MSC/M/65/2019
Adopted in written procedure
23 September 2019

Final Minutes

of the 65th Meeting of the Member State Committee (MSC-65)

24-27 June 2019

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 65th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes). The Chairman reminded MSC that the MSC meetings are no longer recorded.

Item 2 - Adoption of the Agenda

As regards the agenda, based on requests from members the Chairman suggested including two any other business-items about an update on the document sent to CARACAL from Germany and an update on the forthcoming Dutch workshop on EORGTS. The latter topics were suggested for a closed session due to their potential regulatory impact. The Agenda was adopted with these modifications (final Agenda is attached to these minutes as Section III).

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

The Chairman declared a potential conflict of interest in respect to the agreement seeking by MSC on identification of 2,3,3,3-tetrafluoro 2(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof) (i.e. HFPO-DA) as a substance of very high concern (SVHC) (agenda item 8.2) and therefore considered not to be in a position to chair this case. The ECHA Executive Director appointed Charmaine AJAO as the MSC Chair to replace him for the full agreement seeking process with MSC involvement, and Tim BOWMER as co-chair for the MSC plenary meeting discussions at MSC-65. No other potential conflicts of interests were declared by any other members, experts or advisers with any other item on the agenda of MSC-65.

Item 4 - Administrative issues

The Chairman remarked that the MSC meetings are no longer recorded. MSC supported the SECR's proposal to extend the minutes drafting period by 2nd week of August 2019 due to the ongoing summer holiday period. A member requested for extended timing of the minute commenting. The Chairman invited MSC to review and, where appropriate, to submit comments on the draft minutes preferably by 21 August or at the latest by 30 August 2019.

- *Outlook for MSC-66*

The Chairman presented an outlook on the potential length of the next meeting which at maximum could require 5 plenary days. The Chairman also presented an early stage estimation for the length of the MSC-67 meeting in December 2019.

Item 5 – Minutes of the MSC-64 meeting

The minutes of MSC-64 were adopted as modified at the meeting.

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 29 May 2019. By the closing date 10 June 2019, MSC reached unanimous agreement on two draft decisions (DD). For the third DD, based on a request from a MSC member, the MSC Chairman terminated the WP.

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

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

SEV-BE-001/2017 2,4-di-tert-butylphenol EC No. 202-532-0

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

The MSC member explained that in their view, based on the weak ED effects observed for this substance, there was not a good case to perform an endocrine disruption (ED) test (OECD TG 234) placed at the level 4 of the OECD Conceptual Framework for Testing and Assessment of Endocrine Disrupting Chemicals. In their view, in such a case, one should perform a level 3 test (OECD TG 229) and stop at a negative result from such a test. They also queried the quality of some of the data used to make the case for the ED concern, as these were tests on mixtures and so not specific to the substance. The eMSCA maintained the view that OECD TG 234 is still the test to request for this case. Based on the concern identified there is a need to generate *in vivo* information to investigate if the substance has the potential to elicit adverse effects. OECD TG 234 provides higher power to detect those effects and has a longer exposure period, while the OECD TG 229 may not present exposure during the most sensitive window. Furthermore, it was argued that since for this case the mammalian dataset showed some indications of ED effects, it was similar to scenario J described in the OECD "Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption" (OECD GD 150). In this scenario (existing positive *in vitro* and positive *in vivo* results), a negative OECD TG 229 would not be conclusive, and follow up testing with OECD TG 234 is suggested. Furthermore, the Registrants expressed in their written comments, support to performing OECD TG 234.

MSC supported this reasoning. The DD was modified slightly to further clarify the advantage of conducting OECD TG 234 as compared to OECD TG 229.

MSC unanimously agreed with the DD as amended at the meeting with an abstention from the UK member.

4. General topics

None

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 twelve dossier evaluation cases (see Section III Final agenda "Appendix to the MSC-65 agenda" for more detailed identification of the cases). WP was launched on 29 May 2019. By the closing date 10 June 2019, MSC reached unanimous agreement on all DDs. One member abstained from voting on ten cases. SECR further informed MSC that in line with some comments made by a MSC member SECR had made an editorial change for internal alignment of the DD text on one case. SECR informed that in future it will continue implementing such editorials without further notice.

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-015/2019 Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine derivs. Residues (EC No. 272-712-1)

Session 1 (open)

Two representatives 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 (PfA) that required discussion in the meeting. It noted that this case comprised the same substance for which the first compliance check DD was agreed on at the MSC-51 meeting; after the assessment of the results from the sub-chronic toxicity (90-day) study ECHA had submitted a new DD requesting the extended one-generation reproductive toxicity study (EOGRTS), suggesting a basic design.

The first PfA suggested requesting cohorts 2A and 2B (developmental neurotoxicity, DNT), based on evidence from two constituents of the registered substance (UVCB) showing neurological effects, and endocrine activity of one constituent based on *in vitro*-based mechanisms/modes of action information and information from fish studies as well as based on the behavioural assessment in the newly provided 90-day repeated dose toxicity (RDT) study, and a concern for endocrine activity for the second constituent. The second PfA suggested requesting cohort 3 (developmental immunotoxicity, DIT), based on sensitising properties of the substance, one of the constituents showing *in vivo* and *in vitro* effects on the immune system, and that two constituents of the registered substance showed endocrine activity in fish studies and in *in vitro* based mechanisms/modes of action information.

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

The representatives of the Registrant reconfirmed their unaltered position on retaining the basic study design, because of lacking evidence from available studies on immunological and neurological effects or skin sensitisation for the substance as registered. In particular, they confirmed that in line with the robust study summary (of the 90-day study) the liver and kidney weights varied but no impacts in any other organs were detected in the standard set of measurements. Also, the representatives of the Registrant deemed the 20% reduced activity observed in the 90-day study to be insignificant when taking into account the high variability of the parameter and the lack of any other significant effects in the study.

The MSC first discussed the DIT cohort. The representatives of the Registrant stated that the observed skin sensitisation was reported for another, although similar, substance with a higher amount of diethylene glycol. It was noted that the boundary conditions for the substance in the Registrant's dossier allow quite high concentrations of diethylene glycol. Furthermore, the MSC considered that there were contradictory results in the available evidence base, and as a whole the evidence indicating that the registered substance would be anti-estrogenic and anti-androgenic was weak.

The MSC then discussed the DNT cohort. It noted information about the constituents of the registered substance indicated a possible concern on developmental neurotoxic effects; however, the newly available 90-day study on the registered substance had not provided supporting evidence to this end. Also, the MSC noted that many effects had been observed at high dose levels in a short acute exposure. The MSC took note of the issue that in the 90-day study there had been some observed effects on reduced animal activity that had affected only the male but not the female rats, and that this parameter was deemed to have high variability in general.

Session 2 (closed)

The MSC noted that the behavioural effects in the newly available 90-day study did not show a dose response relationship. Also, it concluded that effects related to endocrine disruption had been absent in available *in vivo* studies. MSC could support SECR to not include the DNT and DIT cohorts, but considered that this case does not set a precedent for not using *in vitro* data to trigger the inclusion of the cohorts or that suggestions of interference with the sex hormonal system observed in fish cannot be used as triggers for a request for additional cohorts in cases where there is a stronger evidence base.

Based on the discussion, the Chairman concluded that the basic study design of EOGRTS would not be changed to include DIT or DNT cohorts.

MSC agreed unanimously to the DD as provided for the meeting. One MSC member abstained from voting.

4. General topics

1) Request of *in vivo* mutagenicity testing on germ cells under compliance check of Annex IX or X dossiers - Implementation proposal *(Closed session*)

ECHA Secretariat (SECR) presented the background document on scientific and regulatory aspects of mutagenicity testing as well as practical implementation options. The MSC took note of the information and reconfirmed its earlier suggestion to continue providing Registrants the choice between the test guidelines (TG) for comet (OECD TG 489) and TGR (OECD TG 488) studies for addressing somatic cell mutagenicity concerns.

The MSC noted, on the one hand, the advantages of a possible one decision approach, covering all legal requirements and options from collecting both somatic and germ cells to analysing them (depending on the results from the first test). Also, such approach could expedite receiving conclusive results on the substance and maximise the use of animals. On the other hand, a two decision approach should be (a) less complex to prepare; (b) operate on stepwise refined requirements; (c) last up to half a year longer due to an interim follow up assessment period before possible launch of second decision; and (d) be used for only a relatively small number of cases.

The MSC took note of the ongoing update of the OECD TG 488 (TGR) and the current discussions on the collection schedule to analyse germ cells.

The MSC concluded to follow the two decision approach, which shall be implemented as of the MSC-66 round. The first decision, with a request for an *in vivo* somatic cell study, would recommend, instead of require, the collection and analysis of gonadal or germ cells. The MSC additionally suggested to add a short note in the first decision to indicate that if (a) the outcome of the *in vivo* somatic cell study is positive and (b) no clear conclusion about germ cell mutagenicity can be made, a subsequent germ cell testing (study for either the TGR or chromosomal aberration (CA) on spermatogonia) may still be required under REACH Annex IX/X.

The MSC expected that SECR would also inform Registrants, through appropriate channels, on the new approach.

The MSC assessed the required timelines in case Registrants would follow up on the recommendation. It deemed that no additional time (considering the standard timelines provided in the decisions) would be needed to perform additional analyses for collected gonadal or germ cells.

The MSC discussed additional practical aspects on the links with the opinion forming of the Risk Assessment Committee (RAC). It assumed that positive results in gonadal or germ cell testing could establish a sufficient basis for classification as germ cell mutagen category 1B.

Finally, the MSC noted that it may review its approach once there is clarity on the amendment of OECD TG 488 (TGR) by OECD. The default sampling times of the somatic and germ cells might be increased from 3 to 28 days, thus increasing test sensitivity and a (more) definitive conclusion in case of negative germ cell results.

2) Feedback from ED EG on issues raised by MSC in relation to the use of OECD TG 234 in Dossier Evaluation

SECR introduced to MSC the input of the ECHA's Endocrine Disruptor Expert group (ED EG) on issues raised by MSC at MSC-57 during ED-related DEv and SEv case-specific discussions in 2017-2018. The EG had been requested to give an advice on the concentration range setting in the OECD TG 234 and on the type of specific ED data that would trigger an OECD TG 234 to be requested under DEv. SECR noted that the current ECHA's policy regarding the use of OECD TG234 in DEv may be revised in future based on further developments such as the expected BoA decision on an ongoing appeal on a CCH case where an FSDT had been requested.

MSC was also reminded of the agreed policy to be followed in the relevant DEv cases: if data gap for long term fish toxicity is identified (under Annex IX, section 9.1.6.1), the most relevant test method OECD TG 210 is chosen as the default or OECD TG 234 when ED concern is also identified.

The concentration range setting in the OECD TG 234 had been discussed and agreed before in the context of several MSC discussions on substance evaluation cases, whereas for the data required to trigger the OECD TG 234 no clear criteria emerged from the ED EG discussions. Hence, MSC would still require case-by-case discussions for such dossier evaluation decisions.

In conclusion, the MSC Chairman thanked the SECR for the update provided and the ED EG for the recommendations.

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

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

SECR gave a brief report on the outcome of the written procedure for SVHC agreement seeking on the identification of one substance[1], proposed to be identified as a SVHC based on Article 57 of Regulation (EC) 1907/2006, due to its endocrine disrupting properties for the environment (see Appendix to the final agenda in Section III for more detailed identification of the substance).

MSC agreed unanimously on the identification of TNPP as an SVHC in the written procedure launched on 29 May 2019 and closed on 10 June 2019. SECR explained that the final documents have been published on the ECHA website and in MSC S-CIRCABC and this substance will be included in the Candidate List of SVHCs in July 2019.

2. Seeking agreement on Annex XV proposals for identification of SVHC substances

- **2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)**

The dossier submitter representatives (DS) from the Dutch CA presented to MSC the Annex XV proposal for identification of *2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)*, referred further as HFPO-DA, as SVHCs under Article 57 (f) of REACH due to a combination of concerns caused by the properties of HFPO-DA for which there is scientific evidence of probable serious effects to human health (HH) 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 underlined that the current SVHC proposal is based on different elements, none of which may be of ELoC in isolation, but in combination, they demonstrate that there is scientific evidence of probable serious effects of these substances to human health and the environment, jointly constituting ELoC to those CMR and PBT/vPvB substances which are identified as SVHC on the basis of points (a) to (e) in Article 57.

The DS presented as well a brief overview of the comments received in the public consultation on this Annex XV proposal and of the responses provided in the Response-to-comments document (RCOM) and the modifications made in this regard in the Support document (SD).

The adviser to the Cefic observer brought some further clarification on their comments submitted in the public consultation, in particular challenging the arguments for irreversible and increasing presence of HFPO-DA in the environment. He claimed that

[1] Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)

these substances are used by a single registrant within the EU and referred to the Registrant's commitment to limit the HFPO-DA emissions and reduce their environmental occurrence. In response, DS referred to recent monitoring data showing an increasing presence of these substances in water even far away from the source that do not support these claims and maintained their concern regarding emissions of HFPO-DA.

The MSC observer from EEB[2] also expressed a particular concern for these substances, noting that such small amounts (based on only one registration) for a short period of usage (since 2012) have led to really wide distribution in the environment.

In the following discussion, the Committee's members, their advisers and observers also exchanged views concerning severity of the observed adverse effects on HH and the environment and the characterisation of these effects, threshold effects from continuous/chronic exposure in the light of life-long studies, difficulty to derive safe level values (i.e. DNELs, PNECs) when most of the effects have thresholds.

With regard to the observed uncertain adverse effects in humans, the adviser to the Cefic observer referred to a study published a few days prior to the plenary, pointing out that most of these effects are irrelevant for humans (due to PPAR-α pathway). In response, the DS underlined that biological plausibility of the PPAR-α induction as a relevant mechanism underlying human carcinogenicity is still under review. DS explained that necrosis (evidence of relevance for human health) was observed in almost all repeated dose studies in rodents for liver hence attributing all the observed effects to PPAR-α mode of action only cannot be concluded with the current data. Moreover, from the side of pharmaceutics, there is information on PPAR-alpha mediated treatment suggesting that PPAR-alpha active substances may in fact impact human health. Furthermore there could be interspecies differences.

While one member suggested awaiting for the further studies requested already under SEv to reduce the uncertainty of the reported effects before concluding on this substance identification as an SVHC, several other members, observers and the DS disagreed and expressed the view that the currently available information, as provided in the SVHC proposal is sufficient to conclude on these substances' identification under Article 57 (f). Furthermore, the DS considered it would be disproportionate to request for more data when sufficient information supporting this concern already exist. Some suggestions for better addressing these concerns in the WoE were implemented in the agreement seeking documentation.

The Committee also compared the concerns from HFPO-DA with the concerns of PBT/vPvB based on the REACH Annex XIII criteria. Majority of the MSC supported the DS's argumentation regarding the difficulty to derive DNELs and PNECs, pointing out that the standard toxicity testing setting may not allow drawing a clear conclusion on these substances' toxicity.

As regards the need for harmonised classification and labelling of a substance subject to an SVHC proposal, several MSC members noted that SVHC identification following Article 57(f) is a case-by-case decision which allows MSC to continue identifying SVHCs with ELoC regardless of the existence or potential consideration of CLH.

Further views were exchanged regarding some other concerns for HFPO-DA, such as potential co-exposure with other contaminants with similar effects in the environment and in humans, concern for wildlife from secondary poisoning (in addition to the concern for unknown direct toxicity), difficulties to quantify with sufficient certainty the exposure and related risks, as well as societal concern. Regarding co-exposure, majority of the MSC supported the DS's conclusions and decided to reflect the concern on co-exposure as additional information, supporting the main ELoC considerations in the agreement seeking documentation.

Assessment of secondary poisoning due to accumulation of HFPO-DA in terrestrial plants had been added by the DS in the draft support document based on comments received in

[2] Representing a rotation group of seven MSC regular observers from ENV & HH NGOs (ChemSec, Client Earth, EEB, Greenpeace, HEAL, Health Care without harm Europe and Women in Europe for Common Future)

the public consultation. The DS provided further clarification on the available data explaining that secondary poisoning is not only a concern to herbivores but also to fish eating wildlife.

Regarding the difficulty to quantify with sufficient certainty the exposure and related risks, most MSC members supported the DS's conclusions that there are no such exposure tools available which would, with acceptable reliability, predict exposures which would occur after decades of release and distribution of the substance because of its high persistence and difficulty to remove from the environment.

MSC also exchanged views on high societal concerns, noting the Cefic adviser's remark on some technologies being used in USA for removal of HFPO-DA and DS's response about their high costs to apply over large scale and absence of proper controlling methodologies this point in time. SECR reminded that the MSC decision on this proposal should be based on the currently available information about decontamination and removal techniques, as provided in the dossier and in the public consultation.

MSC thoroughly considered the comments received in the public and MSCAs' consultations, the way the new data had been assessed, addressed in the SD and/or responded in the RCOM by DS in a WoE approach, taking into consideration the further remarks made by the adviser to the MSC observer from Cefic. On that basis, some additional changes were made in the SD to further clarify and strengthen the argumentation provided in the ELoC assessment and in the overall conclusions.

MSC supported the DSs' conclusions on the elements of concern arising from the properties of HFPO-DA based on the application of a WoE approach by taking into account all available relevant information and the MSC conclusions made in the context of the previously identified SVHCs under Article 57 (f).

Consequently, MSC unanimously agreed to the SD and respective agreement, as modified at the meeting, and thus identified HFPO-DA as SVHCs in accordance with Article 57(f) of the REACH Regulation. Three MSC members abstained from voting and two of them (from FI and UK) made statements regarding this SVHC identification and some more generic aspects. Both statements are attached to the minutes (see Section V).

The MSC Chair thanked the DS and the Committee for the successful discussion and outcome on this SVHC proposal.

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

1. 9th Draft recommendation for inclusion of substances into Annex XIV

- Update from SECR
- MSC opinion on ECHA's Draft 9th recommendation of priority substances to be included in Annex XIV
    - Discussion on the draft MSC opinion
    - Adoption of MSC opinion

SECR provided to MSC an update of the progress made since the May meeting and further clarified specific topics that were discussed then. Subsequently, the Rapporteur presented the draft opinion and its support document highlighting main changes since the previous draft taking into account the feedback received from MSC. MSC first discussed the text of the support document of its opinion on ECHA's 9th draft recommendation for inclusion of priority substances in Annex XIV. MSC supported recommending all 18 substances that were subject of the public consultation for inclusion in Annex XIV as well as the transitional arrangements suggested. The discussion mainly focused on possible exemptions for certain uses of substances according to Article 58(2), and on the open issues for which the Rapporteur suggested solutions on the exact wordings. MSC discussed the impact of the upcoming restriction for lead stabilisers in PVC but considered it cannot be taken into account at this stage for priority setting, nor as basis for recommending exemptions. In relation to Article 58(2) exemptions, MSC noted that ECHA intends to invite COM to assess

whether the conditions for an exemption of the uses of lead stabilisers in PVC, of tetraethyllead in aviation fuel and of DOTE and reaction mass of DOTE and MOTE in immediate packaging of pharmaceuticals, in line with those granted for DEHP, BBP and DBP for a similar use, may be met. With respect to the latter, MSC considered that such an assessment should take into account MSC's opinion on ECHA's draft amendment recommendation. An observer reminded MSC about the importance of assessing which uses are considered intermediate uses by referring also to the comments in the public consultation. He also expressed his confusion that neither ECHA nor MSC considered it appropriate to pursue assessing equivalent level of concern for Art. 57(f) substances also at this stage. Another observer welcomed the MSC opinion as a well-elaborated document.

MSC adopted the opinion as amended at the meeting and the Chairman closed the item by thanking the Rapporteur and the Working Group for their work. As regards next steps SECR mentioned that the 9th recommendation of priority substances will be finalised and sent to the Commission in September.

2. Draft recommendation to amend entries of DEHP, BBP, DBP, and DIBP in Annex XIV

- Update from SECR
- MSC opinion on ECHA's Draft recommendation to amend entries of DEHP, BBP, DBP, and DIBP in Annex XIV
    - Discussion on the draft MSC opinion
    - Adoption of MSC opinion

MSC discussed ECHA's draft recommendation for amending entries in Annex XIV based on the presentation of the draft opinion by the MSC Rapporteur. He drew attention of MSC to the updates in the text since the previous discussion. MSC supported the opinion on the draft recommendation to amend the entries of four phthalates in Annex XIV as prepared by the rapporteurs. The continuation of the exemption for DBP and BBP in the immediate packaging of medicinal products was one of the main discussion points by MSC at the meeting. Another topic which was briefly discussed was the request from public consultation to exempt the use of DEHP in blood bags as well as the use of DEHP in EEE (electrical or electronic equipment) under RoHS. MSC was of the opinion that no information was submitted which would form the basis for inclusion of a further specific exemption. MSC adopted the opinion as amended at the meeting and the Chairman closed the item by thanking the Rapporteur and Co-Rapporteur for their work in drafting the opinion. As regards next steps SECR mentioned that the recommendation will be finalised and sent to the Commission shortly.

Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2020-2022)

Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update

- **Draft terms of Reference and possible appointment of the Rapporteur and Co-Rapporteur**

MSC adopted the mandate and the tasks of the rapporteur, and appointed one member as the Rapporteur and another member as the Co-Rapporteur for drafting the opinion of the MSC on the draft CoRAP 2020-2022 update. MSC mandated the Rapporteur to decide on the size of the working group later in the year, depending on the number of substances on the draft CoRAP update. MSC agreed that a written procedure could be used for establishing a Working Group to support the Rapporteur, in advance of the October plenary.

Item 11 – Any other business

1. **Update on appeals and court cases of relevance to MSC (*Closed session)***

SECR updated MSC on the ongoing appeal and Court cases of relevance to the MSC work.

2. ECHA's approach to grouping of substances

SECR gave a presentation focussing on ECHA's approach to grouping of substances. The aim of the presentation was to explain to MSC the so-called chemical universe and what methods ECHA uses to group substances in order to address all substances registered in the EU. SECR provided an overview of the main pools of substances, highlighting the uncertain area which includes the higher amount of substances not yet considered under the regulatory processes. Grouping is done firstly using supporting tools and secondly following two methods: read-across and structural similarity. SECR provided the foreseen status of the chemical universe mapping in 2020: the aim is to allocate all substances placed in the uncertain area to one of the other pools of substances.

3. MSC and the development of OECD test guidelines

SECR presented how ECHA, Commission (incl. the Joint Research Centre (JRC)) and National Coordinators work with OECD's test guidelines (TG), and also the principles of TG development from project proposals until the stage where a new TG could be requested in ECHA's decisions. It drew attention to the 18-month transition period when both the old and updated TG can be used. SECR took note of MSC as a unique body having an insight in regulatory use of TGs and in the relevance of results, whereby it can identify deficiencies and suggest improvements through their National Coordinator contacts or the Parere network of JRC.

The MSC welcomed the information provided and highlighted the importance of alternative methods, the speed of implementing revisions, and assessment mechanisms to further develop TGs. SECR clarified that the timeline for TG updates, which are a couple annually, starting from a project proposal to final adoption by the Joint Meeting could amount to about two and a half years, and that for new TGs there would be no consequent transition period. In addition to experts from Member States, company scientists are also participating the OECD expert group work. SECR also informed that Member States, or relevant bodies such as the MSC, are relied on to follow the usefulness and scientific status of TGs and, when needed, to submit project proposals for improvement.

The MSC finally emphasized that its members could be linked with National Coordinators for identifying improvements and amendments to existing TGs.

4. Use and exposure information in regulatory risk management *(Closed session)*

SECR gave an overview on the use and exposure information in regulatory risk management, partly based on a CARACAL document. The quality of the use and exposure information submitted in technical dossiers, for which the industry has the responsibility, has raised concerns on the safe use of substances and may hamper the certainty, enforceability or effectiveness of regulatory work. SECR noted that the required level of detail and related uncertainty may vary depending on the case and the consequent regulatory step. It also informed that one remedial action may be an enhanced completeness check for elements of the Registrant's Chemical Safety Report (CSR) and that the REACH Exposure Expert Group (REEG) may be asked to clarify the necessary level and type of information required and also suggest the best regulatory tools for obtaining it. In particular, related to assessments within the substance evaluation, SECR encouraged the evaluating Member State Competent Authorities (eMSCA) to make early contact with ECHA in case of doubts about use and exposure information, e.g. when considering EU-wide risk management measures.

The MSC welcomed the presentation and noted that several Member States had submitted comments to the CARACAL document. SECR noted that all comments will be analysed and have an impact on further discourse. It further highlighted the need to assess which information is necessary for regulatory work and which tools could support the work. Finally, SECR welcomed experts from all Member States to support the work in REEG.

5. **Suggestions from members**

1) EOGRTS Workshop update

The Chairman of the Organising Committee of the Dutch EOGRTS Workshop informed MSC that he had circulated the invitations and the programme of the Workshop which is to take place on 8-9 October 2019 at ECHA premises. The programme includes several discussions on the association of sex steroid hormonal activity with developmental neurotoxicity (DNT) and developmental immunotoxicity (DIT) and several presentations on design of cohorts studies, in order to facilitate a discussion about what kind of evidence can be used to trigger requests for cohorts. Furthermore, the aforementioned Chairman invited MSC to indicate by the first week of September which experts will attend the Workshop at ECHA premises. He proposed to follow up with a discussion in MSC reporting back the outcome of the Workshop.

2) Notification about ongoing consultation in CARACAL *(Closed session)*

The DE member informed MSC about an ongoing consultation on a recently distributed CARACAL document of relevance for the SVHC identification of substances with persistent, mobile and toxic or very persistent and very mobile properties.

Item 12 - Adoption of main conclusions and action points

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

II. List of attendees

Members/Alternate members
AAVIK, Jaanika (EE)
ALMEIDA, Inês (PT)
ANDRIJEWSKI, Michal (PL)
ATTIAS, Leonello (IT)
COCKSHOTT, Amanda (UK)
CONWAY, Louise (IE)
COPOIU, Oana (RO)
DE KNECHT, Joop (NL)
DEIM, Szilvia (HU)
DUNAUSKIENE, Lina (LT)
ELLUL, Nathanael (MT)
FERNANDEZ SANCHEZ, Raquel (ES)
FILIPOVA, Hristina (BG)
FINDENEGG, Helene (DE)
FRANZ, Michel (FR)
HERMES, Joe (LU)
HJORTH, Rune (DK)
HORSKA, Alexandra (SK)
HUMAR-JURIC, Tatjana (SI)
KREKOVIĆ, Dubravka (HR)
KULHANKOVA, Pavlína (CZ)
LUNDBERGH, Ivar (SE)
REIERSON, Linda (NO)
RISSANEN, Eeva (FI)
STESSEL, Helmut (AT)
VANDERSTEEN, Kelly (BE)
Representatives of the Commission:
SCHUTTE, Katrin (DG ENV)
Observers
CINGOTTI, Natacha (HEAL)
FAßBENDER, Christopher (PISC)
FERNANDES DE BARROS, Mariana (Cefic)
FORNABAIO, Lara (ClientEarth)
GRANGE, Emma (ECEAE)
KERÄNEN, Hannu (CONCAWE)
LOONEN, Helene (EEB)
TILLIEUX, Geoffroy (EuPC)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AHRENS, Birgit
AJAO, Charmaine
ANASTASI, Audrey Anne
BASMATZI, Theodora
BELL, David
BERCARU, Ofelia
BOWMER, Tim
CALEY, Jane
CARLON, Claudio
CESNAITIS, Romanas
DE WOLF, Watze
HALLING, Katrin
HERBATSCHEK, Nicolas
HUUSKONEN, Hannele
JOHANSSON, Matti
KARAMERTZANIS, Panos
KARHU, Elina
KLOSLOVA, Zuzana
KREUZER, Paul
LE CURIEUX, Frank
LEPPÄRANTA, Outi
LOUEKARI, Kimmo
NAUR, Liina
NICOLAS, Ronan
O'FARRELL, Norah
PELLIZZATO, Francesca
PELTOLA-THIES, Johanna
RALLO, Claudia
RÖNTY, Kaisu
VAHTERISTO, Liisa
VASILEVA, Katya
VAZQUEZ RODRIGUEZ, Jesus

Proxies

- ATTIAS, Leonello (IT) also acting as proxy of KOUTSODIMOU, Aglaia (EL)
- FERNANDEZ SANCHEZ, Raquel (ES) also acting as proxy of FRANZ, Michel (FR) on 27 June
- FILIPOVA, Hristina (BG) also acting as proxy of PALEOMILITOU, Maria (CY)
- DE KNECHT, Joop (NL) also acting as proxy of DUNAUSKIENE, Lina (LT) during short periods
- HUMAR-JURIC, Tatjana (SI) also acting as proxy of JANTONE, Anta (LV)
- STESSEL, Helmut (AT) also acting as proxy of HERMES, Joe (LU) on 24 June

Experts and advisers to MSC members

AVIZIENE, Monika (LT) (expert to DUNAUSKIENE, Lina)
BARTHELEMY-BERNERON, Johanna (FR) (expert to FRANZ, Michel)
BOISEN, Anne (DK) (adviser to HJORTH, Rune)
BOLWIG, Asger (DK) (expert to HJORTH, Rune)
BIL, Wieneke (NL) (adviser to DE KNECHT, Joop)

CHAUDRON, Yohann (FR) (adviser to FRANZ, Michel)
CIESLA, Jacek (PL) (expert to ANDRIJEWSKI, Michal)
COSGRAVE, Majella (IE) (expert to CONWAY, Louise)
DOBRAK-VAN BERLO, Agnieszka (BE) (expert to VANDERSTEEN, Kelly)
DOYLE, Ian (UK) (expert to COCKSHOTT, Amanda)
EINOLA, Juha (FI) (adviser to RISSANEN, Eeva)
JÖHNCKE, Ulrich (DE) (expert to FINDENEGG; Helene)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
KUROVA, Martina (SK) (expert to HORSKA, Alexandra)
LANDVIK, Nina (NO) (expert to REIERSON, Linda)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBERGH, Ivar)
MUNCRIEF, Sandi (DK) (adviser to HJORTH, Rune)
PASQUIER, Elodie (FR) (adviser to FRANZ, Michel)
PERSSON DAHLBERG, Marie Johanne (NO) (adviser to REIERSON, Linda)
ROSENTHAL, Esther (DE) (adviser to FINDENEGG, Helene)
TARNOCZAI, Timea (HU) (expert to DEIM, Szilvia)
VERBRUGGEN, Eric (NL) (adviser to DE KNECHT, Joop)
WIJMENGA, Jan (NL) (expert to DE KNECHT, Joop)

MSCA experts for SVHC cases:
VAN BROEKHUIZEN, Fleur (NL)

Advisers to the regular observers:
BOCK, Ronald (adviser to Cefic observer)

Registered to the Secure WEBEX-phone connection:
BERTATO, Valentina (DG ENV)
BJERVE GÜZKOW, Kristine (NO)
BOYSEN, Lykke (DK)
GÜNDEL, Ulrike (DE)
HAUZENBERGER, Ingrid (AT)
HEGGELUND, Audun (NO)
HORNEK-GAUSTERER, Romana (AT)
KAARTINEN, Tomi (FI)
KOBE, Andrej (DE ENV)
KOPANGEN, Marit (NO)
LEKATOS, Stylianos (DG GROW)
MCGARRY, Helen (UK)
MENDONÇA, Elsa (PT)
MEYS, Catherine (BE)
MÜHLEGGER, Simone (AT)
PIÑEROS, Juan (BE)
RÖHL, Martine (BE)
STOCKER, Eva (AT)
STRECK, Georg (DG GROW)
SVÄRD, Amie (DG GROW)

Case owners:
Representatives of the Registrants were attending under the Agenda Item 7.2 for CCH-015/2019.

Apologies:
DIMITROVA, Rada (BG)
JANTONE, Anta (LV)
KOUTSODIMOU, Aglaia (EL)
MARTIN, Esther (ES)
MIHALCEA UDREA, Mariana (RO)
PALEOMILITOU, Maria (CY)
WAGENER, Alex (LU)

III. Final Agenda

MSC/A/065/2019

Agenda

65th meeting of the Member State Committee

24-27 June 2019
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

24 June: starts at 9 am
27 June: ends at 1 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/065/2019
For adoption

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

Item 4 – Administrative issues

- Outlook for MSC-66

For information

Item 5 – Minutes of the MSC-64

- Draft minutes of MSC-64

MSC/M/64/2019
For adoption

Item 6 – Substance evaluation

Closed session for 6.3

1. **Written procedure report on seeking agreement on draft decisions on substance evaluation**[3]

   ECHA/MSC-65/2019/007
   For information

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

   No cases

[3] List of agreed cases can be found as an appendix at the end of this draft agenda

[***For discussion]***

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

A case stopped in written procedure:
SEV-BE-001/2017[4] 2,4-di-tert-butylphenol EC No. 202-532-0

For agreement

4. General topics

No topics

[For information]

Item 7 – Dossier evaluation

Closed session for 7.3 and partly for 7.4

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

ECHA/MSC-65/2019/002
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-65/2019/003
For information

For discussion followed by agreement seeking under 7.3:

Compliance checks

MSC code	Substance name	EC No./ Doc.
CCH-015/2019	Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine derivs. residues	272-712-1

ECHA/MSC-65/2019/004-5
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)*

Case as listed above under 7.2

For agreement

4. General topics

1) Request of *in vivo* mutagenicity testing on germ cells under compliance check of Annex IX or X dossiers - Implementation proposal *(Closed session)*
ECHA/MSC-65/2019/006
For discussion and agreement

2) Feedback from ED EG on issues raised by MSC in relation to the use of OECD TG 234 in Dossier Evaluation

For information

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

Timing: Start Day 1 morning

[4] Documents are available in the substance specific folder in MSC Circabc under 06. Substance evaluation

1. Written procedure report on seeking agreement on identification of SVHC[1]

ECHA/MSC-65/2019/008
For information

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

Substance[5]

2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)

ECHA/MSC-65/2019/009-010
For discussion and agreement

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

1. 9th Draft recommendation for inclusion of substances into Annex XIV

- Update from SECR

For information and discussion

- MSC opinion on ECHA's Draft 9th recommendation of priority substances to be included in Annex XIV
  - Discussion on the draft MSC opinion
  - Adoption of MSC opinion

ECHA/MSC-65/2019/011
For discussion and adoption

2. Draft recommendation to amend entries of DEHP, BBP, DBP, and DIBP in Annex XIV

- Update from SECR

For information and discussion

- MSC opinion on ECHA's Draft recommendation to amend entries of DEHP, BBP, DBP, and DIBP in Annex XIV
  - Discussion on the draft MSC opinion
  - Adoption of MSC opinion

ECHA/MSC-65/2019/012
For discussion and adoption

Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2020-2022)

Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update

- Draft terms of Reference and possible appointment of the Rapporteur and Co-Rapporteur

ECHA/MSC-65/2019/001
For discussion & decision

Item 11 – Any other business

Partly closed session

1. Update on appeals and court cases of relevance to MSC (*Closed session)*

For information

2. ECHA's approach to grouping of substances

[5]RCOM is available in MSC S-CIRCABC, 03 SVHC folder, in corresponding Substance-specific folder

3. MSC and the development of OECD test guidelines

For information

4. Use and exposure information in regulatory risk management *(Closed session)*

ECHA/MSC-65/2019/013

For information

5. Suggestions from members
    1) EORGTS Workshop update
    2) Notification about ongoing consultation in CARACAL *(Closed session)*

For information

Item 12 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-65

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

- Status report on on-going substance evaluation work (presentation slides)
- Status report on on-going dossier evaluation work (presentation slides)
- Option to address non-extractable residues in regulatory persistence assessment (ECHA/MSC-65/2019/014)

APPENDIX to the MSC-65 agenda:

List of evaluation and SVHC cases agreed by MSC in written procedure in advance of the MSC-65 meeting:

Substance evaluation

MSC code	Substance name	EC No.
SEV-2-SE-032/2013	Bis(isopropyl)naphthalene	254-052-6
SEV-IT-015/2017	Quaternary ammonium compounds, tri-C8-10-alkylmethyl, chlorides	264-120-7

Dossier evaluation

Compliance checks

MSC code	Substance name	EC/List No.
CCH-017/2019	2-hydroxyethyl acrylate	212-454-9
CCH-020/2019	Violet sodium polysulfide aluminosilicate with a SOD-type framework structure	701-186-2
CCH-021/2019	N,N',N'',N'''-tetrakis(4,6-bis(butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)-amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine	401-990-0
CCH-022/2019	N,N',N'',N'''-tetrakis(4,6-bis(butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)-triazin-2-yl)-4,7-diazadecane-1,10-diamine	401-990-0
CCH-023/2019	Cyclohexylidenebis[tert-butyl] peroxide	221-111-2
CCH-033/2019	Cetrimonium chloride	203-928-6
CCH-037/2019	Bis(2-(2-butoxyethoxy)ethyl) adipate	205-465-5

Testing proposal examinations

MSC code	Substance name	EC/List No.
TPE-049/2019	Terpineol	701-188-3
TPE-050/2019	Silver	231-131-3
TPE-053/2019	Aluminium oxide	215-691-6
TPE-054/2019	2-(2-thienyl)ethyl toluene-p-sulphonate	254-911-5
TPE-055/2019	Fatty acids, C16-18 and C18-unsatd., branched and linear, butyl esters	441-620-5

Substances of Very High Concern (SVHC)

Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-65 (24-27 June 2019)
(adopted at MSC-65)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues	
MSC agreed with the SECR's suggestion to extend the minutes preparation period until 2nd week of August 2019, due to the ongoing holiday period.	**MSC-S** to launch the MSC consultation on the MSC-65 draft minutes by 8 August 2019. **Members** to review and, where appropriate, to send their comments on the draft minutes preferably by 21 August or at the latest by 30 August 2019. **MSC Chairs** to assess the comments received, responses provided and the possibility for minutes adoption in written procedure (currently envisaged in September 2019).
Item 5 – Minutes of the MSC-64	
MSC adopted the draft minutes as modified at the meeting.	**MSC-S** to upload final version of the minutes on MSC S-CIRCABC by 1 July 2019 and on ECHA website without undue delay.
Item 6 – Substance evaluation **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.
Item 6 – Substance evaluation **3. Seeking agreement on draft decisions when amendments were proposed by MSCA's / ECHA *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decision (as modified in the meeting): SEV-BE-001/2017, 2,4-di-tert-butylphenol (EC No. 202-532-)	**MSC-S** to upload on MSC S-CIRCABC the agreed decision 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.
Item 7 – Dossier evaluation	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
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 decision: **<u>Compliance check</u>** CCH-015/2019 Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine derivs. Residues (EC Nr. 272-712-1)	**MSC-S** to upload on MSC S-CIRCABC the agreed decision in the respective case folder.
Item 7.4 – Dossier evaluation - General topics 1. Request of *in vivo* mutagenicity testing on germ cells under compliance check of Annex IX or X dossiers - Implementation proposal *(Closed session)*	
MSC took note of the document and the presentation on practical implementation options. MSC agreed to suggest a two decision approach for forthcoming dossier evaluation draft decisions on mutagenicity concern: (i) in first decision with both the comet and Transgenic Rodent (TGR) studies to recommend, instead of requesting, of collecting and analysing germ or gonadal cells; and, (ii) in follow up for the cases where no definitive conclusion can be reached on germ cell mutagenicity after a positive result has been obtained in somatic cells, suggest to use a second decision requesting further mutagenicity testing (germ cells).	**MSC** requested **SECR** to ensure that the new approach is externally communicated in time for finalising the MSC-66 draft decisions. **MSC** to review its approach once there is clarity on the amendment of the OECD TG 488 (TGR).
Item 7.4 – Dossier evaluation - General topics 2. Feedback from ED EG on issues raised by MSC in relation to the use of OECD TG 234 in Dossier Evaluation	
MSC took note of the report by SECR and considered that its questions to the ED EG had been sufficiently addressed.	
Item 8 – SVHC identification - Seeking agreement on Annex XV proposals for identification of SVHC **1. Written procedure report on seeking agreement on identification of SVHC**	
MSC took note of the report.	**MSC-S** to upload the MSC agreement documentation on written procedure case on MSC S-CIRCABC and to publish it on ECHA website. **SECR** to add the newly identified SVHC to the Candidate List (update foreseen by mid-July 2019).
Item 8.2 – SVHC identification - General topics **2. 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): • 2,3,3,3-tetrafluoro-2-	**MSC-S** to upload the MSC agreement, as well as the support document and RCOM, on MSC S-CIRCABC and to publish them on the ECHA website.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)	**SECR** to add the newly identified SVHCs to the Candidate List (update foreseen by mid-July 2019). **MSC members who made statements** regarding this SVHC proposal and **requested for their attachment to the minutes** to provide these statements in writing to MSC-S **by 1 July 2019**.

Item 9 – ECHA's recommendations of priority substances to be included in Annex XIV and opinion of MSC
• **9th Draft recommendation for inclusion of substances into Annex XIV**
• Update from SECR MSC
• MSC opinion on ECHA's Draft 9th recommendation of priority substances to be included in Annex XIV
  • Discussion on the draft MSC opinion
  • Adoption of MSC opinion	

MSC discussed the 9th ECHA's draft recommendation for inclusion of priority substances in Annex XIV. MSC in its opinion supported recommending the 18 substances that were subject of the public consultation for inclusion in Annex XIV. MSC adopted the opinion on ECHA's draft 9th recommendation (as amended at the meeting).	**MSC-S** to submit the opinion to ECHA's prioritisation unit and publish the final MSC opinion on MSC S-CIRCABC and on ECHA website without undue delay. **SECR** to take into account the MSC opinion when finalising ECHA's 9th recommendation for inclusion of substances in Annex XIV and to submit it to the Commission.

Item 9 – ECHA's recommendations of priority substances to be included in Annex XIV and opinion of MSC
• **Draft recommendation to amend entries of DEHP, BBP, DBP, and DIBP in Annex XIV**
• Update from SECR MSC
• MSC opinion on ECHA's Draft recommendation to amend entries of DEHP, BBP, DBP, and DIBP in Annex XIV
  • Discussion on the draft MSC opinion
  • Adoption of MSC opinion	

MSC discussed ECHA's draft recommendation for amending entries in Annex XIV. MSC in its opinion supported recommending the amendment of the entries of four phthalates, subject of the public consultation, in Annex XIV. MSC adopted the opinion on ECHA's draft recommendation for amending Annex XIV entries (as amended at the meeting).	**MSC-S** to inform ECHA's prioritisation unit and publish the final MSC opinion on MSC S-CIRCABC by 1 July and on ECHA website without undue delay. **SECR** to take into account the MSC opinion when finalising ECHA's recommendation for amending entries in Annex XIV and to submit it to the Commission.
Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2020-2022) Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update • Draft terms of Reference and possible appointment of the Rapporteur and Co-Rapporteur	
MSC adopted the mandate and the tasks of the rapporteur, and appointed one member as a Rapporteur and another member as a Co-Rapporteur for drafting the opinion of the MSC on the CoRAP 2020-2022 update. MSC mandated the Rapporteur to decide on the size	**MSC-S** to send the appointment letters to the Rapporteur and the Co-Rapporteur after the meeting. **Rapporteur** to assess the size of the working group once further information on the draft CoRAP 2020-2022 is available.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
of the working group.	**MSC-S** to launch a written procedure for the appointment of the WG by October 2019.
Item 12 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-65 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC S-CIRCABC by 28 June 2019.

Annex V Statements related to agenda item 8.2 with regard to the SVHC identification of HFPO-DA

FI member´s statement

The FI member of the MSC agrees that there is a concern with HFPO-DA. However, the reasoning on why the substance is considered to have an equivalent level of concern with probable serious effects on human health and on the environment include several concern elements which are new in the context of SVHC identification. The FI member abstained since due to the many new issues compared to previous SVHC cases it has not been possible to sufficiently resolve all the issues in the time available during the MSC process. The new issues include for example the co-exposure with other similar substances, secondary poisoning, and the comparability of very persistent and mobile substances to PBT and vPvB substances. We consider that some of the questions need to be discussed also in a more general context in other forums.

UK member's statement

We recognise the specific concern of the dossier submitter, clearly a substance which has only been used for a relatively short time but is detected widely should be a priority for regulatory evaluation. We also agree that the inherent properties described in the dossier such as very high persistence and mobility, high potential for continuing contamination and difficulty to treat or remove the substance from water resources in combination give rise to a high concern for this substance.

We highlight that there are a number of risk management options available to address this concern; In choosing to identify the substance as SVHC under Article 57(f), the question for MSC is whether the dossier provides sufficiently compelling 'scientific evidence of probable serious effects on human health or the environment which give rise to an equivalent level of concern (ELoC) to those of other substances listed in Article 57 (a) to (e)'. This wording suggests to us that a boundary exists in terms of the probability of effects being serious or less so and as such the UK believes that toxicity is a very relevant consideration – if a substance is not demonstrably toxic in a relevant hazard category or with a high potency then it is questionable whether it should be considered to pose a "very high" concern. In this case, we do not consider that there is clear evidence that HFPO-DA is significantly toxic in either aquatic or mammalian studies.

Uncertainty has been referred to a number of times to build the ELoC case. Uncertainty is inherent in all chemical assessments, otherwise it would not be possible to conclude whether the use of any chemical was acceptable, and is generally addressed through the use of elements such as assessment factors, or a clear policy agreement that a combination of properties leads to unacceptable uncertainty. We agree that for highly persistent substances, uncertainty is increased due to continuous and growing exposure over time. However, we are not convinced that a case has been made that the uncertainty associated with vPvB substances (addressed by their SVHC category) is analogous to that for chemicals such as HFPO-DA. The properties of vPvB substances can limit the ability of laboratory studies to identify relevant effects due to either slow uptake or adsorption to surfaces. The vPvB designation is therefore a surrogate for the likelihood of unpredictable toxic effects in the food chain. In contrast, the solubility of HFPO-DA means it is amenable to standard regulatory toxicity tests. Where substances such as these are demonstrated not to bioaccumulate significantly and their toxicity has low potency, unexpected effects in food chains would appear much less likely. We note that differing views have been expressed about what the concerns underlying vPvB concept itself are, so we suggest that further technical discussion on this is needed, for example at the PBT Expert Group.

In addition, we are not convinced that "unknown effects" should be included in reasoning to reach a conclusion that serious effects will be "probable". If uncertainty exists, the concern could be addressed

by other regulatory or policy action (such as voluntary measures, etc.) or by requesting additional regulatory studies. In this case we consider awaiting the results of the studies requested in the recent substance evaluation decision could remove some of the uncertainties used to build the case.

The absence of significant toxicity in either aquatic or mammalian studies (such that the Annex XIII "T" criterion would be met), means that we are less convinced that the secondary poisoning concern in this case is equivalent to the PBT 'hazard' concern. A secondary poisoning concern is usually managed via risk assessment, and could be in this case. Using co-exposure as a supporting argument seems inconsistent with previously agreed SVHC cases (such as PAHs). We recognise that mixture toxicity is a regulatory concern, but, at present, SVHC identification is about the inherent properties of the specific substance.

In conclusion we consider that the scientific evidence currently presented does not indicate probable serious effects to human health or the environment. Based on this we consider that a decision to identify HFDO-DA as an SVHC under these circumstances invokes the precautionary principle, which is a policy matter, and therefore within the remit of the REACH Committee and the Commission rather than the MSC. We recognise and share the high regulatory concern for PFAS in general, but we need to make sure (as far as possible) that regulatory precedents are based on a fair and consistent appraisal of the best available scientific evidence, and that the policy goals are clearly communicated as part of the decision making. Since we are the only Member State to express such a strong view, we have decided to abstain rather than vote against this proposal.