterated by the representatives of the Registrants at the meeting.

In the following discussion, regarding the use of five concentrations in the FSDT test, it was pointed out that since the Registrant had not challenged this in their comments on the PfAs, and five concentrations increase the statistical robustness of the results, the DD should request, and not only recommend, the use of five test concentrations. This would also be in line with the test guideline and would allow to derive a more precise NOEC/LOEC or ECx, which would be useful for risk management. Furthermore, the Registrants indicated their willingness to test five concentrations at the meeting.

Regarding the choice of test to be requested, one expert explained that only weak evidence on the endocrine system via interference with the hypothalamus-pituitary-thyroid axis (HPT-axis) was presented to justify the concern, as no *in vivo* or mammalian evidence indicate thyroid effects for PFHxA. All the observed effects were from *in vitro* data and that it was not clear what the *in vivo* effects of any higher homologues were. The effects observed with PFOA in their view could not be simply expected as similar to those of PFHxA.

Another expert considered that potential thyroid effects to some sensitive species could not be excluded and wondered if the LAGDA test might be more sensitive, but fully agreed that a good chronic study was needed.

Some preference for the use of LAGDA was also expressed to avoid the need of doing both tests in case the AMA test gave a positive result. Another member pointed to the need for including an assessment of the strength of evidence if the request for LAGDA would remain, and noted that the differences of opinions expressed would require more discussion.

An expert from the eMSCA also provided some clarification as regards the evidence for thyroidal activity of PFHxA compared with structurally related substances. These were to help in understanding the possible modes of action, but also any trends in effects.

An expert asked for a clarification about availability of any amphibian data and also a study in quails was brought up to ensure all available data on PFHxA was assessed. A brief discussion about the studies summarised in Borghoff *et al.* (2018), as referred in the written comments of the registrants to the PfAs, also took place.

At the meeting the Registrant reminded about their written comments to the PfAs that information can only be requested on polymers which were manufactured and/or supplied by the Registrants themselves. In its response SECR clarified that this concern had been addressed by a precise wording in the DD.

Session 2 (closed)

MSC discussed the spacing and the maximum test concentrations to be used in the FSDT test. In order to assess estrogenic properties of 6:2 FTOH, MSC agreed to recommend the use of five concentrations to increase the probability to derive a more precise NOEC/LOEC or ECx to be used for further risk management considerations.

Further discussion took place on how best to assess potential thyroid disrupting properties of PFHxA. One view was that since there are not that many aquatic species tested, LAGDA might provide more robust data. For screening of endocrine activity an AMA test should be sufficient but if there is more certainty that endocrine activity will occur, the use of LAGDA would be justified. MSC also considered the Registrants' clear preference for AMA test. MSC concluded that the studies summarised in Borghoff *et al.* (2018) did not remove the concern for PFHxA, acting via the HPT-axis, as a possible ED substance in the environment and more certainty on the long-term effects of PFHxA was needed to better describe the risk.

Based on the discussions MSC agreed unanimously to amend the DD and request the AMA test instead of the LAGDA to further clarify the environmental ED concern and potential thyroid disrupting properties of PFHxA, in accordance with the OECD Conceptual Framework for Testing and Assessment of Endocrine Disrupters. MSC decided to also recommend the use of five test concentrations in the FSDT test, and further modified the reasoning in the DD accordingly.

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

SEV-DE-011/2017 Ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate EC No 700-242-3

Session 1 (open)

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

The eMSCAs from Germany and the Netherlands (DE-CA and NL-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 and exposure to the environment. In the course of the evaluation, the evaluating MSCAs identified additional concerns regarding carcinogenicity and bioaccumulation in humans.

MSC was guided by the expert from the NL-CA through the information on the substance and through the proposals for amendment (PfAs) received from three Member State Competent Authorities (MSCAs) and from ECHA, the Registrants' comments on the PfAs and the eMSCA's response to them.
Some of the PfAs submitted were agreed by the eMSCA and led to an amendment in the draft decision (DD) in advance of the meeting. The MSC discussion therefore focused on the unresolved PfAs.

Regarding the proposed carcinogenicity study in mice via the oral route – OECD TG 451, one PfA requested that this proposed study be removed from the draft decision. It was argued by the PfA submitter that a guideline carcinogenicity study in rats was already available and the proposed peroxisome proliferator-activated receptor alpha (PPARα) agonist mode of action of this non-genotoxic substance is not expected to be relevant for humans. In their view a second carcinogenicity study would likely still only support

classification in Category 2, since they predicted that a similar pattern of tumours as in the first carcinogenicity study would be observed in mice, and there would therefore be no change or 'improvement' in risk management measures.

Furthermore, since the substance is used in processes operated, in the view of the PfA submitter, with a high degree of containment, the current DNEL (for workers) would be protective for any potential carcinogenicity concerns. Regarding exposure of this substance to the general population, this PfA submitter considered that the environmental monitoring data presented by the eMSCA could not necessarily be linked to this specific source and it seemed disproportionate to request further testing from this single, relatively low tonnage importer. In their view it should be possible to conduct a back-calculation using the available environmental data and compare this with a general population DNEL.

In the event that the request for the carcinogenicity study would remain, this PfA submitter suggested further detail on the level of exposure of workers should be provided and some text suggestions to the current DD regarding the similarities between the registered substance and PFOA.

Regarding the human biomonitoring study in workers proposed at the Registrant's site, another unresolved PfA requested to remove it. In the view of the PfA submitter, since the DD stated that the Registrant would not be held responsible should the volunteering workers not cooperate, they doubted if this study would be undertaken. Hence the eMSCAs concerns would remain and instead they wondered if the recent (2017) blood sampling data from workers could be used in some way to get a better idea of worker exposure and if it was actually of concern.

Regarding the use of an assessment factor (AF) of 66 by the eMSCA in deriving the worker DNEL (based on PFOA data to account for interspecies differences), this PfA submitter questioned why this AF was appropriate for this substance, given the differences in the available half-lives for the registered substance and PFOA, since it was not explained in the DD. The DD also indicated that RCR >1 was obtained on the use of this AF but no actual numbers were given. However, the PfA submitter believed that when using the exposure estimates from the registration dossier, the RCR would not be much greater than 1 and the registrant could then introduce further controls to bring the RCR to below 1 and remove the concern.

Regarding exposure to humans via the environment, for which there was no assessment in the draft decision, the PfA submitter was of the view that if the request remained, further redrafting of the DD was needed.

The Registrants submitted written comments on the PfAs which were partly reiterated at the meeting. Regarding the carcinogenicity study, they agreed with the assessment from the PfA submitter that since the observed tumours suggested to result via a PPARα mode of action, they are rodent specific and appear not to be relevant to humans. Hence, they agreed that there was no value in conducting a second carcinogenicity study as it was expected that rats and mice would react similarly. However, in the meeting, when questioned, they responded that no studies with regard to carcinogenic mode of action had been carried out on the registered substance.

The Registrants noted that the DNEL was based on the clear NOAEL for liver toxicity, which would protect against any theoretical carcinogenicity risk.

Regarding the human biomonitoring, the Registrants stated that there was no evidence of significant or widespread occurrence of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)-propanoate ions, HFPO-DA, in the human blood either due to the expected rapid elimination of HFPO-DA from the body or from extremely limited exposure. Hence in their view there was no appropriate basis for conducting the invasive study. In response to questions raised by MSC members and Stakeholder observers, they explained that the 2017 study carried out at the request of the workers council at the manufacturing site by an independent contractor, was not a biomonitoring study but a sampling study to see if

the substance behaved similarly to PFOA or not. In the view of the Registrants' representatives HFPO-DA (also referred to as Gen-X) might have a similar fate to PFOA in water but its biology in the body is different hence it is easily eliminated as the parent molecule. To prove this point, the Registrants' representatives referred to a recent large study done in North Carolina in the US, where 345 people including 56 children exposed via drinking water were sampled. They stated that their blood did not contain Gen-X but contained PFOA.

In this regards the eMSCA representative explained that they were aware that the North Carolina US study referred to by the Registrants' representatives was initiated, but they had not been informed about its outcome prior to the meeting. In their active search for new studies for the substance, the eMSCA did find a toxicity assessment drafted by the USEPA in November 2018 just after the commenting phase of the Registrant on the PfAs closed, in which the USEPA sees it useful to perform a carcinogenicity study on mice for Gen-X.
On this last study, the Registrants' representatives noted that they were aware of this document, but that it, being a draft assessment still open for comments, could not be seen as a final USEPA position.

The eMSCA representative stated that both these reports were considered as late information in this process and should therefore not influence the decision making in MSC. Furthermore, both US study reports were not yet part of the registration dossier. The Registrant acknowledged that the US study reports were new.

Additionally, in the view of the Registrants' representatives even if the study had to be conducted, the sample size, lack of workers with blood levels meeting the criteria and the low probability of full compliance by the participants, made the study inadequate for the derivation of a meaningful human elimination half-life. The eMSCA expert based on the PfAs and the Registrant's comments on the PfA proposed a revision to the human biomonitoring request by recommending a tiered approach with the intention of reducing the invasiveness of the procedure and disruption to the work schedule. The Registrants' representatives confirmed that they saw this proposal before the MSC-62 meeting and appreciated this compromise.

Session 2 (closed)

The possibility of a carcinogenicity study in mice leading to a Carc. 1B classification of the substance was discussed by MSC. It was acknowledged that sufficient evidence that the effects seen were not relevant to humans was needed in order to make this conclusion for classification. In this case, apart from liver tumours there were also pancreatic tumours and tumours in leydig cells. Hence, a study in mice, could be helpful to confirm or remove the concern for pancreatic tumours. It was also recognised that any mechanistic studies to understand other possible modes of action of Gen-X would be useful.

MSC therefore proceeded in discussing some text refinement in the DD, amongst which the setting of the doses in the study was specified to be based on the results from the subchronic 90 day study and the current knowledge about the toxicokinetics in mice with the aim to induce systemic toxicity at the highest dose level.

Additionally, the evidence of exposure of the general population to the registered substance via several routes lead to MSC agreeing to keep the request for a carcinogenicity study in mice as amended during the meeting.

Regarding the human biomonitoring study in workers MSC accepted the proposal by the eMSCA to recommend a tiered approach. With reference to the draft report on the US study MSC acknowledged this as being late information by the Registrants' representatives. In this regard, the MSC member representing the eMSCA stated that, at a first glance at this information, it seemed that the study did not provide half-lives in humans. He explained that reference to this report was not made in the DD, as this report

was not formally submitted by the Registrant as an update to the Registration dossier and consequently the eMSCA was not able to assess whether the people in the study have been exposed and to what extent they have been exposed.

The MSC unanimously agreed on the decision as further amended in the meeting as indicated above. UK member abstained from voting.

Item 7 – Dossier evaluation

1. 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 six dossier evaluation cases (see Section III Final agenda "Appendix to the MSC-62 agenda" for more detailed identification of the cases). WP was launched on 15 November 2018. By the closing date 26 November 2018, MSC reached unanimous agreement on all DDs. Two members abstained from voting on five cases. The MSC member who abstained from voting on one case requested to include the justification for abstention in the annex of the written procedure report.

2. 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)*

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

CCH-095/2018: 3-aminopropyldiethylamine; 203-236-4

Session 1 (open)

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

SECR explained that proposals for amendment (PfAs) to ECHA's DD had been submitted. The first PfA on transgenic rodent (TGR) somatic and germ cell gene mutation assays suggested alignment with the approach used in previously agreed cases, that is, collecting somatic cells from three tissues (liver, glandular stomach and duodenum) and analysing two tissues (liver and glandular stomach); it further suggested analysing duodenum if the results of the glandular stomach and of the liver were negative or inconclusive.

The second and third PfA on the same endpoint suggested adding a note on the 28+28 day testing strategy for TGR (OECD Test Guideline 488) and requiring analyses of germ cells if any of the somatic tissues yielded a positive result, respectively.

The fourth PfA on a pre-natal developmental toxicity (PNDT) study suggested having a testing strategy to first perform an extended one-generation reproductive toxicity study (EOGRTS) and then evaluate the possibility to self-classify as Repr 1B; and if not classified, then carry out a PNDT study using a second species.

The fifth PfA on EOGRTS suggested including cohort 3 (developmental immunotoxicity, DIT), justified by test item-related vacuoles in lymphoid organs, and polychlorinated biphenyls (PCB) affecting oestrus cycle and disturbing the immune system.

The Registrants had submitted written comments on the PfAs and MSC duly considered them in its discussion.

In the discussion on the PfAs on TGR and somatic and germ cell gene mutation assays the MSC firstly took note of the general agreement, reached earlier in the meeting (see item 7 section 4. General topics), during the discussion on germ cell sampling in mutagenicity testing. It then noted that the Registrant had informed of his intention to perform the comet assay, where the sampled gonads contain a mixture of somatic and germ cells and a positive result would not necessarily reflect germ cell damage. The MSC also (a) agreed to wait for the outcome of OECD discussions on 28+28 day sampling; (b) took note that a

28+3 day sampling time may not be optimal for germ cell analysis; and, (c) concluded that the second PfA on this would not need to be taken into account.

The MSC noted, in relation to the PfAs on PNDT and EOGRTS, that the Registrant had disagreed with both PfAs. As regards the fourth on PNDT he intended to perform a PNDT to identify possible classification for reproduction; expressed concern that a sequential strategy of first performing EOGRTS could be preferred to avoid unnecessary testing in whole and in respect of animal testing as last resort; agreed that no PfA had presented legal requirements for tiered testing.

Session 2 (closed)

MSC summarized its agreement (a) to align this case with the approach used in previously agreed cases on TGR somatic and germ cell gene mutation assays; to not request 28+28 day sampling in TGR; at this stage, not to require analyses of germ cells if any of the somatic tissues yields a positive result; (b) to remind the Registrant to consider the order of the studies in view of the possible classification; (c) to request cohort 3 (DIT).

MSC agreed unanimously to the DD as provided for the meeting.

TPE-076/2018 – Bis(4-chlorophenyl) sulphone; 201-247-9

Session 1 (open)

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

SECR introduced the proposals for amendment (PfAs) on EOGRTS that were received to the ECHA's DD. SECR also reminded that the substance was in the Community rolling action plan (CoRAP) list for substance evaluation by Austria in 2019, because of, *inter alia,* considerations on exposure due to high aggregated tonnage and wide-dispersive use of manufactured articles. The first PfA expressed a concern on the currently known uses leading potentially to widespread emissions and suggested including such additional considerations in the DD text.

The second PfA suggested including cohorts 2A and 2B (developmental neurotoxicity, DNT) based on available *in vitro* and *in vivo* data on interference with signalling via the (anti)androgenic, (anti)estrogenic and/or thyroid pathways.

The third PfA suggested including cohort 3 (DIT) with reference to information on hormonal mechanisms and/or modes of action associated with immune systems and adverse effects on immune system organs.

The Registrants had submitted written comments on the PfAs and MSC duly considered them in its discussion.

In the discussion on the PfAs the MSC took note that the Registrant in his written comments prior to the meeting had requested an agreed decision between dossier and substance evaluation processes. On the second PfA to trigger DNT cohort, the MSC first took note of the differing views on available data for providing evidence on (anti)androgenic, (anti)estrogenic and thyroid perturbing activities, on which there did not seem to be consensus. It did not consider that in this particular case there was sufficient available evidence on hormonal mechanisms. The MSC then, on the third PfA on DIT, (a) took note that the DIT cohort would be triggered based on adverse effects on thymus, that is, significant reductions in thymus weight in available studies; (b) did not consider that there was sufficient available evidence on hormonal mechanisms in this particular case; and, (c) shared the view that referenced changes in relative and absolute weights should be expressed more clearly. Finally, the MSC agreed to SECR extending the deadline from 24 to 30 months based on the Registrant's request with documentary evidence from a testing laboratory with the indicative timelines to perform the requested tests.

Session 2 (closed)

In the discussion, focusing on the second PfA on the DNT cohort, the MSC firstly took note that the Registrant in his comments on the DD had indicated willingness to include all

extensions (DNT, DIT, F2), mainly because of some uncertainties on the potential for bioaccumulation and endocrine activity, some structural similarity to other molecules flagged for endocrine disruption concerns. The MSC noted the effects reported in various studies but considered that these are not strong enough evidence in relation to triggering the DNT cohort. Further, it (a) considered the scientific background in detail and noted that there were some indications for an antiandrogenic mode of action of the substance (specifically, the NTP 14-week study with increased absolute testis weight in rats and Toxcast data (at https://actor.epa.gov/dashboard/) showing positive assay responses for antiandrogenic activity); (b) supported exploring structurally possibly similar group of neurotoxic PCBs; and, (c) encouraged the Registrant to look for effects in the initial stages of the EOGRTS (e.g. changes in anogenital distance, changes in sex organ weights or other relevant parameters) and consider including DNT cohort later in the EOGRTS study. The MSC argued that the standard form of the "Notes for consideration" in the DD already provided the Registrant a possibility to include DNT if a trigger was justified based on new data, along with existing information. Finally, the MSC agreed to extend the "Notes for consideration" with text describing that new evidence could comprise, for example, significant consumer or professional exposure from articles, neurotoxic effects of structural analogues, and changes in relevant parameters when performing the study; and, requested documenting any conclusions based on available and new information indicating triggers for the expansion of the study.

In the further discussion on other PfAs, the MSC (a) noted that there was neither wide-dispersive use described in any of the dossiers nor signs of significant consumer or professional exposure, including any release from articles; (b) took note that there could hardly be a back reaction from polymers in articles to regain monomers, or significant exposure from leaching of residual monomers according to the dossier data; and, (c) concluded that there was no trigger to extend cohort 1B to produce the F2 generation resulting from exposure as described in the registration dossier. The MSC confirmed that the DIT cohort was to be requested based on the PfA. Additionally, it noted that the Registrant in his comments on the DD had indicated willingness to extend the EOGRTS to extend cohort 1B to produce the F2 generation, and concluded that F2 could not be requested as there was no PfA on it.

MSC summarized its agreement to add clarifying text on exposure and DNT in the DD and to have SECR extend the deadline from 24 to 30 months based on the Registrant's request with documentary evidence from a testing laboratory with the indicative timelines to perform the requested.

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

TPE-088/2018: Triethoxy(2,4,4-trimethylpentyl)silane; 252-558-1

Session 1 (open)

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

SECR explained the proposal for amendment (PfA) that was received to the ECHA's DD on EOGRTS suggesting to include cohort 3 (developmental immunotoxicity, DIT), in addition to the currently requested cohorts 2A and 2B (developmental neurotoxicity, DNT). The PfA did not support the available 90-day study as compliant with the test guideline (OECD TG 408), specifically in setting of an adequate top dose, and, with reference to the impossibility in this case for a request to repeat the 90-day study and the precautionary principle, proposed to include the DIT cohort.

The Registrant had not provided any comments on the PfA.

In the discussion the MSC first noted that dose level setting in general had been discussed in the MSC-RAC workshop in October 2018, but that the report was not yet available for any conclusive discussion at MSC. It then took note that ECHA had, in an earlier process, (a) accepted the results from the 90-day study in its follow-up to a previous testing proposal decision on the substance; (b) conducted an evaluation of the information

provided at follow-up, (c) considers the importance of the 90-day study for identifying possible triggers for the EOGRTS design, a factor which had emerged only at a later stage than the follow-up evaluation of this case; (d) indicated that the discussion of high dose selection in the current decision had been in the context of a read-across justification.; Some MSC members expressed the view that the top dose selection in the 90-day study was insufficiently high and not compliant with the test guidelines. Further, the MSC took note that, in some instances, ECHA has issued an Article 42(1) decision if results were found incompliant. The MSC also noted that, in this particular case, the precautionary principle and an inadequate 90-day study were not a valid basis for triggering the DIT cohort. Finally, the MSC considered, in the context of a repeated dose toxicity study, that an insufficiently high top dose level may lead to a variety of deficits for important information; such deficits could *inter alia* include the lack of information which can be used to trigger the inclusion of cohorts in the EOGRT study design. MSC welcomed that SECR now considers the potential information gained from a sufficiently high dose level (and its relevance for *inter alia* EOGRT study design) when evaluating information at follow-up.

Session 2 (closed)

Further in its discussion the MSC noted the clarifications on ECHA's follow up action, where a an Article 42(2) note is sent to Member States when the results are accepted, and an Article 42(1) decision is sent when results would not be accepted. It then agreed that the aim of sufficiently high dosing should be evident from the test guidelines, but expressed understanding that correct dosing for some substances may not be easy.

MSC summarized its conclusion that a new 90-day study could not be requested, because the earlier study had been found acceptable, but noted that those dosing levels had not been justified for read-across purposes.

MSC agreed unanimously to the DD as amended at the meeting to reflect its summary conclusion.

The member from the Netherlands abstained from voting.

4. General topics

Request of *in vivo* mutagenicity testing on germ cells under compliance check of Annex IX or X dossiers *(closed session)*

SECR gave a presentation on the *in vivo* mutagenicity testing on germ cells under compliance check of Annex IX or X dossiers. The topic links to activities of the Risk Assessment Committee (RAC) and classification and labelling of substances, which may benefit from data generated already under dossier evaluation. The links to classification had been discussed, at expert level, in the MSC-RAC workshop in October 2018, among other items. Although the workshop report was not yet available, SECR noted that the workshop generally supported that data generated under REACH dossier evaluation should enable RAC to classify a hazardous substance. Until now such data have not been provided on mutagenicity in germ cells.

SECR presented a proposal to change from the current approach under dossier evaluation, when there is a positive result in an *in vivo* somatic cell genotoxicity study. Instead of "recommending" *in vivo* mutagenicity testing on germ cells, this would now be "requested".

MSC expressed general support for this proposal, while taking note that such requests may sometimes use more animals, so all available information should first be considered and there should be sufficient certainty that the substance reaches gonads.

SECR continued presenting possible ways for practical implementation of the new approach and provided details on various tests addressing different types of effects.

MSC welcomed the initiative from SECR to start preparing a document on implementation aspects. The work should also (a) cover testing proposals and the link with substance evaluation, (b) include experts from Member States, and (c) present options for testing

strategies. MSC agreed to request SECR to prepare, in consultation with appropriate Member State experts, such a document. It should include both the scientific background and practical implementation for the main scenarios identified in regards of the already available mutagenicity information in a registration dossier. MSC invited SECR to present the status of this work in its next meeting, with the aim to have the document available at MSC-64 for discussion.

Item 8 – SVHC identification - Seeking agreement on Annex XV proposals for identification of SVHC

- Benzo[k]fluoranthene (EC No. 205-916-6)
- Fluoranthene (EC No. 205-912-4)
- Phenanthrene (EC No. 201-581-5)
- Pyrene (EC No. 204-927-3)

The dossier submitter (DS) representatives from the Belgian CA and from the French CA introduced jointly their Annex XV proposals for these substances and explained that the substances were proposed for SVHC identification due to their specific hazardous properties, as follows: *benzo[k]fluoranthene* – under Article 57 (a),(d)&(e) due to its carcinogenic, persistent, bioaccumulative and toxic (PBT) & very persistent and very bioaccumulative (vPvB) properties; *fluoranthene* and *pyrene* – under Article 57 (d)&(e) due to their PBT & vPvB properties, and *phenanthrene* – under Article 57 (e) due to its vPvB properties. The DSs presented a brief overview of the comments received in the public consultation on these Annex XV proposals, of the responses provided in the Response-to-comments documents (RCOMs) and the modifications made in this regard in the respective Support documents (SDs).

Furthermore, the DSs noted that many of the points raised in the public consultations were already considered and concluded by MSC in the context of the previously identified SVHCs, in particular Coal Tar Pitch High temperature (CTPHT), benzo(a)pyrene, chrysene and other polycyclic aromatic hydrocarbons (PAHs), identified as SVHCs in the past 10 years. Thus, the focus of their assessment was on the new information provided in the public consultation, in particular with regard to *phenanthrene*, and if it would lead to a change in their conclusions on the hazardous properties of these substances, within an overall weight of evidence (WoE) approach applied in accordance with Article XIII of the REACH Regulation.

The DS representatives provided further insights into the way the SDs were modified to address public consultation comments. They highlighted that the new information was assessed in line with the ECHA R.11 Guidance and in their view did not lead to a change in the overall conclusions made for any of the substances.

The adviser to the Concawe observer brought some further clarification on their comments submitted in the public consultation, in particular challenging the vPvB conclusion for *phenanthrene* based on their interpretation of results of recently carried-out biodegradability studies (with regard to the data for trend analysis from peer-reviewed literature, on-going research work on the role of temperature on biodegradation of hydrocarbons, etc.) and newly provided bioaccumulation information. The latter refers to fish bioconcentration factors (BCFs), biomagnification factors (BMFs) and trophic magnification factors (TMFs) derived from data that, in their view, should be considered more relevant than bioconcentration data using aquatic invertebrate species.

Concerning biodegradation, the DSs noted that when applying the temperature correction, using the Arrhenius equation, to the results of the newly-provided OECD 308 water-sediment simulation test, the resulting half-lives exceeded the Regulatory threshold value for considering *phenanthrene* as vP in sediments. MSC thoroughly discussed the results on phenanthrene degradation in soil, noting the substance's fast degradation in laboratory conditions and slower degradation indications from the available field studies. Thus, MSC agreed that the current information does not allow drawing a conclusion on persistency of phenanthrene in soil.

Concerning bioaccumulation, the DSs referred to the ECHA's R.11 Guideline which indicates that valid BCFs determined in other taxonomic groups than fish data, for measuring bioconcentration in the aquatic environment, can be used in assessing whether or not the B/vB-criteria are met. Invertebrate species may have a lower metabolic capacity than fish species, potentially rendering bioaccumulation in these species higher than in fish under the same exposure.

MSC thoroughly considered the comments received in the public and MSCAs' consultations, the way the new data had been considered for all dossiers by DSs in a weight of evidence approach, taking in to considerations the further remarks made by the adviser to the MSC observer from Concawe.

Few members proposed modifications to the SD for *phenanthrene* to increase clarity on the assessment of the new information and interpretation of the results. These included proposals to elaborate further on the results of the OECD 308 study and the related temperature correction of the degradation half-lives in order to align with the ECHA's Guideline R.11 and the approach followed in previous similar cases. It was also proposed to include in the SD considerations of a high percentage of non-extractable residues (NER 42- 51%) for the samples tested in the OECD 307 soil simulation, insufficiency of the posters' information to allow proper conclusions to be drawn, etc. Where relevant, further alignments across the SDs for the four PAHs substances were considered. The potential use of monitoring data was considered in the context of the bioaccumulation assessment and to further strengthen the conclusions made, in particular for *benzo[k]fluoranthene*.

MSC supported the DSs' conclusions on the hazardous properties of *benzo[k]fluoranthene*, *fluoranthene, phenanthrene* and *pyrene* based on the application of a Weight of Evidence approach by taking into account all available relevant information in accordance with Annex XIII of REACH and the MSC conclusions made in the context of the previously identified as SVHCs PAHs.

Consequently, MSC unanimously agreed to the SDs and respective agreements, as modified at the meeting, and thus identified as SVHCs: *benzo[k]fluoranthene* as carcinogen, PBT and vPvB (in accordance with REACH Article 57a,d&e), *phenanthrene* as vPvB (REACH Article 57e), *fluoranthene* and *pyrene* as PBTs and vPvBs (REACH Article 57d&e).

The MSC Chairman thanked the DSs and the Committee for the successful discussion and outcome on these SVHC proposals.

- Undecafluorohexanoic acid (PFHxA) and its ammonium salt (EC No. 206-196-6, 244-479-6)

The dossier submitter (DS) representative from the German CA presented to MSC the Annex XV proposal for identification of PFHxA and its ammonium salt as SVHCs under Article 57 (f) of REACH due to their hazardous properties for which there is evidence of probable serious adverse effects to human health and the environment giving rise to equivalent level of concern (ELoC) to CMR and PBT/vPvB substances under Article 57 (a)-(e) of the REACH Regulation. The DS explained the rationale for preparing the dossier and noted that PFHxA is extremely persistent, difficult to remove, almost not degrading substance that enriches in plants and has broad environmental distribution, high potential for long-range transport, low to moderate adsorption potential, atypical bioaccumulation (via protein binding and effective distribution throughout the body), mobile in the aquatic environmental compartments, for which there are indications for probably adverse effects on human health via the drinking water. It was noted that this protein-binding substance is found in drinking water, as well as in brain, lung, kidney, liver, bones in humans, wild boars, roe dears and other species, and is distributed across the body. The DS outlined also the main comments received in the public consultation on the proposal and the DS's responses to them. It was underlined that the current SVHC proposal is based on different hazardous characteristics of PFHxA, and its ammonium salt, considered jointly in a Weight of Evidence (WoE) assessment thus constituting an Equivalent Level of Concern (ELoC) to substances meeting the criteria of Article 57 (a)-(e) of REACH. The DS noted as well that

any references to the newly developed, but not agreed yet concept on 'Persistent, mobile and toxic (PMT) substances' were removed from the SD provided for MSC consideration.

The adviser to the MSC observer from CEFIC brought further clarification on their comments provided in the public consultation and made suggestions for their further consideration.

In the following discussion, many MSC members and two MSC accredited stakeholder organisation (ASO) observers expressed their support for this SVHC proposal. They highlighted the relevant concern and further provided views on data robustness.

MSC generally acknowledged that there are concerns regarding the adverse effects this substance could cause related to reproductive toxicity. However, some further deliberations took place as regards the need for the risk assessment committee (RAC) to assess these data, the scope of the ELoC assessment in this particular case, the substances' potential to cause toxicity in humans via the environment, based on the currently available studies. Some discussions took place on the definition of 'extreme persistence' or 'mobility' in the absence of clear criteria for such in the current REACH text.

Majority of MSC supported DS's conclusion that PFHxA is a very persistent substance and that its degradation half-life *"by far exceeds the trigger of being very persistent (vP)".* Some changes in the SD were considered to clarify the justifications for the conclusion on degradation. MSC also supported that PFHxA predominantly stays in the aqueous compartments of the environment, like surface water, oceans and ground water. The Committee also noted that the usually applied techniques in water and wastewater treatment plants are not capable of removing PFHxA. Members also acknowledged the substance's high long-range transport potential, as confirmed by PFHxA findings from several studies in remote regions. Furthermore, it was noted that although PFHxA is less bioaccumulative than PFHxS and PFOA, it binds to blood proteins, which might lead to facilitated tissue and organ distribution in the body, as confirmed in several human biomonitoring (HBM) and toxicokinetic studies.

Some members could not agree with the conclusions drawn on substance toxicity for human health based on the available dataset, in particular as regards the toxic for reproduction properties of PFHxA. Since conclusion on toxicity had been changed after the public consultation based on one non-guideline reproductive toxicity study only, few members considered that there should be more time to evaluate this one study. Few members suggested the data should first be assessed for purpose of harmonised classification and labelling, however this view was not supported by the majority of members.

A member's adviser noted that, in the absence of a numerical criterion, it is difficult to consider the relevance for the ELoC assessment of PFHxA's ability to accumulate/enrich in plants, and that this enrichment also should be considered in light of the substances' potential toxicity to plants.

Referring to the Commission's statement made on the scope of the 2018 REACH review conclusion and actions, two members proposed to the DS to withdraw this SVHC proposal to allow, before proceeding with SVHC identification, a clarification on ELoC criteria for other cases than sensitisers, and robust evaluation of the reproductive toxicity study.
It was discussed whether T is an essential element of ELoC, however, no agreement was reached on this point.

In response, the Commission observer and several MSC members noted the SVHC identification following Article 57(f) is a case-by-case decision which allows MSC to continue identifying SVHCs with ELoC, as usual. Furthermore, it was noted that a harmonised classification and labelling was never before, and still is not, a pre-requisite for SVHC agreement seeking under ELoC. Further concerns for PFHxA exist such as formation of PFHxA from precursors, potential co-exposure of the environment and humans with other PFASs, probability for adverse effects in humans, if releases are not minimised, as well as difficulties to quantify with sufficient certainty the exposure and related risks. A member's advisor disagreed with these further concerns related to SVHC identification.

Some changes in the SD were considered in the ELoC assessment.

Taking into account the views exchanged and the likelihood of reaching MSC unanimous agreement on this SVHC proposal, the MSC member from Germany, on behalf of the DS, informed the committee of her Member State's decision to withdraw the PFHxA proposal from this MSC agreement seeking process, for the reasons outlined in her statement (attached in Section VI).

Consequently, 17 MSC members expressed explicitly their support to this SVHC proposal in a joint statement, whereas two other MSC members made a joint statement, expressing some reservations as regards the PFHxA identification as an SVHC based on ELoC considerations. All statements made are attached to the minutes (see Section VI).

The Chairman thanked the dossier submitter for providing the proposal to the SVHC identification process and MSC for the thorough discussion on the case.

Item 9 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2019-2021)

- First discussion on the draft opinion

The Rapporteur introduced the working group (WG) members and explained how the work was organised to assess the draft CoRAP update 2019-2021 and prepare the draft MSC opinion on it. MSC was invited to send comments to the Rapporteur on the Annex and draft opinion by 17 January 2019. The Rapporteur thanked the Member State Competent Authorities (MSCAs) for the good quality justification documents that were provided and for their quick action, when requested, to make updates by the WG.

The discussion focused mostly on the possibility to re-open a substance evaluation, by a different MSCA, when closed by one evaluating MSCA. This is the current situation with resorcinol - a substance proposed to be included in the draft CoRAP update 2019-2021 by France following an evaluation by Finland and which Finland decided to close without issuing a draft decision (= conclusion). France proposes to put the substance back on the CoRAP because they are convinced that it requires further investigation for the environment.

It was explained that there was legally no contraindication since the evaluation was closed without a request. It was further elaborated that the other MSCAs did not have the possibility to comment on the evaluation performed, and therefore it should be allowed for another MSCA to propose the substance to be re-introduced in the CoRAP. In analogy, there is also a possibility to perform multiple compliance checks on the same dossier. The representative of the Commission felt that the legal analysis provided by ECHA was reasonable and had no immediate objection. However, he expressed the wish to ask his Commission colleagues to see, whether they would agree with this interpretation.

A MSC member recalled that such scenario was discussed in one of the SEv workshops held in previous years but did not recall the precise outcome.

The MSC member representing the MSCA that proposed the inclusion of resorcinol on the draft CoRAP, explained that different evaluators might have different scientific interpretations of the same data and that they also took the efficient use of resources of all Member States into account when they proposed resorcinol to be included once more in the draft CoRAP.

There was an independent expression of the wish to avoid these kind of situation in the future due to the elongation of the process as well as duplication of work by regulators. It was therefore agreed that the re-introduction of cases to the CoRAP after evaluation must be seen as an exception.

An industry stakeholder observer stated that the current process is transparent, however, re-introducing cases in the draft CoRAP makes the process unpredictable. He also

reminded MSC on the strong plea for efficiency from the ECHA Management Board. In his view the process should be transparent and predictable.

The Chairman concluded the discussion by asking MSC to prepare for the MSC-63 discussion and the adoption of the draft MSC opinion by looking into the conclusions of the aforementioned SEv workshop. He asked the Commission representative, in case his colleagues hold a view that reintroduction of a substance in the CoRAP cannot be supported legally, to present their arguments as soon as possible to the ECHA legal team.

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

1. Request from the Commission regarding inclusion of Art. 57(f) properties (i.e. as endocrine disruptors) of DEHP, BBP, DBP and DIBP in Annex XIV

SECR presented a request from the Commission (COM) regarding inclusion of Article 57(f) properties of four phthalates (DEHP, BBP, DBP and DIBP) in Annex XIV of REACH. COM now considers that in line with Art. 58(3) and 58(4) a recommendation process should be followed, including a three months public consultation of a draft recommendation about the foreseen Annex XIV amendment. Consequently, MSC needs to provide its opinion to ECHA before ECHA submits its recommendation to COM. SECR pointed out the reduced scope of this 'amendment recommendation' as prioritisation of those substances does not need to be covered. SECR noted, however, that this 'amendment recommendation' is to be considered a self-standing recommendation, and that it will partly run in parallel to the 9th recommendation process, and that the public consultation process had just started. Since MSC opinion would be expected in June 2019 the Chairman closed this item by encouraging MSC members to volunteer for this rapporteurship with the anticipation that the appointment could take place during the February plenary.

2. Brief report from the Rapporteur and Working Group

The Rapporteur informed MSC that the Working Group has discussed the division of tasks and substances within the group and that a brief meeting took place during the plenary. The comments from the public consultation on the 9th draft recommendation are available, also on the ECHA website, since the end of this week. Further highlights will be provided to MSC during its plenary meeting in February.

Item 11 – Any other business

1. How to deal with information submitted to the MSC not contained in the proposals for amendment submitted by MSCAs and Registrants' comments on them (final) *(closed session)*

The MSC Chairman introduced the document on late information and invited MSC to finish reviewing it. MSC agreed to take into account the annotated suggestions with some additional clarifications. MSC confirmed that the document lays out how to deal with information submitted to the MSC at a late stage, that is, after PfAs and Registrants' comments on them. MSC asked SECR to revise the document accordingly and make it available to MSC members' tacit agreement and thereafter share the finalised document as well with the stakeholders.

2. Update on appeals and court cases of relevance to MSC

SECR updated MSC on 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. MSC was further provided with a brief analysis on these BoA/Court decisions. MSC took note of the information received and further discussed the learnings from these decisions and the

interplay between ECHA and OECD. SECR clarified that, in its decisions, the BoA applies the EU Law and it is not directly bound by decisions issued by any international organisations that the EU is not part of and the BoA further concluded that ECHA decision did not, in any case, breach OECD rules.

3. INTERACT IT-project: update and call for pilot cases to test the collaboration module

SECR informed MSC on the progress with version one of the ECHA Interact Project, which is scheduled for release in April 2019. The scope covers two aspects: the Interact Portal which is foreseen as a single point of entry for all interactions with ECHA (with single sign in) and the first Interact component – a collaboration tool, facilitating the drafting of co-authored documents.

4. Introduction to the Metals and Inorganics Sectorial Approach (MISA) for dossier improvement and scientific and methodological development

SECR introduced to the MSC the Metals and Inorganics Sectorial Approach (MISA). Both the SECR and some members urged the MSC members to get involved and familiarise themselves with the model. SECR also informed MSC that the plan for MISA and the list of substances involved will be published on the ECHA website, and invited all members to take part to the workshop organised in February 2019, back-to-back with MSC-63.

5. Suggestions from members

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

Item 12 - Adoption of main conclusions and action points

Table with conclusions and action points from MSC-62 was adopted at the meeting.

The MSC Chairman extensively thanked the Danish member, leaving MSC after MSC-62, for his insights and many valuable contributions since MSC-4.

II. List of attendees

Members/Alternate members
AAVIK, Jaanika (EE)
ALMEIDA, Inês (PT)
ANDRIJEWSKI, Michal (PL)
ATTIAS, Leonello (IT)
COCKSHOTT, Amanda (UK)
DEIM, Szilvia (HU)
DIMITROVA, Rada (BG)
DOBRAK-VAN BERLO, Agnieszka (BE)
DUNAUSKIENE, Lina (LT)
ELLUL, Nathanael (MT)
FINDENEGG, Helene (DE)
FRANZ, Michel (FR)
HERMES, Joe (LU)
HORSKA, Alexandra (SK)
HUMAR-JURIC, Tatjana (SI)
JANTONE, Anta (LV)
KREKOVIĆ, Dubravka (HR)
KULHANKOVA, Pavlína(CZ)
LUNDBERGH, Ivar (SE)
MARTIN, Esther (ES)
MIHALCEA UDREA, Mariana (RO)
REIERSON, Linda (NO)
RISSANEN, Eeva (FI)
STESSEL, Helmut (AT)
TYLE, Henrik (DK)
WIJMENGA, Jan (NL)
Representatives of the Commission:
KOBE, Andrej (DG ENV)
Observers
ANNYS, Erwin (Cefic)
GRANGE, Emma (ECEAE)
KERÄNEN, Hannu (CONCAWE)
LOONEN, Helene (EEB)
MUSU, Tony (ETUC)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AHRENS, Birgit
ANASTASI, Audrey Anne
AJAO, Charmaine
BELL, David
BERCARU, Ofelia
BICHLMEIER, Ingo
BIGI, Elena
BOWMER, Tim
BROERE, William
BORNATOWICZ, Norbert
CALEY, Jane
CARLON, Claudio
CONSOLI, Elisa
DE WOLF, Watze
HALLING, Katrin
HAUTAMÄKI, Anne
HERBATSCHECK, Nicolas
HUUSKONEN, Hannele
JOHANSSON, Matti
KLOSLOVA, Zuzana
KORJUS, Pia
LE CURIEUX, Frank
MOSSINK, Jos
MUSSET, Christel
NYGREN, Jonas
NAUR, Liina
O'FARRELL, Norah
PELTOLA-THIES, Johanna
PELLIZZATO, Francesca
PREVEDOUROS, Konstantinos
ROBERTS, Julian
RÖNTY, Kaisu
SOSNOWSKI, Piotr
VAHTERISTO, Liisa
VASILEVA, Katya
WOLLENBERGER, Leah

Proxies
- ATTIAS, Leonello (IT) also acting as proxy of KOUTSODIMOU, Aglaia (EL)
- COCKSHOTT, Amanda (UK) also acting as proxy of CONWAY, Louise (IE)
- DIMITROVA, Rada (BG) also acting as proxy of PALEOMILITOU, Maria (CY)
- ATTIAS, Leonello (IT) also acting as proxy of MARTIN, Esther (ES) on 14 December from 14:30 onwards
- LUNDBERGH, Ivar (SE) also acting as proxy of ALMEIDA, Inês (PT) on 14 December from 15:00 onwards
- RISSANEN, Eeva (FI) also acting as proxy of COCKSHOTT, Amanda (UK) on 14 December afternoon
- STESSEL, Helmut (AT) also acting as proxy of HERMES, Joe on 14 December
- STESSEL, Helmut (AT) also acting as proxy of HUMAR-JURIC, Tatjana (SI) on 14 December from 14:00 onwards
- TYLE, Henrik (DK) also acting as proxy of DUNAUSKIENE, Lina (LT) during short periods

Experts and advisers to MSC members
ALIVERNINI, Silvia (IT) (expert to ATTIAS, Leonello)

BARTHELEMY-BERNERON, Johanna (FR) (expert to FRANZ, Michel)
CIESLA, Jacek (PL) (expert to ANDRIJEWSKI, Michal)
COPOIU, Oana (RO) (expert to MIHALCEA UDREA, Mariana)
DE KNECHT, Joop (NL) (expert to WIJMENGA, Jan)
EINOLA, Juha (FI) (adviser to RISSANEN, Eeva)
FILIPOVA, Hristina (BG) (expert to DIMITROVA, Rada)
HJORTH, Rune (DK) (expert to TYLE, Henrik)
JÖHNCKE, Ulrich (DE) (adviser to FINDENEGG, Helene)
KOZMIKOVA, Jana (CZ) (exert to KULHANKOVA, Pavina)
KUITTINEN, Marko (FI) (adviser to RISSANEN, Eeva)
KUROVA, Martina (SK) (expert to HORSKA, Alexandra)
LANDVIK, Nina (NO) (adviser to REIERSON, Linda)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBERGH, Ivar)
MÜHLEGGER, Simone (AT) (adviser to STESSEL, Helmut)
PEPPIN, Lindsay (UK) (adviser to COCKSHOTT, Amanda)
ROSENTHAL, Esther (DE) (expert to FINDENEGG, Helene)
SPURIENE, Otilija (LT) (expert to DUNAUSKIENE, Lina)
TARNOCZAI, Timea (HU) (expert to DEIM, Szilvia)
UHL, Maria (AT) (expert to STESSEL, Helmut)
VAN KESTEREN, Petra (NL) (adviser to WIJMENGA, Jan)
VERBRUGGEN, Eric (NL) (adviser to WIJMENGA, Jan)
VIERKE, Lena (DE) (adviser to FINDENEGG, Helene)

MSCA experts for SEv cases:
ARNING, Jürgen (DE)
BIL, Wieneke (NL)
DOYLE, Ian (UK)
HEESCHE-WAGNER, Kerstin (DE)
KINZL, Max (AT)

MSCA experts for SVHC cases:
BALLIAUW, Sharissa (BE)
BURGA, Karen (FR)
DROST, Wiebke (DE)
JOMINI, Stéphane (FR)

Advisers to the regular observers:
YADA, Makiko (adviser to Cefic observer)
REDMAN, Aron (adviser to CONCAWE observer)

Registered to the WEBEX-phone connection:
AVERBECK, Frauke (DE)
BAUMBUSCH, Angelika (NO)
BERTATO, Valentina (DG ENV)
CONWAY, Louise (IE)
COSGRAVE, Majella (IE)
DAHLBERG PERSSON, Marie (NO)
FERNÁNDEZ SÁNCHEZ, Raquel (ES)
GARCIA JOHN, Enrique (DG GROW)
GUDBRANDSEN, Marius (NO)
HAKKERT, Betty (NL)
HEGGELUND, Audun (NO)
HORNEK-GAUSTERER, Romana (AT)
HOY, Simon (UK)
KAARTINEN, Tomi (FI)
KOPANGEN, Marit (NO)
LEKATOS, Stylianos (DG GROW)
LOSERT, Annemarie (AT)
MENDONÇA, Elsa (PT)

MÜHLEGGER, Simone (AT)
PASQUIER, Elodie (FR)
PIÑEROS GARCET, Juan David (BE)
SCHULTZ, Thomas (DE)
SCHUTTE, Katrin (DG ENV)
STOCKER, Eva (AT)
STRECK, Georg (DG GROW)
VAN ELSACKER, Paul (BE)
ZENNER BOISEN, Anne Mette (DK)

Case owners:
Representatives of the Registrants were attending under the Agenda Item 6.2 for SEV-DE-011/2016, SEV-DE-012/2016 and SEV-DE-011/2017

Apologies:
CONWAY, Louise (IE)
KOUTSODIMOU, Aglaia (EL)
PALEOMILITOU, Maria (CY)
VANDERSTEEN, Kelly (BE)
WAGENER, Alex (LU)

MSC/A/062/2018

Agenda

62nd meeting of the Member State Committee

10-14 December 2018
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

10 December: starts at 9 am
14 December: ends at 4 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/062/2018
For adoption

Item 3 – Declaration of specific interests to items on the Agenda

Item 4 – Administrative issues

- Outlook for MSC-63

For information

Item 5 – Minutes of the MSC-61

- Final minutes of MSC-61

MSC/M/61/2018
For information

Item 6 – Substance evaluation

Closed session for 6.3

1. Written procedure report on seeking agreement on draft decisions on substance evaluation[2]

ECHA/MSC-62/2018/003
For information

[2] Please see the Appendix at the end to see the list of cases agreed in MSC written procedure in advance of the meeting.

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

ECHA/MSC-62/2018/004
For information

MSC code	Substance name	EC/List No.
SEV-AT-001/2015	6,6'-di-tert-butyl-4,4'-thiodi-m-cresol	202-525-2
		ECHA/MSC-62/2018/021-022
SEV-UK-022/2017	Triphenyl phosphate	204-112-2
		ECHA/MSC-62/2018/013-014
SEV-DE-011/2016	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate	218-407-9
		ECHA/MSC-62/2018/015-016
SEV-DE-012/2016	3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate	241-527-8
		ECHA/MSC-62/2018/017-018
SEV-DE-011/2017	Ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate	700-242-3
		ECHA/MSC-62/2018/019-020

For discussion

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

Cases as listed above under 6.2

For agreement

Item 7 – Dossier evaluation

Closed session for 7.3 & 7.4

1. Written procedure report on seeking agreement on draft decisions on dossier evaluation[1]

ECHA/MSC-62/2018/001
For information

2. 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-62/2018/002
For information

For discussion followed by agreement seeking under 7.3:

Compliance checks

MSC code	Substance name	EC No./Doc's
CCH-095/2018	3-aminopropyldiethylamine	203-236-4 / ECHA/MSC-62/2018/005-6

Testing proposal examinations

MSC code	Substance name	EC No./Doc's
TPE-076/2018	Bis(4-chlorophenyl) sulphone	201-247-9 / ECHA/MSC-62/2018/007-8
TPE-088/2018	Triethoxy(2,4,4-trimethylpentyl)silane	252-558-1 ECHA/MSC-62/2018/009-10

For discussion

3. 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 7.2

For agreement

4. General topics

Request of *in vivo* mutagenicity testing on germ cells under compliance check of Annex IX or X dossiers

(Closed session)
ECHA/MSC-62/2018/034
For discussion and agreement

Item 8 – SVHC identification - Seeking agreement on Annex XV proposals for identification of SVHC

Seeking agreement on Annex XV proposals for identification of SVHC

Substance name	EC Number	Documents[3]
Benzo[k]fluoranthene	205-916-6	ECHA/MSC-60/2018/024-025
Fluoranthene	205-912-4	ECHA/MSC-60/2018/026-027
Phenanthrene	201-581-5	ECHA/MSC-60/2018/028-029
Pyrene	204-927-3	ECHA/MSC-60/2018/030-031
Undecafluorohexanoic acid and its ammonium salt (PFHxA)	206-196-6, 244-479-6	ECHA/MSC-60/2018/032-033, ECHA/MSC-60/2018/035

For discussion and agreement

Item 9 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2019-2021)

- First discussion on the draft opinion

ECHA/MSC-62/2018/023
For discussion

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

1. Request from the Commission regarding inclusion of Art. 57(f) properties of DEHP, BBP, DBP and DIBP in Annex XIV

2. Brief report from the Rapporteur and Working Group

For information and discussion

Item 11 – Any other business

Partly closed session

1. How to deal with information submitted to the MSC not contained in the proposals for amendment submitted by MSCAs and Registrants' comments on them (final)

[3]RCOMs for the SVHC cases are available in MSC S-CIRCABC, 03 SVHC folder, in corresponding Substance-specific folders, apart from the updated RCOM (confidential or public version) for PFHxA which is provided as meeting document for information.

(C*losed session)*
For discussion and agreement

2. Update on appeals and court cases of relevance to MSC

(Partly closed session)
For information

3. INTERACT IT-project: update and call for pilot cases to test the collaboration module

For discussion

4. Introduction to the Metals and Inorganics Sectorial Approach (MISA) for dossier improvement and scientific and methodological development

For information

5. Suggestions from members

For information

Item 12 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-62

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

1) Status report on on-going substance evaluation work (presentation slides)
2) Status report on on-going dossier evaluation work (presentation slides)

APPENDIX to the MSC-62 agenda:

List of evaluation cases agreed by MSC in written procedure in advance of the MSC-62 meeting:

Substance evaluation

SEV-2-FR-012/2013	1,4,5,6,7,7-hexachloro-8,9,10-trinorborn-5-ene-2,3-dicarboxylic anhydride	(EC No. 204-077-3)
SEV-FR-019/2015	Methyl salicylate	(EC No. 204-317-7)
SEV-SE-021/2017	Dicyclohexyl phthalate	(EC No. 201-545-9)

Dossier evaluation

Compliance checks

CCH-089/2018	3,5,5-trimethylcyclohex-2-enone	(EC No. 201-126-0)
CCH-101/2018	Dierbium trioxide	(EC No. 235-045-7)
CCH-108/2018	3-methoxybutyl acetate	(EC No. 224-644-9)
CCH-116/2018	N-acetylsulphanilyl chloride	(EC No. 204-485-1)
CCH-117/2018	Methyl 5-nitrohydrogen isophthalate	(EC No. 217-793-6)

Testing proposal examinations

TPE-098/2018	Everzol Red CDN Crude	(EC No. 483-940-8)

Main conclusions and action points
MSC-62, 10-14 December 2018
(adopted at MSC-62)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues	
	MSC-S to update the written procedure voting sheets to more clearly distinguish between comments and justifications requested to be included in a written procedure report.
Item 6 – Substance evaluation 1. Written procedure report on seeking agreement on draft decisions on substance evaluation	
MSC took note of the report.	MSC to consider the decisions uploaded on MSC S-CIRCABC for the written procedure as agreed ones.
3. Seeking agreement on draft decisions when amendments were proposed by MS-CA's/ECHA	
MSC reached unanimous agreement on the following ECHA draft decision (as modified in the meeting): SEV-AT-001/2015 6,6'-di-tert-butyl-4,4'-thiodi-m-cresol (EC Nr. 202-525-2) SEV-UK-022/2017 Triphenyl phosphate (EC Nr. 204-112-2) SEV-DE-011/2016 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate (EC Nr. 218-407-9) SEV-DE-012/2016 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate (EC Nr. 241-527-8) SEV-DE-011/2017 Ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate (EC Nr. 700-242-3)	MSC-S to upload on MSC S-CIRCABC the agreed decisions in the respective case folder.
Item 7 – Dossier evaluation 1. 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. MSC-S to upload a revised written procedure report including the justification for abstention for one case by a member.
3. 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): Compliance checks (CCH) CCH-095/2018 3-aminopropyldiethylamine (EC Nr. 203-236-4)	MSC-S to upload on MSC S-CIRCABC the agreed decisions in the respective case folders.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
<u>Testing proposal examinations (TPE)</u> TPE-076/2018 Bis(4-chlorophenyl) sulphone (EC Nr. 201-247-9) TPE-088/2018 Triethoxy(2,4,4-trimethylpentyl)silane (EC Nr. 252-558-1)	
4. General topics Request of *in vivo* mutagenicity testing on germ cells under compliance check of Annex IX or X dossiers	
MSC supported the ECHA Secretariat's (SECR) proposal to request an appropriate germ cell genotoxicity test in case of positive result in an *in vivo* somatic cell genotoxicity study.	MSC agreed to request SECR to prepare, in consultation with appropriate experts, both scientific background for such a proposal and, based on the main scenarios in regards to the available mutagenicity information in a registration dossier, for practical implementation; and to present the status of this work in the next MSC-63 meeting, with aim to have a document on this matter for MSC-64 for discussion; and look at the reapplication of regulatory strategy also to testing proposals.
Item 8 – SVHC identification • Seeking agreement on Annex XV proposals for identification of SVHC	
MSC unanimously agreed to identify the following substances as SVHCs (and unanimously agreed on their respective DA and SD): • Benzo[k]fluoranthene (EC No. 205-916-6) • Fluoranthene (EC No. 205-912-4) • Phenanthrene (EC No. 201-581-5) • Pyrene (EC No. 204-927-3) MSC considered the Annex XV proposal for SVHC identification of • Undecafluorohexanoic acid and its ammonium salt (PFHxA) (EC No. 206-196-6, 244-479-6). Following the plenary deliberations and views exchanged, the dossier submitter informed MSC of its decision to withdraw the above-mentioned SVHC proposal from this MSC agreement seeking process.	MSC-S to upload the MSC agreements, as well as the support documents and RCOMs, on MSC S-CIRCABC and to publish them on the ECHA website. SECR to add the newly identified SVHCs to the Candidate List (update foreseen in January 2019). MSC members who made statements regarding PFHxA proposal and requested for their attachment to the minutes to provide these statements in writing to MSC-S by 18 December 2018.
Item 9 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2019-2021) • First discussion on the draft opinion	
MSC took note of the first draft opinion prepared by the Rapporteur and the WG, and provided some initial feedback on it.	MSC members to provide any comments on the draft opinion to the Rapporteur by 17 January 2019.
Item 10 – ECHA's recommendations of priority substances to be included in Annex XIV and opinion of MSC 1. Request from the Commission regarding inclusion of Art. 57(f) properties of DEHP, BBP, DBP and DIBP in Annex XIV	
MSC took note of the request and the need for an MSC opinion.	MSC-S to launch a call for volunteers to act as a Rapporteur for the draft recommendation for an amendment of Annex XIV. MSC members to indicate an interest in the rapporteurship to the Secretariat by 15 January 2019.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 11 – Any other business	
1) How to deal with information submitted to the MSC not contained in the proposals for amendment submitted by MSCAs and Registrants' comments on them (final) 2) Introduction to the Metals and Inorganics Sectorial Approach (MISA) for dossier improvement and scientific and methodological development	1) MSC-S to revise the document based on comments made and to upload to MSC S-CIRCABC for MSC members' tacit agreement by 15 January 2019. MSC-S to thereafter share the document as an MSC-information document for MSC-63 and include stakeholders. 2) SECR to distribute agenda of MISA workshop in February 2019 to MSC. MSC to indicate interested in joining the workshop and contributing to contact classification@echa.europa.eu.
Item 12 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-62 at the meeting.	MSC-S to upload the main conclusions and action points on MSC S-CIRCABC by 17 December 2018.

V. The following participants declared a specific interest with the indicated agenda items (according to Art 9 (2) of MSC RoPs)

AP / Dossier	MSC Chairman	Reason for specific interest / mitigating measures
AP 6 2&3: SEV-DE-011/2017	Watze de Wolf	Annual declaration as published on the ECHA website. No participation in any of the MSC preparatory activities, chairing the case nor supporting the preparation of the minutes.

VI Statements as regards agenda item 8 SVHC identification - Seeking agreement on Annex XV proposals for SVHC identification

I. Statement of MSC member from DE regarding the withdrawal of the Annex XV proposal for SVHC identification of Undecafluorohexanoic acid (PFHxA) and its ammonium salt

The German CA sees an urgent need for risk management for PFHxA, because of all the concerns of PFHxA (as outlined in the SVHC dossier) and the fact that humans and the environment are already exposed to PFHxA as shown by monitoring data.

We appreciate very much the large support for our proposal. This also demonstrates the need for regulatory action on this substance.

Following the diverging views of very few members, unanimous agreement is not likely. Therefore, we are withdrawing this proposal now.

The reason for this withdrawal is that we see an undesirable delay in risk management if this case will be send to the Commission.

Our preferred way would have been to have the SVHC identification first, followed by restriction. But as there is no formal need for an SVHC identification before a restriction, we will now move on with discussing the preparations for a restriction proposal for PFHxA, its salts and related substances.

In our view the discussions here in MSC and the large support for our proposal were very helpful not only for this case but also for potential future cases – thank you all very much for this fruitful discussion.

II. Statement of MSC members from AT, BE, BG, CY, DK, EE, HR, FR, IT, LT, LU, NL, NO, PL, PT, RO, SE regarding the SVHC identification of Undecafluorohexanoic acid (PFHxA) and its ammonium salt as substances of Equivalent level of concern having probable serious effects to human health and the environment under article 57(f) of the REACH regulation

The members of the MSC for the Member States listed in alphabetical order below would like to state our support for the identification of Undecafluorohexanoic acid (PFHxA) and its ammonium salt as substances of very high concern based on REACH article 57 (f), although this proposal has been withdrawn.

Austria, Belgium, Bulgaria, Croatia, Cyprus, Denmark, Estonia, France, Italy, Latvia, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Sweden

III. Statement of MSC members from FI and UK regarding the SVHC identification of PFHxA

We agree with the dossier submitter that there is a concern for PFHxA. As stated before our position could have been different on this identification if there would have been possibility to evaluate the toxicity data robustly (the UK opinion is that this should be done by RAC) and fulfilment of Repr. 2 criteria would have been stated in the documents. This is one of the reasons why we suggested a timeout for this dossier and it is unfortunate that this withdrawal may mean that the proposal will not be submitted again for MSC approval.

Since this dossier has now been withdrawn there will not be discussion and possible agreement in REACH committee. While that would have not been an ideal way of establishing policy agreement on this type of ELoC, it could have benefited SVHC identification of substances with similar properties to PFHxA. However, we understand that the dossier submitter´s reason for not taking agreement seeking to the REACH committee was the possible delay in risk management. Instead they will now prepare a Restriction dossier for the substance. We look forward to discussions on this proposal.

We thank the dossier submitter and the MSC for the discussions during MSC-62. We also thank the Commission for their statement on the REACH review action point regarding ELoC and we believe that the planned work on this issue will be essential for future work on SVHC identification.