MSC/M/61/2018
(Adopted in written procedure
on 23 November 2018)

Minutes
of the 61th Meeting of the Member State Committee (MSC-61)
10-11 October 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 61st meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

The Chairman informed MSC of the plans to hold short interviews with members in the coming months. The Chairmen of the ECHA Committees will prepare a report for the Management Board for next March based on those interviews. It was highlighted that the Commission's expectations of the ECHA Committees are very high and MSC has to continue to refine its work and deliver.

Item 2 - Adoption of the Agenda

The Agenda was adopted as modified by the MSC Secretariat (MSC-S) with removal of an item under Dossier Evaluation as the Registrant concerned had informed ECHA of a cease of manufacture of the substance CCH-075/2018. SECR also suggested to introduce a revised title for Item 3 and change the word 'conflicts of' to 'specific' (final Agenda is attached to these minutes as Section III).

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

No specific interests were declared by the Chairman, any members, experts or advisers with any item on the agenda of MSC-61.

Item 4 - Administrative issues

1. Outlook for MSC-62 & MSC-63

The Chairman presented an outlook on the potential length of the next meeting which is expected to require 5 full plenary days. The Chairman also presented an early stage estimation for the length of the MSC-63 meeting in February 2019 which is expected to require 2,5 days.

2. Feedback from Committees Satisfaction Survey 2018

The MSC Chairman informed that the feedback received from MSC members and accredited stakeholder observers have been provided in the respective document. Further to the feedback consideration outlined in part III, the Chairman noted that some further clarification and views of the individual members and regular observers will be sought during the bi-lateral phone interviews that will take place in the coming months.

Item 5 – Minutes of the MSC-60 meeting

MSC Chairman informed the Committee that the minutes of MSC-60 were adopted by MSC in written procedure and published on ECHA website and in MSC S-CIRCABC.

Item 6 – Substance evaluation

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

Not applicable to this meeting round

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

Not applicable to this meeting round

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

Not applicable to this meeting round

4. General topics

1. Status report on on-going substance evaluation work

SECR provided an update on the number of substance evaluation cases (SEv) final decisions for 2018 and the combo approach. This latter approach allows, from the start of the substance evaluation, an evaluating Member State (eMS) to bring to ECHA's attention aspects for compliance check hence integrating substance and dossier evaluation. Prompted by questions, SECR explained that the combo approach was a voluntary approach where the eMS broadens their evaluation, not only on the concern identified, but also whether the dossiers are lacking important information from the 8 super endpoints that could be requested under compliance check (CCH). This approach had already been discussed in CARACAL. The practicalities of this approach were being devised in a pilot project with the intention of making this approach flexible leading. The learnings from this pilot including the amount of resources required will be presented and discussed at CARACAL. Regarding the number of SEv final decisions for 2018, which is lower than originally planned for, it was explained that there can be several reasons to delay a decision on the evaluation of a substance, which in many cases are not within the control of the eMS, for example when awaiting the outcome of a CCH or discussing some specific points with the Registrants. In any case eMSs facing these cases and problems are invited to work closely with ECHA substance managers to find the most workable solutions as fast as possible.

2. Rethinking MSC SEV Webex - Suggestions for way forward

Following the discussion on a revised approach to the SEv webex at MSC-60, SECR launched a survey over the summer.

At MSC-61, SECR presented an amended proposal following receipt of the replies to the webropol survey from the MSC members and the eMS. In this revised proposal the aim of the SEv webex would change from information exchange to identification of still unresolved issues and preliminary conclusions, the SEv webex would be held in the current time frame where the meeting documentation is available and MSC-S would continue to chair the webex. The main change proposed was to add whether the eMS assessment considered the diverging view(s) as resolved/unresolved, for each proposal for amendment (PfA), including as well, which PfA would benefit from bi-/tri-lateral discussion to further clarify the views and possible options to resolve them. MSC members expressed a preference to hold the SEv webex as early as possible once all the meeting documentation has been made available, but no common view existed whether to hold such webex on the Friday or Monday afternoon. A Member's participation in the webex is not considered mandatory, but to support the eMS in their preparation for the plenary meeting a wish for plenary discussion of an issue should be flagged in advance of the MSC meeting. SECR made a call for volunteers whose eMS wish to try the proposed approach for their SEv cases at MSC-62 as a pilot project, and suggested to take their availabilities into account when inviting for the webex.

MSC reflected on the possibility of using the S-CIRCABC Newsgroups for the bi-/tri-lateral discussions. Comments in favour and of caution were received on this for the SECR to further consider. Comments in favour were that this could be a way to get people involved and to open up bi/trilateral discussions for all MSC members to follow. Comments expressing caution were related to the occasional technical issues preventing logging into S-CIRCABC and the status of such Newgroups if formal or informal, voluntary or obligatory.

The Chairman concluded that the pilot project would be kicked off as proposed without the use of the S-CIRCABC Newsgroups. SECR would weigh the pros and the cons of the use of Newsgroups and prepare for a discussion with MSC after the completion of the pilot project.

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-61 agenda" for more detailed identification of the cases). WP was launched on 13 September 2018. By the closing date 24 September 2018, MSC reached unanimous

agreement on five draft decisions (DD)[1]. One member abstained from voting on three cases. For one DD, based on request from MSC members, the MSC Chairman terminated the WP (see item 2 above on changes made to the meeting agenda on this particular case).

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)*

SFWA category on stilbene fluorescent whitening agents (CCH-048 to CCH-061/2018):

CCH-048/2018	Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-(diethylamino)-1,3,5-triazine-4,2-diyl]imino]]bis(benzene-1,4-disulphonate) (EC No. 255-217-5)
CCH-049/2018	Disodium 4,4'-bis[(4-anilino-6-morpholino-1,3,5-triazin-2-yl)amino]stilbene-2,2'-disulphonate (EC No. 240-245-2)
CCH-050/2018	Tetrasodium 4,4'-bis[[4-[bis(2-hydroxyethyl)amino]-6-(4-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate] (EC No. 240-521-2)
CCH-051/2018	Disodium 4,4'-bis[6-anilino-[4-[bis(2-hydroxyethyl)-amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate (EC No. 224-073-5)
CCH-052/2018	Tetrasodium 4,4'-bis[[4-[bis(2-hydroxypropyl)-amino]-6-[(4-sulphonatophenyl)amino]-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate (EC No. 267-097-1)
CCH-053/2018	Disodium 4,4'-bis[[4-anilino-6-[(2-carbamoylethyl)-(2-hydroxyethyl)amino]-1,3,5,-triazin-2-yl]amino]-stilbene-2,2'-disulphonate (EC No. 248-420-5)
CCH-054/2018	Disodium 4,4'-bis[[6-anilino-4-[(2-hydroxyethyl)-methylamino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate (EC No. 237-600-9)
CCH-055/2018	Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-[bis(2-hydroxyethyl)amino]-1,3,5-triazine-4,2-diyl]imino]]bis(benzene-1,4-disulphonate) (EC No. 273-468-9)
CCH-056/2018	Tetrasodium 2,2'-ethene-1,2-diylbis[5-({4-[diethylamino]-6-[(4-sulfonatophenyl)amino]-1,3,5-triazin-2-yl}amino)benzenesulfonate] (EC No. 619-874-5)
CCH-057/2018	Tetrasodium 4,4'-bis[[4-[(2-hydroxyethyl)amino]-6-(m-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate (EC No. 240-400-4)
CCH-058/2018	Disodium 4,4'-bis[[4-anilino-6-[(2-hydroxyethyl)-amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate (EC No. 241-883-4)
CCH-059/2018	Tetrasodium 4,4'-bis[[4-morpholino-6-(p-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate (EC No. 249-323-0)
CCH-060/2018	Potassium sodium 4,4'-bis[6-anilino-4-[bis(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate (EC No. 275-031-8)
CCH-061/2018	Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-morpholino-1,3,5-triazine-4,2-diyl]imino]]bis(benzene-1,4-disulphonate) (EC No. 257-827-7)

[1] For details see description on case CCH-075/2018 in section 7.3.

Session 1 (open)

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

SECR first reminded that this was a novel approach to manage a category using only one DD text for all category substances and endpoints. The category was divided further in a few sub-categories to cover remaining structural variations which might impact on the hazard profile. In the discussions the DD of the "master case" CCH-048/2018 was used as reference point, while agreed modifications would simultaneously apply also to other category cases. SECR continued explaining the four PfAs received to ECHA's DD, which represents altogether 14 cases on substances within the category. The PfAs were discussed in the meeting and are outlined below.

The first PfA suggested noting, in the end of the section with the information requests, that other adaptation possibilities may be possible as new data are generated as a consequence of requests in this decision.

The second PfA on two extended one-generation reproductive toxicity studies (EOGRTS) requested to perform initially only one EOGRTS and justify whether the second study requested could be adapted based on newly generated information, including results of a repeated dose/reproductive toxicity screening study (OECD TG 422) on the substance of case CCH-061/2018 in subcategory 2. The third PfA, also on the EOGRTS, suggested revising DD text, claiming it did not accurately reflect the Registrant's comments to first complete some of the steps in their testing strategy before considering the need for reproductive toxicity investigations.

The fourth PfA on long-term toxicity testing on fish suggested, for CCH-056/2018 of subcategory 1, replacing the proposed toxicity test on fish, early-life stage (FELS, OECD TG 210) with the fish sexual development test (FSDT, OECD TG 234). The latter test would additionally address the concern for potential endocrine activity based on the available results of the 90-day study for CCH-048/2018 of subcategory 1.

SECR had modified the DD in advance of the meeting based on the PfAs on adaptation possibilities and EOGRTS.

The Registrant had provided comments prior to the meeting and agreed with the PfAs on adaptation possibilities and selected aspects of those on EOGRTS, while disagreeing with the PfA on the change of the test guideline (TG) for long-term fish toxicity testing. The representatives of the Registrant reiterated their views on agreeing with selected PfAs. They additionally clarified that in their proposed strategy they intend to perform their analysis step-by-step, where the new information generated would be the basis to consider the need for reproductive toxicity testing, emphasizing that the Registrant had not seen such needs yet. They also confirmed their view to keep FELS test for fish toxicity studies consistently for all category cases.

The discussion first covered the three PfAs on adaptation possibilities and EOGRTS.

An MSC expert highlighted that the DD mentioned that further adaptations to the information required were not expected, whereas, in the view of that expert, with categories and read across in the past it was either explicitly or implicitly acknowledged that they all were work-in-progress and new information generated may open up new adaptation possibilities. The expert also supported the stepwise testing emphasizing that the major concern of testicular toxicity could be clarified by the studies conducted in a first step preceding the second EOGRTS. As an example of this stepwise approach, he referred to another category previously agreed by MSC. SECR noted that MSC so far only has considered categories under testing proposal examinations.

The representatives of the Registrants commented why they, in hindsight, raised questions on the validity of the results from the 90-day study in subcategory 1, which triggered the request for an extension of cohort 1B to produce the F2 generation. However, no diverging views on the validity of the 90-day study or its results had been raised in any PfA, and MSC did not consider the general referencing to literature on testicular toxicity a convincing argument for reconsidering the EOGRTS requests.

SECR clarified that this category of compliance checks differed from earlier categories of testing proposals, as this one requires dossiers to become compliant with requests not on all substances but taking into account the proposed read across. SECR maintained the view that the wording on agreeing to proposed studies in the Registrants' comments on the DD was unambiguous. SECR also stressed that the studies requested aimed to strengthen the read-across in order to ensure the compliance while avoiding the need for testing on all substances. Although the grouping proposed by the Registrant was considered possible, the read-across within the category was currently not deemed acceptable due to the limited coverage of the structural differences in the available data set. SECR continued with highlighting the general approach for compliance checks, where normally testing is requested in the DD but the possibility for adaptations remains. Here another, exceptional route was taken to consolidate a read-across adaptation which aims to achieve compliance for all dossiers of a category. It reminded that earlier categories comprised testing proposal examinations. It pointed out that while the purpose of testing proposal evaluation is to assess whether a testing strategy fulfil real information needs, the purpose of compliance check is to ensure actual compliance after the decision is implemented. SECR's views were not challenged.

An MSC member supported SECR's understanding of the registrants comments on the proposed strategy text, but considered the further clarification from the representatives of the Registrants sufficient to reflect it in the DD, where necessary. He queried whether CCH-048/2018 was a worst case, as suggested in the PfA, and how that would affect the read-across feasibility. The member also disagreed with the view expressed that clean results on testicles in the repeat dose and screening studies for reproductive and developmental toxicity could exclude other developmental toxicity or fertility effects in the EOGRTS studies.

This was supported by another MSC member, who agreed that there was no other way for a complete view on the toxicity profile but to have studies requested as in the DD, also arguing that sulphonation could increase bioavailability.

A third MSC member queried whether the morpholino function of CCH-049/2018 in subcategory 2 should trigger the need for a second EOGRTS. SECR considered that the draft decision has to address the potential impact on toxicity of morpholino as well as sulphonation functional groups in the category.

The representative of the Registrants acknowledged that a first EOGRTS is a requirement in the DD for dossier compliance. They underlined their consideration that any EOGRTS required in the legal text under Annex IX is triggered by results from a long-term repeated dose study. In addition, they argued that there was no evidence of such trigger for any of the other substances in the category, including the morpholino derivative. They concluded that the test results from the information requests for relevant endpoints should be taken into account , before starting a second EOGRTS.

The discussion then moved further to long-term fish toxicity testing, where MSC tentatively queried a third option of removing fish toxicity testing from the current decision altogether and only addressing the data gap later when information now to be generated could inform on the selection of the most appropriate test guideline, although there was no PfA to that end.

An MSC expert further justified that the PfA requesting OECD TG 234 aimed to clarify the endocrine disrupting (ED) properties already at this stage, also because the expert considered this study to be feasible to that end. The expert initially questioned a possibility to remove the long-term fish toxicity request as it would result in a data gap.

Another MSC expert supported SECR's view arguing that based on the current information it would be premature to change the test guideline from OECD TG 210 to OECD TG 234 to fulfil a data gap for long-term toxicity to fish. They reiterated their view that the OECD TG 234 should not be triggered under dossier evaluation.

Two MSC members sympathized with the PfA. However, they agreed with SECR position that there were no indications on ED concern for the substance itself at this moment. The concern was identified in a 90-day study with rat, conducted with another substance in the same subcategory (CCH-048/2018). The read-across was not yet substantiated.

Additionally, due to the overall low toxicity observed within the category possibly a limit test for OECD TG 210 could be sufficient across the category. Thus, they favoured keeping OECD TG 210.

The representatives of the Registrants confirmed their initial view that OECD TG 210 would be a sufficient test to perform, preferably after long-term daphnia study and other possible improvements of the category.

The Chairman of MSC concluded the discussion on the PfAs for the category. In summary, the DD with requests on the category was developed by choosing an optimal study design for consolidation of the category developed by the Registrants based on currently available data. Later, ECHA may still need to request further information depending on study results becoming available.

The representatives of the Registrants stated that they support the approach of ECHA to consolidate categories that are possible but still unsatisfactory. They also appreciated the interaction with ECHA over years in building a consolidated category. In addition, they acknowledged their responsibility to ensure that their category approach was solid for ECHA's evaluation.

Three stakeholder observers considered this category experiment a successful pilot with efficient work and good results, and supported future grouping approaches for both compliance checks and testing proposals.

Session 2 (closed)

Some MSC members were of the opinion that the need for a second EOGRTS seemed to remain unclear, arguing that there was no prior information to know which substance properties contributed to bioavailability. It was considered possible that new studies may result in disagreement with existing information, but maintained the opinion that requesting sequential testing would take too long to ensure compliance with the information requirement.
SECR reasoned that the number of tests was not excessive, instead the number was reduced through interaction with ECHA after the first round of compliance checks. The aimed outcome of the DD text is to attain compliant dossiers for all category members.

Several MSC members and experts deliberated on the Registrants' intention to carry out further assessment on toxicokinetics and bioavailability to provide further support to requirements on reproductive toxicity and category consolidation. They took note of the importance of information generated in studies to the design of latter ones in the category, but also considered that the available information indicates there is systemic toxicity, hence bioavailability.

As for fish toxicity testing, they took note of the current ED indications and concluded that based on existing information the request for FELS test OECD TG 210 should be maintained in the decision. The option to request OECD TG 210 but to recommend to the registrant to consider performing OECD TG 234 instead to fulfil the information requirement was also considered; however, at this stage, it was not clear how to formulate the related advice in the DD and it might not give the Registrant sufficient legal certainty on MSC's intent.

MSC concluded that all current requests in the category DD are justified and founded based on existing information, with the aim to attain compliance of the dossiers with the implementation of this decision, which is based on current data gaps and deficiencies of adaptations. Based on the discussion, it agreed to modify the DD by deleting selected wording on further adaptation possibilities; modified the text where the Registrants' comments on the draft decision was addressed to reflect the absence of disagreement of the Registrant on ECHA's assessment; and, added clarifying text on dose level setting in the section describing the design of the EOGRTS requested in this DD.

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

The member from Germany abstained from voting.

CCH-073/2018 Fatty acids, C16-18 (even numbered) and C18 unsatd., reaction products with triethanolamine, di-Me sulfate- quaternized (List No. 931-203-0)

Session 1 (open)

No representative of the Registrant participated in the initial discussion.

SECR explained the PfA which was received to the ECHA's DD on *Pre-natal developmental toxicity study in a second species (rat or rabbit), oral route,* (PNDT) and discussed in the meeting, as outlined below. In summary, the PfA requested to remind the Registrant to consider the adaptation possibilities for this information requirement in case both the first species PNDT and EOGRTS, dosed up to the limit dose, show no toxicity.

SECR modified the DD in advance of the meeting based on the PfA.

The Registrant had provided written comments on the PfA and agreed to perform the two PNDT studies sequentially and take the results of the PNDT study in a first species and from the EOGRTS to assess if the PNDT study in a second species is still needed. The Registrant in his comments also indicated that, based on existing data on the registered substance, the substance and its metabolites have low toxicity, and an exposure based adaptation may apply, and he considered a read-across to an analogue substance.

One MSC member voiced the concern that including the additional statement could be misinterpreted (as there is already one note which gives the registrant the possibility for adaptation). Furthermore, the Registrant when using an adaptation will have to give a proper assessment of the uncertainties in the exposure assessment, as well as the derivation of a DNEL based on limit dose information and in absence of a second species PNDT study. Another MSC member supported not to include the additional note, however indicated that on a case by case basis an additional note – as it is phrased in the updated DD for this case - could be relevant.

During the discussion, views were shared with regard to reasons and benefits for including or not including the additional note.

SECR considered that the general note with possibility for adaptation, mentioned in the DD sent for Registrant's commenting, would be sufficient in itself. However the more specific note as suggested in the PfA could bring additional clarification.

Session 2 (closed)

The MSC member from the PfA-submitting country informed MSC that several projects on species differences in PNDT testing are expected to be finalised shortly, which may further inform a general scientific debate with MSC on those circumstances where a second species PNDT study adds value to the overall hazard assessment of the substance.

Several MSC members shared their views on ways of indicating in the DD the adaptation possibilities, raising concerns mainly as regards the circumstances where MSC could consider exposure based adaptation to be acceptable. Members stressed that both the general and particular adaptation criteria have to be taken into account and a case-specific adaptation is developed based on: a) the overall toxicity of the substance (e.g. address whether there is a difference in PNDT sensitivities between the two species for low toxicity or high toxicity substances); b) the use of additional assessment factors in absence of a second species PNDT; c) minor or substantial data refinement (possible to be added) in the CSR; d) specific information from recent literature on the substance; e) relevant and robust assessment of consumer and/or professional exposure (e. g. absence or non-significant exposure on all scenarios); f) a reasoned risk characterisation ratio which takes into account any residual uncertainty.

COM representative noted that although the suggested additional note gives some constraints, it gives also guidance to the Registrant to develop robust results sustaining the adaptation as an option.

SECR summarised the main guidance aspects as regards adaptation possibilities and further stressed it should remain a registrant's responsibility to develop any case-specific adaptation, hence ECHA and MSC should not detail in the DD specific ways of adaptation.

Sharing of ECHA's experiences in the dossier evaluation decisions follow-up evaluation may inform future MSC discussions regarding the practices with adaptations to information requirements.

MSC concluded to modify the additional note on adaptation, by removing reference to the Annex XI, 3.2 or Annex XI, 1.2.

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

4. General topics

- Update from SECR about DEv policy changes

SECR introduced recent and upcoming changes in dossier evaluation policies resulting from the REACH review actions on improving efficiency. These include, inter alia, expanding decisions to all members concerned of a joint submission, a new template for draft decisions with requests per annex (tonnage band), and no longer taking into account tonnage band downgrades or changes of registration status (intermediate) after the draft decision is sent to the registrants. SECR also explained that the practice of offering informal interaction after the issue of a draft decision will be discontinued. Instead, interaction may come to take place at an earlier stage, i.a. when addressing groups of substances. These changes will be implemented as of 1 January 2019. SECR also drew attention to the new dossier evaluation case status list, available as part of the public activities coordination (PACT) tool. ECHA will no longer publish the early warning list of candidates for compliance check. As for scientific changes, data gaps for the 90-day study and EOGRTS will be addressed in two separate consecutive decisions, thereby requiring only a one-time assessment of the EOGRTS design. It was also noted that the approach for information requests on germ cell mutagenicity under dossier evaluation is under review.

An MSC member welcomed the action resulting from the REACH review. Another MSC member would have welcomed an earlier discussion at MSC in addressing 90-day and EOGRTS, and a stakeholder observer queried how the communication to registrants would be ensured in an efficient manner. SECR responded that CARACAL was informed before the summer, and that a webex to inform registrants took place. It further emphasized the importance for registrants to keep their dossiers updated.

- Suggestions for improvement of MSC DEv Webex

SECR introduced the results of a survey on the aims of preparatory teleconferences on dossier evaluation prior to MSC meetings. In summary of the survey, the teleconference for DEv process seems to be largely on the right track with timing and contents, especially given its informal consultative nature. Many placed emphasis on having all plenary meeting documentation available for the webex, thus an earlier one may not be equally effective. Some suggested “polling” the views of all participants on the PfAs at the time of webex, whether attending or not.

In addition to the teleconference survey, SECR clarified selected aspects based on the MSC satisfaction survey. The documentation on DEv process (presentations) are published in MSC S-CIRCABC IG at the same time for MSC members and stakeholder observers. Possibilities in having more details on DEv cases for written procedure, as was suggested by an MSC observer, have been explored and were further considered. The minutes on DEv cases aim to provide only concise justifications for conclusions reached in a result-oriented manner.

Item 8 – SVHC identification

1. Discussion on any potential process/procedural modifications in the Working procedures of MSC in SVHC identification

SECR presented briefly document ECHA/MSC-61/2018/009 which compiled submitted comments and suggestions for potential changes in the MSC SVHC working procedure by two MSC members and SECR’s responses to them. Major suggestions referred to the chosen way of agreement seeking, in particular when significant new data have been provided in the public consultation, and the possibility for further interactions with comment submitters, where necessary.

MSC took note on SECR's remarks on the flexibility of the current procedure in this regard and supported the SECR's conclusion that currently there is no need to modify the SVHC working procedures of MSC.

2. Suggestions for improvement of MSC Webex in SVHC identification

SECR presented shortly the outcome of the MSC Webex survey concerning the SVHC identification process. It was noted that all responding members were satisfied with the current SVHC WEBEX structure, organisation, chairing, objective and outcome to facilitate the plenary agreement seeking.

However, in order to further improve the MSC SVHC Webex, the Committee took note of, and discussed the comments received on the *Currently applied SVHC Webex approach* (i.e. full case introduction during the Webex and shorter introduction in plenary with focus on open issues) and on the *Newly suggested approach* (i.e. issue identification and reflection during the Webex and plenary discussion on a few highlighted unresolved issues only - used in D4, D5 and D6 SVHC agreement seeking at MSC-60), and agreed to continue following the Newly suggested approach in future.

Members also agreed to support MSC-S in providing guidance to their MS colleagues, acting as SVHC dossier submitters, in their preparations for MSC SVHC Webex and plenary meetings with regard to the new approach on issue identification.

With regard to the suggested potential usage of S-CIRCABC newsgroups for informal exchange of views among members, dossier submitters and ECHA, the SECR noted on some logistic complications if this suggestion is to be followed. For the sake of time, the MSC Chairman, supported by the Committee, proposed to explore further these possibilities in the context of the SVHC process and to discuss it again in one of the forthcoming plenary meetings.

In conclusion, MSC welcomed members' strong commitment to the Webex participation. In this regard, when a member is prevented from Webex participation, but has an issue to raise, the member should submit comments/views (if not provided in public consultation), in advance of the Webex to allow proper preparation and issue consideration by the dossier submitter and other members of MSC.

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

- Update on review of the process for Annex XIV recommendations

SECR provided an update to MSC on the work carried out to review the process for Annex XIV recommendations. In this update SECR suggested changes which could bring improvements to the process and explained how the documentation that ECHA considers to provide to MSC in future will help MSC in its tasks in a more focussed way. These changes should also reduce the editorial work as fewer documents, e.g. background documents, would need to be updated on multiple occasions without any loss of information. Another suggested change was that, since currently all substances on the candidate list are considered for any next recommendation round, there is no longer a need to share with MSC the preliminary priority assessment results of newly added substances. SECR concluded the update by introducing the timings for the next steps for the ongoing draft recommendation, and when MSC could expect the new documents.

One observer requested clarification on how the assessment for intersubstitutability and whether grouping is relevant will now be judged, or possibly confirmed after the initial assessment. SECR replied that no changes to the process in this regard are anticipated. In response to another question SECR explained that the update to the process does not shorten the MSC opinion forming process, but it rather aims to bring more focus on what is expected from MSC, and to enable the early identification of any critical points by MSC in easily accessible way and also to allow efficient use of resources.

Item 10 – Opinion of MSC on ECHA's draft 9th recommendation of priority substances to be included in Annex XIV

The MSC Rapporteur provided a brief update regarding work by her and the Working Group in streamlining the MSC opinion template. Besides improving readability, the aim of the revision is to have a template that would enable MSC to focus on issues that are

important to it. She suggested that once the proposal is more advanced it will be shared with MSC for possible commenting.

Item 11 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2019-2021)

1. Report by SECR on the establishment of a MSC Working Group to support the Rapporteur in drafting the opinion of the MSC on the CoRAP update

SECR informed MSC that the MSC Working Group to support the Rapporteur in drafting the opinion of the MSC on the CoRAP update was established by written procedure on 24 September. The working group is made up of seven members including the (Co)-Rapporteur. This number of members was considered enough by the Rapporteur to assess the new substances and updated justification documents found on the draft CoRAP update.

2. Introduction of the annual draft CoRAP update (CoRAP 2019-2021) by ECHA

SECR presented the draft CoRAP update for 2019-2021. As per previous years, each substance has an accompanying justification document. The draft CoRAP including the initial grounds for concern and contact details of the evaluating Member State Competent Authorities (eMSCA) was published on the ECHA's website during the MSC meeting week i.e. on 10 October 2018. Substances on the CoRAP list were identified through the ECHA's common screening activities ACROSS, which started with IT pre-selection followed by manual screening performed by Member State Competent Authorities (MSCAs). The draft CoRAP update for years 2019-2021 has a total of 107 substances, 20 new CoRAP candidates, 76 already included in the CoRAP and 11 withdrawals. ECHA also named group of substances for common evaluation. SECR provided a template to eMSCAs to document their reasons for withdrawel of a substance from the CoRAP.

Stakeholder Observers (StOs) welcomed the introduction of the withdrawal document. A StO expressed concern with the withdrawal of substances from the CoRAP and with the number of substances with a potential concern that reside on the CoRAP for some time without being evaluated. SECR explained that a possible reason for such occurrences is the clarification of a concern through a CCH. Another StO asked for clarification on the naming of the group of substances and whether industry is involved in the group identification for the CoRAP. SECR mentioned that most of the groups come from the Registrants and other times from the evaluating MS.

The Rapporteur and working group have started reviewing the draft CoRAP update aiming to submit a first draft opinion to MSC for discussion at the MSC-62 meeting in December.

Item 12 - Annual review of stakeholder observers' participation at MSC *(Closed session)*

SECR presented the outcome of the MSC accredited stakeholder organisations (ASO) participation review, the feedback received from the regular ASO observers in this regard, the expressions of interest in MSC work of new ASOs and the expressed preferences of the new ASOs for their observer status (to become occasional MSC observers) and proposed way forward, as outlined in a respective document.

MSC considered the ASO participation in the past year in line with the MSC General approach[2] for admission of observers from ASOs and commitments made by MSC permanent observers in different quotas.

The Committee decided to re-confirm, within 'NGOs and Trade union' quota[3], the MSC regular observer status of: ETUC; the seven ENV & HH NGOs (ChemSec, Client Earth, EEB, Greenpeace, HEAL, Health Care without harm Europe and Women in Europe for Common Future) to share four seats[4] when participating in MSC plenary meetings within their rotation group; the four "Animal Welfare NGOs" (ECEAE, Eurogroup for Animals, HSI and PISC) to share two seats[5] when participating in MSC plenary meetings within their group.

[2] http://echa.europa.eu/documents/10162/13578/general_approach_aso_in_msc_work_en.pdf
[3] With seven seats allocated as follows: one seat for trade unions, four seats for ENV&HH NGOs, two seats for Animal Welfare NGOs
[4] i.e. four representatives from this rotation group to be physically present per meeting
[5] i.e. two representatives from this rotation group to be physically present per meeting

Furthermore, MSC decided to re-confirm within the 'Industry' quota[6] the regular observer status of Cefic, CONCAWE, Eurometaux, ORO, CEPE and FECC (the latter two to share one seat[7] when participating in MSC plenary meetings) and of UEAPME with possible occasional participation in MSC meetings, acknowledging the collaboration agreement of this ASO with the MSC observer from Cefic.

MSC decided also to re-confirm the occasional observer status of the remaining ASOs with maintained interest in MSC work (mainly sectorial ones). These are invited to follow the MSC work as occasional observers and participate in MSC plenary meetings on an occasional basis, in accordance with MSC General Approach on the ASO admission to the MSC work at the discretion of the MSC Chairman's decision.

The Committee also agreed on admission of three new ASOs (Bureau of International Recycling (BIR), European Association for Chemicals and Molecular Sciences (EuCheMS), MedTech Europe) as MSC occasional observers.

Members noted the feedback and the suggestions for improvement provided by the regular MSC ASO observers and agreed to share with the MSC regular ASO observers the Secretariat's review documents on ASO participation for the past year.

The MSC Chairman thanked MSC for the decisions taken and pointed out that MSC-S will inform ASOs concerned of these MSC decisions and will update the list of the MSC ASO observers[8] on ECHA's website after the meeting.

Item 13 – 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)

The MSC Chairman introduced the revisions and annotations made to the meeting document presented and discussed in MSC-60. Some MSC members asked clarifying questions on the document based on learnings from evaluation cases discussed in previous meetings. SECR noted that some rephrasing could make the text clearer, and stressed that the efficiency of the evaluation process is served with inclusion of all relevant information in the DD and PfAs, while only in exceptional cases a draft decision should be reverted back to an earlier step in the evaluation process. The document will be further revised by defining certain terminology used and it will be presented for further discussion in a later MSC meeting.

2. Report on MSC priorities action plan – Action 5 Rethink Webex aim – survey results

SECR introduced the results of a survey on the aims of preparatory teleconferences prior to MSC meetings. This was a follow-up for action on rethinking the ways of work of the MSC. Overall, 39% of the MSC members and alternates, and 15% of the eMSCAs submitted a response to the survey. The responses specific to three processes (dossier and substance evaluation, SVHC) were discussed under the relevant agenda items.

3. Update on appeals and court cases of relevance to MSC *(Partially closed session)*

SECR updated MSC on the status of cases submitted to the European Court of Justice relating to the authorisation process and of recent appeals submitted to the Board of Appeal (BoA) of ECHA on ECHA's evaluation decisions. MSC was further provided with analysis on these BoA/Court decisions.

MSC took note of the information received and further discussed the learnings from these decisions and possible remedial measures to be applied in future similar cases. It was underlined that it is important to respect the Registrant's right to be heard. Furthermore, Registrants' presence in MSC meetings does not necessarily provide an arena for registrants to be heard, but is an opportunity to follow the line of MSC deliberations on PfAs, but not a possibility for bringing new arguments. Thus, clearer PfAs could be made indicating explicitly the need to re-consult the registrant when decisive issues appear during MSC decision-making on evaluation draft decisions.

[6] With seven seats allocated to ASOs representing general industry interests
[7] i.e. one representative from this rotation group to be physically present per meeting
[8] http://echa.europa.eu/documents/10162/13578/list_aso_msc_observers_en.pdf

This issue has been further considered in the scope of dealing with late information, as outlined under agenda item 13.1.

4. EOGRTS status updates:

a) Report from COM on EOGRTS workshop and follow-up actions (e.g. REACH Committee)

A COM representative informed MSC on the REACH Committee expert workshop organised on 18 June 2018 in Brussels. Learnings from the workshop have been fed into the REACH Committee's ongoing discussions on three dossier evaluation cases which MSC had referred to the REACH Committee for decision making.

b) October workshop by NL

The alternate member from the Netherlands informed MSC that the workshop, originally scheduled for early October in the Netherlands, had to be postponed in light of the ongoing discussions in the REACH Committee. The MSC members and alternates from Germany, Denmark and Sweden who had volunteered to participate in the organising committee, supplemented by one ECHA expert and the MSC Chairman, would discuss the possible continued planning for a workshop, to be held in 2019, shortly after the MSC meeting.

5. Interpreting liver effects in toxicological studies in rodents – a brief report on UK authority work

An MSC expert from the United Kingdom introduced a document describing recent work agreed by an EFSA working group on interpreting liver effects in toxicological studies in rodents. The summarizing information on interpreting hepato-cellular hypertrophy, enzyme induction and liver weight increases was also made available as meeting document. The literature review suggested that normally liver cell hypertrophy and liver weight increase should be considered as potentially adverse effects. On a case-by-case basis hepatocellular hypertrophy, leading to ≤15% increased liver weight (mean absolute or relative), should not be regarded as adverse. MSC appreciated the provided information on ongoing scientific activities.

Item 14 – Adoption of main conclusions and action points

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

The MSC Chairman thanked the Estonian alternate member, leaving MSC on 3rd November, for her valuable contributions since 2015.

The MSC Chairman also specifically thanked the expert to the MSC member from the UK on the occasion of his last attendance of an MSC meeting, as well as a seconded national expert for her work as a member of the MSC secretariat.

II. List of attendees

Members/Alternate members	ECHA staff
AAVIK, Jaanika (EE)	AHRENS, Birgit
ALMEIDA, Inês (PT)	ANASTASI, Audrey Anne
ANDRIJEWSKI, Michal (PL)	AJAO, Charmaine
ATTIAS, Leonello (IT)	BELL, David
COCKSHOTT, Amanda (UK)	BERCARU, Ofelia
CONWAY, Louise (IE)	BROERE, William
DE KNECHT, Joop (NL)	CARLON, Claudio
DIMITROVA, Rada (BG)	CONSOLI, Elisa
DOBRAK-VAN BERLO, Agnieszka (BE)	DE WOLF, Watze
DUNAUSKIENE, Lina (LT)	DELOFF BIALEK, Anna
FINDENEGG, Helene (DE)	DREVE, Simina
HORSKA, Alexandra (SK)	HALLING, Katrin
HUMAR-JURIC, Tatjana (SI)	HAUTAMÄKI, Anne
JANTONE, Anta (LV)	JACQUET, Cyril
KOUTSODIMOU, Aglaia (EL)	JOHANSSON, Matti
KREKOVIĆ, Dubravka (HR)	KARJALAINEN, Anne-Mari
KULHANKOVA, Pavlína(CZ)	KORJUS, Pia
LE, Elisa (FR)	NYMAN, Anna-Maija
LUNDBERGH, Ivar (SE)	NAUR, Liina
MARTIN, Esther (ES)	RÖNTY, Kaisu
MIHALCEA UDREA, Mariana (RO)	STILGENBAUER, Eric
PALEOMILITOU, Maria (CY)	SIMON, Rupert
REIERSON, Linda (NO)	VAHTERISTO, Liisa
RISSANEN, Eeva (FI)	VALENTINI, Marco
TYLE, Henrik (DK)	VASILEVA, Katya
WAGENER, Alex (LU)	VERSONNEN, Bram
Representatives of the Commission:	VIEIRA LISBOA, Duarte
KOBE, Andrej (DG ENV)	
BARICIC, Peter (DG GROW)	
Observers	
ANNYS, Erwin (Cefic)	
BERNHARD, Alice (ClientEarth)	
DROHMANN, Dieter (ORO)	
FAßBENDER, Christopher (PETA)	
HÖK, Frida (ChemSec)	
KERÄNEN, Hannu (CONCAWE)	
LOONEN, Helene (EEB)	
MUSU, Tony (ETUC)	
WAETERSCHOOT, Hugo (Eurometaux)	

Proxies
- CONWAY, Louise (IE) also acting as proxy of DEIM, Szilvia (HU)
- HUMAR-JURIC, Tatjana (SI) also acting as proxy of STESSEL, Helmut (AT)
- TYLE, Henrik (DK) also acting as proxy of DUNAUSKIENE, Lina (LT) during short periods

Experts and advisers to MSC members
BARTHELEMY-BERNERON, Johanna (FR) (expert to LE, Elisa)
CIESLA, Jacek (PL) (expert to ANDRIJEWSKI, Michal)
COPOIU, Oana (RO) (expert to MIHALCEA UDREA, Mariana)
DOYLE, Ian (UK) (adviser to COCKSHOTT, Amanda)
EINOLA, Juha (FI) (adviser to RISSANEN, Eeva)
HASSOLD, Enken (DE) (expert to FINDENEGG, Helene)
HJORTH, Rune (DK) (expert to TYLE, Henrik)
INDANS, Ian (UK) (expert to COCKSHOTT, Amanda)
KUROVA, Martina (SK) (expert to HORSKA, Alexandra)
LANDVIK, Nina (NO) (adviser to REIERSON, Linda)

MALKIEWICZ, Katarzyna (SE) (expert to LUNDBERGH, Ivar)
ROSENTHAL, Esther (DE) (adviser to FINDENEGG, Helene)
SPURIENE, Otilija (LT) (expert to DUNAUSKIENE, Lina)

Registered to the WEBEX-phone connection:
BOISEN, Anne (DK)
DOYLE, Ian (UK)
GARCIA JOHN, Enrique (DG GROW)
HOY, Simon (UK)
KINZL, Max (AT)
SCHÖNING, Gabriele (DE)
STOCKER, Eva (AT)
TARNOCZAI, Timea (HU)

Case owners:
Representatives of the Registrants were attending under the Agenda Item 7.2 for SFWA category on stilbene fluorescent whitening agents (CCH-048 to CCH-061/2018).

Apologies:
DEIM, Szilvia (HU)
FRANZ, Michel (FR)
STESSEL, Helmut (AT)
VANDERSTEEN, Kelly (BE)
WIJMENGA, Jan (NL)

MSC/A/061/2018

Agenda

61st meeting of the Member State Committee

10-11 October 2018
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

10 October: starts at 9 am
11 October: ends at 12 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/061/2018
For adoption

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

Item 4 – Administrative issues

1 Outlook for MSC-62
2 Feedback from Committees Satisfaction Survey 2018

ECHA/MSC-61/2018/008
For information

Item 5 – Minutes of the MSC-60

- Final minutes of MSC-60

For information

Item 6 – Substance evaluation

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

   Not applicable to this meeting round

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

   Not applicable to this meeting round
3. Seeking agreement on draft decisions when amendments were proposed by MS-CA's/ECHA *(Session 2, closed)*

   Not applicable to this meeting round

[For agreement]

4. General topics

- Status report on on-going substance evaluation work

For information

- Rethinking MSC SEV Webex - Suggestions for way forward

ECHA/MSC-61/2018/014
For discussion and decision

Item 7 – Dossier evaluation

Start on Day 1
Closed session for 7.3

1. Written procedure report on seeking agreement on draft decisions on dossier evaluation[9]

ECHA/MSC-61/2018/002
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-61/2018/003
For information

For discussion followed by agreement seeking under 7.3:

Compliance checks

MSC code	Substance name	EC/List No.
SFWA category on stilbene fluorescent whitening agents (CCH-048 to CCH-061/2018):		
CCH-048/2018	Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-(diethylamino)-1,3,5-triazine-4,2-diyl]imino]]bis(benzene-1,4-disulphonate)	255-217-5
CCH-049/2018	Disodium 4,4'-bis[(4-anilino-6-morpholino-1,3,5-triazin-2-yl)amino]stilbene-2,2'-disulphonate	240-245-2
CCH-050/2018	Tetrasodium 4,4'-bis[[4-[bis(2-hydroxyethyl)amino]-6-(4-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate]	240-521-2
CCH-051/2018	Disodium 4,4'-bis[6-anilino-[4-[bis(2-hydroxyethyl)-amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate	224-073-5
CCH-052/2018	Tetrasodium 4,4'-bis[[4-[bis(2-hydroxypropyl)-amino]-6-[(4-sulphonatophenyl)amino]-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate	267-097-1
CCH-053/2018	Disodium 4,4'-bis[[4-anilino-6-[(2-carbamoylethyl)-(2-hydroxyethyl)amino]-1,3,5,-triazin-2-yl]amino]-stilbene-2,2'-disulphonate	248-420-5
CCH-054/2018	Disodium 4,4'-bis[[6-anilino-4-[(2-hydroxyethyl)-methylamino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate	237-600-9
CCH-055/2018	Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-[bis(2-hydroxyethyl)amino]-1,3,5-triazine-4,2-diyl]imino]]bis(benzene-1,4-disulphonate)	273-468-9
CCH-056/2018	Tetrasodium 2,2'-ethene-1,2-diylbis[5-({4-[diethylamino]-6-[(4-sulfonatophenyl)amino]-1,3,5-triazin-2-yl}amino)benzenesulfonate]	619-874-5
CCH-057/2018	Tetrasodium 4,4'-bis[[4-[(2-hydroxyethyl)amino]-	

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

	6-(m-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate	240-400-4
CCH-058/2018	Disodium 4,4'-bis[[4-anilino-6-[(2-hydroxyethyl)-amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate	241-883-4
CCH-059/2018	Tetrasodium 4,4'-bis[[4-morpholino-6-(p-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate	249-323-0
CCH-060/2018	Potassium sodium 4,4'-bis[6-anilino-4-[bis(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate	275-031-8
CCH-061/2018	Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-morpholino-1,3,5-triazine-4,2-diyl]imino]]bis(benzene-1,4-disulphonate)	257-827-7

ECHA/MSC-61/2018/004-5

CCH-073/2018	Fatty acids, C16-18 (even numbered) and C18 unsatd., reaction products with triethanolamine, di-Me sulfate-quaternized	931-203-0

ECHA/MSC-61/2018/006-7

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

   - Update from SECR about policy changes concerning dossier evaluation

For information

   - Suggestions for improvement of MSC Webex in dossier evaluation

ECHA/MSC-61/2018/017

For information

Item 8 – SVHC identification

1. Discussion on any potential process/procedural modifications in the Working procedures of MSC in SVHC identification

ECHA/MSC-61/2018/009

For discussion

2. Suggestions for improvement of MSC Webex in SVHC identification

ECHA/MSC-61/2018/015

For discussion

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

Update on review of the process for Annex XIV recommendations

For information and discussion

Item 10 – Opinion of MSC on ECHA's draft 9th recommendation of priority substances to be included in Annex XIV

Brief update from the Rapporteur and Working Group regarding MSC opinion template

For information and discussion

Item 11 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2019-2021)

1. Report by SECR on the establishment of a MSC Working Group to support the Rapporteur in drafting the opinion of the MSC on the CoRAP update

For information

2. Introduction of the annual draft CoRAP update (CoRAP 2019-2021) by ECHA

ECHA/MSC-61/2018/001
For information and discussion

Item 12 – Annual review of stakeholder observers' participation at MSC

Closed session

- Discussion and update of the MSC decision about the invited organisations

ECHA/MSC-61/2018/010
For discussion and decision

Item 13 – 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)

ECHA/MSC-61/2018/011
(*Closed session)*
For discussion

2. Report on MSC priorities action plan – Action 5 Rethink Webex aim – survey results

ECHA/MSC-61/2018/013
For information and discussion

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

(Open and closed session)
For information

4. EOGRTS status updates:
    a. Report from COM on EOGRTS workshop and follow-up actions (e.g. REACH Committee)

For information

    b. October workshop by NL

For information

5. Interpreting liver effects in toxicological studies in rodents – a brief report on UK authority work

ECHA/MSC-61/2018/018
For information

Item 14 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-61

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 dossier evaluation work (presentation slides)
2) RiME paper on identification of SVHCs under Article 57(f) – ELoC overview (ECHA/MSC-61/2018/012)
3) PfA types: Possible categorisation of types of PfAs in dossier evaluation cases (ECHA/MSC-61/2018/016, For members only)

APPENDIX to the MSC-61 agenda:

List of evaluation cases agreed by MSC in written procedure in advance of the MSC-61 meeting:

Dossier evaluation

Compliance checks

CCH-043/2018	p-(2,3-epoxypropoxy)-N,N-bis(2,3-epoxypropyl)aniline (EC No. 225-716-2)
CCH-044/2018	Hydrogenated rosin alcohols (List No. 701-057-0)
CCH-047/2018	2,4,6-tris(dimethylaminomethyl)phenol (EC No. 202-013-9)
CCH-088/2018	Neodymium oxide (EC No. 215-214-1)

Testing proposal examinations

TPE-056/2018	Reaction mass of 2-(1,1-dimethylpropyl)anthraquinone and 2-(1,2-dimethylpropyl)anthraquinone (List No. 915-623-1)

Main conclusions and action points
MSC-61, 10-11 October 2018
(adopted at MSC-61)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 6 – Substance evaluation 4. General topics • Rethinking MSC SEV Webex - Suggestions for way forward	
MSC took note and discussed the revised proposal. MSC agreed to try the presented revised proposal with pilot cases for MSC-62. MSC agreed to postpone the analysis of the use of MSC S-CIRCABC Newsgroup for bilateral discussions for after the pilot cases of MSC-62. MSC expressed preference for having the SEv Webex on a Friday or Monday right after the meeting documents become available to MSC.	eMS that have substance evaluation cases to be agreed at MSC-62 plenary meeting who are willing to "pilot" the approach (without the use of the MSC S-CIRCABC Newsgroup), and use the proposed RCOM template to volunteer by Monday 15 October by sending an email to msc@echa.europa.eu. MSC-S to assess the comments of the MSC members on the possible use of the MSC S-CIRCABC Newsgroup and present a suggestion to MSC after the pilot. MSC-S to update the revised RCOM template based on the discussion at MSC to be used in the pilot.
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. Final ECHA decisions will become available at ECHA website in due course.
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-073/2018 Fatty acids, C16-18 (even numbered) and C18 unsatd., reaction products with triethanolamine, di-Me sulfate-quaternized (EC No. 931-203-0) *SFWA category on stilbene fluorescent whitening agents (CCH-048 to CCH-061/2018):*	MSC-S to upload on MSC S-CIRCABC the agreed decisions in the respective case folders. Final ECHA decisions will become available at ECHA website in due course.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
CCH-048/2018 Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-(diethylamino)-1,3,5-triazine-4,2-diyl]imino]]bis(benzene-1,4-disulphonate) (EC No. 255-217-5) CCH-049/2018 Disodium 4,4'-bis[(4-anilino-6-morpholino-1,3,5-triazin-2-yl)amino]stilbene-2,2'-disulphonate (EC No. 240-245-2) CCH-050/2018 Tetrasodium 4,4'-bis[[4-[bis(2-hydroxyethyl)amino]-6-(4-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate] (EC No. 240-521-2) CCH-051/2018 Disodium 4,4'-bis[6-anilino-[4-[bis(2-hydroxyethyl)-amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate (EC No. 224-073-5) CCH-052/2018 Tetrasodium 4,4'-bis[[4-[bis(2-hydroxypropyl)-amino]-6-[(4-sulphonatophenyl)amino]-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate (EC No. 267-097-1) CCH-053/2018 Disodium 4,4'-bis[[4-anilino-6-[(2-carbamoylethyl)-(2-hydroxyethyl)amino]-1,3,5,-triazin-2-yl]amino]-stilbene-2,2'-disulphonate (EC No. 248-420-5) CCH-054/2018 Disodium 4,4'-bis[[6-anilino-4-[(2-hydroxyethyl)-methylamino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate (EC No. 237-600-9) CCH-055/2018 Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-[bis(2-hydroxyethyl)amino]-1,3,5-triazine-4,2-diyl]imino]]bis(benzene-1,4-disulphonate) (EC No. 273-468-9) CCH-056/2018 Tetrasodium 2,2'-ethene-1,2-diylbis[5-({4-[diethylamino]-6-[(4-sulfonatophenyl)amino]-1,3,5-triazin-2-yl}amino)benzenesulfonate] (EC No. 619-874-5) CCH-057/2018 Tetrasodium 4,4'-bis[[4-[(2-hydroxyethyl)amino]-6-(m-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate (EC No. 240-400-4) CCH-058/2018 Disodium 4,4'-bis[[4-anilino-6-[(2-hydroxyethyl)-amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate (EC No. 241-883-4) CCH-059/2018 Tetrasodium 4,4'-bis[[4-morpholino-6-(p-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate (EC No. 249-323-0)	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
CCH-060/2018 Potassium sodium 4,4'-bis[6-anilino-4-[bis(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate (EC No. 275-031-8) CCH-061/2018 Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-morpholino-1,3,5-triazine-4,2-diyl]imino]]bis(benzene-1,4-disulphonate) (EC No. 257-827-7)	
4. General topic • Suggestions for improvement of MSC Webex in dossier evaluation	
MSC discussed the outcome of MSC survey on DEv teleconferences (Webex). MSC took note of the results.	MSC-S to continue the current approach with DEv teleconferences.
Item 8 – SVHC identification - Seeking agreement on Annex XV proposals for identification of SVHC 3. Discussion on any potential process/procedural modifications in the Working procedures of MSC in SVHC identification	
MSC took note on the suggestions made and the SECR's responses and agreed that there is no need for modification of the MSC SVHC working procedures at this point in time.	
Item 8 – SVHC identification - Seeking agreement on Annex XV proposals for identification of SVHC 4. Suggestions for improvement of MSC Webex in SVHC identification	
MSC discussed the suggestions received for improvement of MSC SVHC Webex, as outlined in document ECHA/MSC-61/2018/015. Members agreed: • To follow the Newly suggested approach - Issue identification and more in-depth discussion during the Webex and plenary discussion on a few highlighted unresolved issues only, • To support MSC-S and provide guidance to their MS colleages, acting as Dossier submitters, in their preparations for MSC Webex and plenary meeting related to the new approach on issue identification, • To commit to the Webex participation or submit comments/views (if not provided in public consultation), in advance of the Webex to allow proper preparation and issue consideration by the dossier submitter and other members of MSC.	MSC-S to follow the agreed way forward and make the necessary adjustments in the current SVHC Webex approach, as relevant. MSC-S to further explore the possibilities for using S-CIRCABC newsgroups for potential informal exchange of views with dossier submitters, Secretariat and other members in the context of the SVHC process and report back to MSC in some of the forthcoming meetings.
Item 9 – ECHA's recommendations of priority substances to be included in Annex XIV Update on review of the process for Annex XIV recommendations	
MSC took note of the planned changes as regards updates and documentation from SECR to MSC after closure of the public consultation.	SECR to provide highlights from the public consultation in MSC-63.
Item 10 – Opinion of MSC on ECHA's draft 9th recommendation of priority substances to be included in Annex XIV	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Brief update from the Rapporteur and Working Group regarding MSC opinion template	
MSC took note of the plans to streamline the MSC opinion template.	Rapporteur to provide an updated opinion template to MSC for possible comments later this year and to report on further progress in one of the upcoming plenaries.
Item 11 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2019-2021) 1. Introduction of the annual draft CoRAP update (CoRAP 2019-2021) by ECHA	
MSC took note of the draft CoRAP update.	MSC-WG to take into account the changes introduced in the draft CoRAP following the referral.
Item 12 – Annual review of stakeholder observers' participation at MSC • Discussion and update of the MSC decision about the invited organisations	
MSC took note of the update of the ASO observers' participation in the MSC work and took the following decisions: 1. With regard to the admission of ASOs as MSC permanent observers in different quotas, MSC decided to: • reconfirm the MSC regular observer status of: ➢ seven Environmental and Health Care NGOs (ChemSec, Client Earth, EEB, Greenpeace, HEAL, Health Care without harm Europe and Women in Europe for Common Future) within their rotation group to share four seats when participating in MSC plenary meetings, ➢ four "Animal Welfare NGOs" (ECEAE, Eurogroup for Animals, HSI and PISC) within their group to share two seats when participating in MSC plenary meetings, ➢ ETUC, Cefic, Concawe, Eurometaux and ORO, ➢ CEPE and FECC within a rotation group to share one seat when participating in MSC plenary meetings. • keep the regular observer status of UEAPME who is to be represented on a regular basis by the MSC observer from Cefic and will participate in the MSC meetings on occasional basis. 2. With regard to the admission of ASOs as MSC occasional observers, MSC desided to: • re-confirm the occasional observer status of the remaining stakeholder organisations (mainly sectorial ones) previously invited to follow the MSC work as sector-specific observers on an occasional basis, in accordance with MSC General approach on the ASO admission to the MSC work at the discretion of the MSC Chair's decision, • agree on admission of BIR, EuCheMS and MedTech Europe as MSC occasional observers. MSC also agreed to share with the MSC regular observers the Annual report regarding the ASO participation in the MSC work and corresponding presentation given at the plenary.	MSC to review ASO participation in its work in one year's time. MSC-S to upload the Annual report regarding the ASO participation in the MSC work and corresponding presentation to MSC S-CIRCABC for MSC regular observers' information. MSC-S to inform ASOs concerned of the MSC decisions taken and to update the list of the MSC ASO observers on ECHA's website after the meeting.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 13 – Any other business	
MSC took note of the information provided on the five items presented. 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)	Specific action: MSC-S to rephrase certain parts of the document based on the discussion. Revised document to be planned for discussion at earliest opportunity e.g. MSC-62
Item 14 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-61 at the meeting.	MSC-S to upload the main conclusions and action points on MSC S-CIRCABC by 12 October 2018.