MSC/M/63/2019
Adopted by written procedure
on 8 April 2019

Minutes
of the 63rd Meeting of the Member State Committee (MSC-63)
5-7 February 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 63rd meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

Item 2 - Adoption of the Agenda

. As regards the agenda the Chairman suggested including an item for discussion and possible adoption under item 6.4 on regular use of updated substance evaluation (SEv) response to comments (RCOM) template. The Chairman also suggested including an any other business-item about a consultation on deviation from test conditions in SEv, based on a request from a member, and an information item proposed by a stakeholder observer on their publication of a report on evaluation. 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

No potential specific interests were declared by the Chairman, any members, experts or advisers with any item on the agenda of MSC-63.

Item 4 - Administrative issues

Outlook for MSC-64

The Chairman presented an outlook on the potential length of the next meeting which is expected to require 2,5 plenary days. The Chairman also presented an early stage estimation for the length of the MSC-65 meeting in June 2019 which is expected to require app. 5 full days.

ECHA Organisation Chart

The Chairman informed MSC of the reorganisation which ECHA has gone through recently. He shared the new organisation chart and explained the new position of the MSC Secretariat. He also highlighted that ECHA has recently published a call for Seconded National experts with a deadline for application of 31 March 2019. He encouraged the colleagues from Member States to specifically join MSC Secretariat as seconded national experts or to promote the call to any potential candidates.

MSC Meeting dates 2020

The Chairman provided an outlook for the planned MSC meeting dates in 2020 and also informed MSC that ECHA will be taking its new building in use in January 2020.

Item 5 – Minutes of the MSC-62 meeting

The minutes of MSC-62 were adopted as modified at the meeting.

Item 6 – Substance evaluation

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

No cases

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-2-UK-037/2014 Climbazole EC No 253-775-4

Session 1 (open)

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

The evaluating Member State Competent Authority (eMSCA) from the United Kingdom (UK-CA) presented the current status of this SEv case (SEV-2-UK-037/2014). The initial grounds of concern when placed on the Community Rolling Action Plan (CoRAP) were relating to human health / suspected CMR (reproductive toxicity with unusual and severe general toxicity noted) and human exposure (wide dispersive use, consumer use). In the course of the evaluation of SEV-UK-037/2014, the evaluating MSCA identified additional concerns regarding worker exposure and, for the environment - the risk assessment and endocrine disruption.

The currently discussed draft decision (DD) covered the concerns related to environment endocrine disruption (ED). These ED concerns were addressed in the previous SEv decision but the request for information was annulled by the Board of Appeal A-009-2016 on procedural grounds.

On this basis, the evaluating MSCA decided to re-submit the requests for the *in vitro* endocrine disruption screening studies in a second decision (SEV-2-UK-037/2014). The DD requested for 1) *H295R steroidgenesis in vitro assay (OECD TG 456)* and *2) Stably Transfected Human Androgen Receptor Transcriptional Activation Assay for Detection of Androgenic Agonist and Antagonist Activity of Chemicals (OECD TG 458)* to investigate the aromatase inhibition and androgen receptor activity.

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

One PfA on the follow-up test proposals was considered as a comment, possibly to the Registrants by the eMSCA. This was considered resolved without leading to an amendment in the DD in advance of the meeting. The MSC discussion focused on the unresolved PfAs.

Both PfA submitters considered that the available data (Tox 21 and Chen *et al.*) was raising sufficient concern to replace the proposed mechanistic *in vitro* studies with an appropriate *in vivo* study. Furthermore, both MSCAs argued that negative results from *in vitro* studies would not be sufficient to remove the ED concerns. Hence they proposed to replace the *in vitro* requests with a request for a Fish Sexual Development Test (FSDT) (OECD TG 234). Additionally, if the eMSCA still wished to keep the two *in vitro* studies, one MSCA proposed to add a request for an FSDT (OECD TG 234). This PfA submitter stressed the agreement by the Registrant to perform an OECD TG 234 as the Registrant considers this as the most appropriate test in their comments to the initial DD of this second evaluation (SEV-2-UK-037/2014) taking into account the alternatives listed as examples in the DD by UK-CA. In their comments the Registrants referred to the previous MSC discussion on the first substance evaluation (SEV-UK-037/2014) DD addressing this concern and agreed that due to effects on vitellogenin seen in an OECD TG 234 for ECHA's proposed read across substance, negative results *in vitro* might still trigger further testing in fish. A separate PfA addressed the proportionality of the FSDT request by assessing alternative approaches such as the Androgenised Female Stickleback Screen (AFSS), which the PfA submitter does not consider as an alternative to the FSDT. The PfA submitter expressed agreement with the DD that the sewage treatment plant simulation test requested in the first SEv decision SEV-UK-037/2014 should not be used for delaying testing related concerns on possible endocrine effects in vertebrate wildlife. Hence it was additionally proposed that if the FSDT was not sufficiently supported to request instead for a Fish Short Term Reproduction Assay (FSTRA, (OECD TG 229)) which measured whether

the test substance induces vitellogenin and impact on fecundity and if neither FSDT nor FSTRA are supported, to request for a fish screening assay (FSA;(OECD TG 230)) which is similar to FSTRA without fecundity as an endpoint.

The Registrants had submitted written comments on the PfAs which they reiterated in the meeting. The Registrants' representatives expressed their agreement with the PfAs to delete the *in vitro* requests and to request for a FSDT instead. In their view the FSDT would address all relevant mode of actions and would allow a final assessment, in contrast to any *in vitro* assay. They argued that information gained with additional *in vitro* tests is a 'waste of money', since it would not provide any additional relevant information for the ED assessment. They highlighted that their support for the *in vivo* test follows the arguments raised by ECHA and the discussions taken place at the MSC meeting, but note that they still do not consider the read across approach used or the *in vitro* data set so straight forward although this seemed to be the consensus of MSC.

The Registrants' representatives also expressed the view that the level 3 tests AFSS, FSTRA or FSDA are not a suitable alternative for the FSDT. Furthermore, the results from these tests cannot be used for risk assessment so an additional Fish Early-Life Stage (FELS) (OECD TG 210) would still need to be performed. They however disagreed with SECR and the PfA submitter on the absence of a link between the results from the sewage treatment plant simulation test and the tests to be requested to address the ED concern. In their view, if the simulation test showed that the exposure of the environment was insignificant or metabolites become more relevant, then a possible endocrine concern in vertebrate wildlife was without relevance or the testing regime might need some modification e.g. number of concentrations to be tested. Hence they were of the view to wait for the results of the sewage treatment plant simulation test (OECD TG 303), available in August 2019, before starting the *in vivo* test. They also expressed their willingness to share the results before updating the registration dossier to allow a decision as soon as possible. Finally, the Registrants' representatives explained that if the *in vitro* tests remained in the decision, the Registrant needed to know the next steps in case there were negative results.

In the following discussion, the eMSCA expert explained that their testing strategy was based on the OECD conceptual framework for evaluating chemicals for endocrine disruption (OECD GD 150. Although the imidazole group, i.e. the chemical group that climbazole is part of, contains several recognised endocrine disruptors, in their view currently there were no sufficiently reliable ED data for climbazole to justify in vivo testing. Therefore *in vitro* testing was proposed first, with higher level test following if required. However, it was counter-argued that for the imidazole group there was sufficient *in vitro* and *in vivo* data to justify an *in vivo* test, and negative *in vitro* results would not be sufficient to remove the ED concerns. The latter view was in line with the ECHA/EFSA guidance for the identification of endocrine disruptors in the context of Regulation (EU) 528/212 and EU 1107/2009. On the contrary, the eMSCA was of the view that a negative *in vitro* result was sufficient to remove ED concerns citing OECD 150 and the *in vitro* test guidelines.

Furthermore, *in vitro* studies, if requested, would be inconclusive because the AhR receptor binding would not be covered by the proposed *in vitro* studies and therefore one cannot definitely conclude on this mode of action.

With regards to the number of concentrations to be tested, if the FSDT is requested, the Registrants' representatives explained that five test concentrations would increase the statistical power of the results hence making it possible to be used for risk assessment. This was also the view expressed by MSC. However, the Registrants' representatives again expressed their preference to wait for the results from the OECD TG 303 to be able to decide on the number of concentrations to test in the FSDT due to animal welfare.

Session 2 (closed)
The eMSCA presented three testing strategy options to MSC. Option 1 to request the two *in vitro* studies. Option 2 to request the FSTRA (OECD TG 229). Option 3 to request for the FSDT (OECD TG 234).

MSC expressed a clear preference for option 3. The change in the approach by MSC as compared to the first decision that was appealed, which requested the same *in vitro* studies as contemplated now, was considered justified due to the change in circumstances as discussed above. Firstly, the recent publication of the ECHA/EFSA guidance and secondly the fact that the AhR receptor binding was not covered by the *in vitro* tests proposed. Furthermore, the Registrant expressed preference in performing the FSDT over the *in vitro* tests.

MSC acknowledged the argument by the Registrants' representatives to await the result from the simulation study for him to assess whether to perform the FSDT only for ED purposes, or ED and risk assessment.

MSC agreed unanimously to 1) remove the requests for the *in vitro* studies, 2) introduce the request for Fish Sexual Development Test (FSDT), test method OECD TG 234, using Zebrafish (*Danio rerio*) or Medaka (*Oryzias latipes*) and 3) to change the deadline from 8 months to 21 months, to reflect the change in the requested studies and time needed to perform them as well as to allow the Registrants to consider the results of the simulation study for deciding on the number of concentrations in the FSDT.

The UK member abstained from voting and submitted a written statement (Annex V).

4. General topics

- Status report on on-going substance evaluation work

SECR informed MSC about the status of the 21 evaluations which started in March 2018 (substances on the CoRAP for 2018) and the plans for sending draft decisions to the registrants. Currently 13 such draft decisions are foreseen and on those the registrants should then be commenting in May. SECR also provided an update on the number of substance evaluation cases from 2013 to 2016 for which the evaluating MS has not yet progressed to the decision making phase. The status update included also information about several substances which are currently under piloting of a more integrated interplay of substance and dossier evaluation.

- Use of updated SEv RCOM template *(Closed session)*

SECR highlighted to MSC the updated substance evaluation response to comments (SEv RCOM) template which has been modified to include which proposal for amendments (PfAs) are considered by the evaluating MSCA to be resolved and not requiring further MSC discussion. SECR also summarised the positive feedback received by the evaluating MSCAs that used it in preparation for MSC-62. The MSC acknowledged as well the usefulness of this updated version and Members agreed to ask their MSCA counterpart to start using the updated SEv RCOM template from now onwards.

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-63 agenda" for more detailed identification of the cases). WP was launched on 10

January 2019. By the closing date 21 January 2019, MSC reached unanimous agreement on all DDs.

SECR referred to an action point from MSC-62, where MSC asked "MSC-S to update the written procedure voting sheets to more clearly distinguish between comments and justifications requested to be included in a written procedure report". This action was implemented in MSC-63 for dossier evaluation written procedure, with a separate sheet for "notes" in the Excel spreadsheet file. SECR noted that it always checks that sheet for any remarks during and after the written procedure. If members have indicated their wish to include such remarks in the annex of the written procedure report, SECR will take action accordingly.

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-130/2018 Ethyl (z,z)-9,9-dioctyl-4,7,11-trioxo-3,8,10-trioxa-9-stannatetradeca-5,12-dien-14-oate (substance defined by its IUPAC name; previously was EC No. 268-500-3)

Session 1 (open)

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

SECR introduced the proposals for amendment (PfA) that required discussion in the meeting. The first PfA on chronic aquatic toxicity suggested, due to a data gap, requesting fish sexual development test (FSDT, OECD testing guideline (TG) 234) with five concentrations conducted with dioctyltin oxide (DOTO). The registered substance is poorly water soluble and potentially hydrolyses to DOTO. Organotins are known for their ED properties and DOTO is listed in CoRAP with a concern for endocrine disrupting properties. The second PfA on the extended one-generation reproductive toxicity study (EOGRTS) suggested removing the request for the EOGRTS. The EOGRTS request is triggered by data from a screening study on DOTO (a read-across substance and putative hydrolysis product). The PfA argues in the lines that the current read-across adaptation of the information requirement is not acceptable, as the Registrants had not provided sufficient evidence that DOTO is a metabolite of the registered substance, and so using DOTO data to trigger the EOGRTS study is not justified.

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

In the discussion on the PfAs the MSC first established that there is a data gap on the fish long-term toxicity. However, the PfA on fish had specifically requested testing on the potential hydrolysis product DOTO, but not the registered substance. ECHA has accepted that the read-across to DOTO is not sufficiently justified and so it considered that a fish test on a read-across substance (the potential hydrolysis product, DOTO) cannot be requested in the current decision.

In respect of the EOGRTS PfA, the MSC took note that the Registrant had waived the 90-day repeated-dose toxicity (RDT) testing using a 28-day reproductive screening study on the read-across substance, DOTO. Based on the results of the reproductive screening study, the Registrant self-classified the registered substance as STOT RE 1 (specific target organ toxicity - repeat exposure). SECR had not considered the provided read-across to adapt the information requirement fully justified at a scientific level, due to lacking information on metabolite formation and kinetics of the registered substance. However noting the self-classification and the fact that an EOGRTS is triggered based on the results of the reproductive screening study, SECR considered that it would not be proportionate to request a 90-day RDT study on the registered substance. The MSC noted that these results submitted as a waiver to the 90-day RDT could provide a trigger for the EOGRTS

on the registered substance, for the purpose of the REACH regulation (Annex IX, column 1, available RDT study, 8.7.3). The MSC took note of the specific concern expressed in the PfA that DOTO is undergoing a dossier evaluation with a decision deadline for EOGRTS results in February 2019 and that EOGRTS could be conducted for both the registered substance and DOTO. The Registrant has raised the possibility of establishing a read-across from DOTO to the registered substance in his comments on the draft decision, and ECHA has commented on the deficiencies of the existing read-across justification in the dossier.

Session 2 (closed)

The MSC first discussed the PfA on long-term fish toxicity testing. It acknowledged that (a) there was no PfA requesting a long-term fish testing on the registered substance, (b) and an information gap exists on aquatic environment, and (c) the possibility to open a new, targeted compliance check to clarify this environmental concern. The MSC agreed on amending the DD to invite the Registrant to consider submitting a testing proposal for long-term fish toxicity testing and conducting a study to fulfil the information requirement for a growth inhibition study on aquatic plants. The MSC took note of the possible delay in aquatic testing due to the timeline of 30 months for this DD and concluded that the updated dossier would be duly assessed in the follow up, in particular if the data gap would still persist.

Then, focusing on the PfA on EOGRTS, the MSC considered that (a) the 28-day study with DOTO has provided legal basis for concern to trigger EOGRTS due to observed adverse effects on reproductive organs or tissues and other concerns in relation with reproductive toxicity; (b) this triggering does not indicate that, for other endpoints, studies with DOTO would constitute a reliable basis to predict properties of the registered substance. The MSC agreed that the read-across to DOTO for the 90-day endpoint can be accepted as 'worst-case', and provides acceptable information to protect human health. The MSC considered that it had to take a decision on the registered substance based on currently available information and data and the text of the DD was amended accordingly.

The MSC summarized its overall agreement, as specified in the amended DD and including also the endpoint requests discussed in the meeting, (a) to request long-term *Daphnia magna* reproduction test; (b) to invite the Registrant to consider submitting a testing proposal for long-term toxicity testing on fish and conducting a study for a growth inhibition study on aquatic plants; (c) to request a pre-natal developmental toxicity study (PNDT); and (d) to request an EOGRTS without extension to mate the cohort 1B animals to produce the F2 generation.

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

CCH-145/2018 1-[(2-chloro-4-nitrophenyl)azo]-2-naphthol (EC No. 220-562-2)

Session 1 (open)

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

SECR introduced the proposals for amendment (PfA) that required discussion in the meeting.

Two PfAs on *in vivo* mammalian alkaline comet assay suggested under this information request to ask also for the collection and processing into slides of gonadal cells, as well as for analysis of these slides in case a positive result from the testing with the registered substance is obtained in any of the somatic tissues. Other PfAs on the same endpoint proposed to modify the respective text to reflect the 1st PfA under Appendix I (Reasons) and under the notes for consideration to clarify the potential interpretation of results in the gonadal cells.

A PfA on transgenic rodent (TGR) somatic and germ cell gene mutation assays suggested to indicate, under the notes for the Registrant's consideration, that for this case TGR is

more appropriate than the comet assay considering that there was only a concern for gene mutations, observed in the *in vitro* assays.

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

Members from the PfA-submitting Member States explained the rationale for their PfAs, and the Committee's discussion focused on the interpretation of potential *in vivo* comet results and on the storage time of the slides prepared from gonadal cells, if the examination of gonadal cells becomes part of the request (instead of only a recommendation).

It was noted that although both TGR and comet assays are considered in the ECHA Guidance as appropriate in vivo follow-up tests to clarify a genotoxicity concern, the results should allow for the ECHA Risk Assessment Committee (RAC) a classification and labelling conclusion on germ cell mutagenicity. However, the comet assay has not been validated yet for germ cell mutagenicity testing. While a positive test result in the gonadal cells (comet assay) could support RAC in classifying a substance as a germ cell mutagen, an ambiguous or negative result is inconclusive for establishing a lack of gene mutation induction in germ cells and may trigger a need for further testing. Thus, the TGR may be a more appropriate choice for the Registrant to follow at first.

The SECR clarified that the storage of slides from gonadal cells do not require any specific treatment: slides can be stored at room temperature, in slide boxes, in dry conditions, during 2-3 months before analysis.

Session 2 (closed)

SECR informed MSC of the ongoing development of an approach (further summarised under item 4.1) on how to deal with germ cell genotoxicity testing under dossier evaluation and proposed to postpone the general discussion, but to focus on case-specific decision-making.

Considering the views exchanged and the way forward proposed, MSC agreed to leave to the Registrant the choice of the *in vivo* test method (TGR or comet) for generating the requested information. Taking into account SECR's remark in case the test results confirm the occurrence of genotoxicity on somatic cells, that additional information on germ cell genotoxicity could be requested via a follow-up compliance check decision for further germ cell mutagenicity testing. MSC supported SECR's suggestion to keep the germ cell mutagenicity considerations as a recommendation for the Registrant.

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

CCH-154/2018 C,C'-azodi(formamide) (EC No. 204-650-8)

Session 1 (open)

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

SECR explained that proposals for amendment (PfAs) to ECHA's DD had been received, which are the same or similar to the ones submitted for CCH-145/2018.

Two PfAs on *in vivo* mammalian alkaline comet assay suggested under this information request to ask also for the collection and processing into slides of gonadal cells, as well as for analysis of these slides in case a positive result from the testing with the registered substance is obtained in any of the somatic tissues. Other PfAs on the same endpoint proposed to modify the respective text to reflect the 1st PfA under Appendix I (Reasons) and under the notes for consideration to clarify the potential interpretation of results in the gonadal cells.

The Registrant had not submitted written comments on the PfAs.

Due to the similarity of the PfAs and issues raised with CCH-145/2018, MSC agreed to discuss both compliance check cases under CCH-145 discussion sessions and to apply by analogy the relevant conclusions made, to the current CCH case.

Session 2 (closed)

In line with the exchanged considerations and conclusions made for CCH-145/2018, MSC supported the SECR's approach followed in this DD.

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

CCH-153/2018 1-(N,N-bis(2-hydroxyethyl)amino)propan-2-ol (EC No. 229-764-5)

Session 1 (open)

One representative of the Registrant participated in the initial discussion. In the absence of specific confidentiality concerns in the draft decision (DD), an open session was held.

SECR introduced the proposal for amendment (PfA) that required discussion in the meeting. The PfA on pre-natal developmental toxicity study (PNDT), second species, suggested removing the request, arguing that the observed effects in available studies would not constitute sufficient concern to trigger testing in second species.

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

The representative of the Registrant reconfirmed its considerations based on the PNDT study in rat, submitted to the technical dossier, that delays in ossification and other observations were not deemed to be related to any developmental effects and would not require further follow-up testing.

The MSC considered that the high incidence of reduced ossification noted specifically in the skull, together with the information on maternal toxicity (minimal or none) and foetal weight (no reduction), provide a sufficient concern for developmental toxicity.

Session 2 (closed)

The MSC noted that, among other observed effects in the available study, there was a statistically-significant and dose-dependent increase in the incidence of foetuses with reduced ossification of several skull bones that could not be considered secondary to maternal toxicity. The MSC considered there were sufficient indications to raise a concern for developmental toxicity, to be followed up with a PNDT on second species.

The MSC summarized its agreement, as specified in the amended DD, to retain the PNDT study in a second species (rabbit), oral route.

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

4. General topics

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

SECR gave a presentation on the status of the work on *in vivo* mutagenicity testing on germ cells under compliance check of Annex IX or X dossiers in line with MSC's decision and requests at MSC-62. The MSC welcomed the action taken so far by SECR, suggested to also establish links with members of the Risk Assessment Committee (RAC), continued supporting the storing of germ cells or of gonadal cells slides for possible later analysis, and expressed the wish to have suggestions for clear paths forward based on the outcome of the requested assays . The Chairman emphasized that the group of experts should focus on scientific aspects of the matter, and that the MSC members should ensure the regulatory context is addressed. MSC invited SECR to make the expert document available for MSC-64 for discussion.

2. **Regulatory challenges in compliance checks *(Closed session)***

SECR informed MSC of some outcomes of the REACH review published early 2018, noticing that REACH progress lags behind initial expectations in some areas due to the quality of the collected registration dossiers and presented to the members actions currently undertaken and further envisaged to ensure the appropriate data quality in the registration dossiers via more efficient use of compliance checks. Furthermore, the committee was introduced with the new compliance check targets, priority settings and other actions planned to address the new regulatory challenges and increase the efficiency of the evaluation process.

MSC was invited to discuss with their CAs and share with ECHA their comments/suggestions where further clarifications of the REACH information requirement annexes could facilitate compliance checks.

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

Not relevant for this meeting.

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

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

The Rapporteur and working group presented their draft of the MSC opinion on the CoRAP 2019-2021. The justification document for Resorcinol had been updated since MSC-62. MSC reflected on the reintroduction of Resorcinol on the CoRAP 2019-2021 upon request from France after Finland had concluded their substance evaluation on Resorcinol with a Member State conclusion document (i.e. not a draft decision). The discussion focussed on a) the legal aspects, b) the sensitivity around divergence of views between two Member States, c) the outcome of substance evaluation (SEv) workshops from a few years ago, and d) the predictability of the process for industry.

Regards the legal aspects, SECR clarified that the provision in Article 47 (1) of REACH refers to cases where decisions on evaluation have already been taken. Hence Article 47 (1) does not apply to cases concluded without issuing a SEv (draft) decision. Hence legally such a case can be re-introduced on the CoRAP even if there are no change of circumstances. The Commission representative concurred with this legal interpretation.

Regards the divergence of views between two Member States, the Finnish member provided suggestions to France for some late revisions of the Justification Document, which were accepted by France. The Finnish member also provided suggestions for text changes to the draft MSC opinion which also were considered acceptable to the Rapporteur and MSC. It was acknowledged by MSC that the diverging views on the applicability of test results for regulatory risk management purposes, from tests which may be requested in a SEv decision, should be expressed through the submission of proposals for amendments in the SEv decision making process. MSC also noted that evaluation and regulation of endocrine disruptors and suspected endocrine disruptors are a priority for the French Authorities, and that this substance is included in the French National Strategy for Endocrine Disruptors. MSC did not consider a national priority as a valid argument for re-introducing resorcinol on the CoRAP 2019-2021. Therefore, MSC agreed to remove the reference to national priority as an additional argument in the MSC opinion.

Therefore MSC was of the opinion that resorcinol can be reinserted in the CoRAP 2019-2021.

To avoid, to the extent possible, potential divergent views between Member States a call for early, informal discussions on draft conclusion documents, for instance in ECHA expert groups, was made. It was noted that in the specific case of resorcinol, a lot of interactions between Member States during ED expert group and RiME meetings took place, prior to this part of the process, which however did not lead to resolution of the diverging views.

The Rapporteur and co-Rapporteur had reviewed the reports of the previous SEv workshops. Similar conclusions regarding the legality of a re-introduction and early, informal interaction with other Member States had been reached, so as to try and incorporate in the same SEv process elements of concern raised by other Member States.

Finally with regards to the predictability of the process, MSC recognised that reintroduction of a substance should remain a highly exceptional situation. In fact, this was the first time since the start of the CoRAP process that a Member State requested a re-introduction.

A stakeholder observer underlined the importance of the COMBO approach (an approach where a dossier evaluation (DEv) compliance check is triggered during an ongoing SEv when such a need is identified by the eMSCA) and the alignment of DEV and SEV so as to reduce the number of cases that reside on the CoRAP for a long time. Also the withdrawal documents were appreciated as they increased the transparency of the process.

MSC adopted by consensus the opinion on the draft annual CoRAP update 2019-2021, as amended at the meeting, and its annex. It was concluded that the MSC opinion together with the final update to CoRAP will be published on the ECHA.

Item 10 – 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

1) Highlights from the comments received in the public consultation - summary by the Secretariat

SECR presented the highlights from the comments received in the public consultation on ECHA's 9th draft recommendation. All 18 substances had received comments which are published on ECHA's website. A summary of the main comments was presented without yet entering into analysing them since that analysis is still ongoing. By the end of March SECR plans to provide the MSC with its assessment on the impact of the comments and of registration updates on priority, latest application dates and exemption requests.

2) Brief report from the Rapporteur and Working Group

The first review by the Rapporteur and Working Group of the comments from the public consultation was much aligned on the highlights by ECHA. Therefore the Rapporteur focused her intervention on the stage of the working group's work, reminding MSC also that revised opinion and support document templates are used. First discussion on MSC's draft opinion on the 9th draft recommendation will take place in May (MSC-64), with adoption of final opinion anticipated then in the June meeting of MSC.

SECR noted that the finalisation of the 9th recommendation and its sending to the COM is foreseen after summer.

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

- Discussion of tasks and appointment of Rapporteur for drafting MSC opinion

MSC agreed by consensus to the terms of reference for the rapporteur and co-rapporteur as was presented by SECR, for the purpose of drafting the MSC opinion on the new draft

ECHA recommendation to amend the entries of Annex XIV of the four phthalates. Following the call for indications of interest to the tasks, two members had indicated interest, one to the rapporteurship and another one for the tasks of a co-rapporteur. MSC appointed these two of its members, respectively.

Item 11 – Any other business

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

SECR gave an overview of litigations during 2018 and updated MSC on the status of recent appeals on evaluation submitted to the Board of Appeal of ECHA and pending cases submitted to the European Court of Justice. MSC was further provided with a brief analysis of a recent Board of Appeal decision relating to substance evaluation (Case A-004-2017) and a recent judgment of the Court relating to the identification of a substance as a substance of very high concern (Case C-419/17 P). MSC took note of the information received and further discussed the learnings from these decisions.

2. **Sterile controls in simulation test requests (OECD TGs 307, 308, and 309) under dossier and substance evaluation** *(Closed session)*

The member requesting for this topic to be discussed shared reasons to ask for sterile controls in simulation test requests under OECD TGs 307, 308 and 309. He explained that the biggest advantage for sterile controls is for highly adsorptive substances. MSC gave its first reactions during the discussion which would be further substantiated in writing after the meeting. It was also acknowledged that since this issue is technical in nature, a more in-depth discussion at the PBT expert group should be considered.

3. **Consultation on deviation from test conditions in substance evaluation** *(Closed session)*

The member requesting for the consultation shared with MSC his CA's observations when evaluating the test results from the information request of a previous substance evaluation decision where the Registrant had run the test with a deviation from the information request. Members exchanged views related to the need for an assessment whether the Registrant's justification for a deviation can be accepted and the possible ways forward based of a negative or positive outcome of such assessment.

4. **Announcement of report by EEB – Review of Evaluation process under REACH** *(open session)*

The stakeholder observer from the European Environmental Bureau (EEB) gave a presentation titled *Evaluation of chemicals under REACH - achievements, challenges and suggestions for improvement*. The reporting focused on substance evaluation with one hundred such cases completed under REACH, with risk management initiated on twelve cases as a follow up. The study recommended, *inter alia*, ECHA to continue increasing transparency, in particular on its website, registrants updating their dossiers and overall improving the interplay between compliance checks and substance evaluation. MSC welcomed the findings and recommendations of the assessment and noted the availability of the full report (*Chemical evaluation - Achievements, challenges and recommendations after a decade of REACH*) at EEB website.

Item 12 - Adoption of main conclusions and action points

Table with conclusions and action points from MSC-63 was adopted at the meeting.

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)	BIGI, Elena
COPOIU, Oana (RO)	BROERE, William
DEIM, Szilvia (HU)	CARLON, Claudio
DE KNECHT, Joop (NL)	CONSOLI, Elisa
DIMITROVA, Rada (BG)	DELOFF-BIALEK, Anna
DUNAUSKIENE, Lina (LT)	DE BACKER, Liisi
FINDENEGG, Helene (DE)	DE WOLF, Watze
GYMNAOU, Panagiotis (CY)	HALLING, Katrin
HERMES, Joe (LU)	JOHANSSON, Matti
HJORTH, Rune (DK)	KAPANEN, Anu
HORSKA, Alexandra (SK)	KARJALAINEN, Anne-Mari
HUMAR-JURIC, Tatjana (SI)	KARHU, Elina
JANTONE, Anta (LV)	KLOSLOVA, Zuzana
KOUTSODIMOU, Aglaia (EL)	KORJUS, Pia
KREKOVIĆ, Dubravka (HR)	LE CURIEUX, Frank
KULHANKOVA, Pavlína (CZ)	NAUR, Liina
LE, Elisa (FR)	RÖNTY, Kaisu
LUNDBERGH, Ivar (SE)	SIMONS, Rupert
MARTIN, Esther (ES)	VAHTERISTO, Liisa
REIERSON, Linda (NO)	VASILEVA, Katya
RISSANEN, Eeva (FI)	VERSONNEN, Bram
STESSEL, Helmut (AT)	WALKER, Lee
Representatives of the Commission:	
SCHUTTE, Katrin (DG ENV)	
BARICIC, Peter (DG GROW)	
Observers	
ANNYS, Erwin (Cefic)	
DROHMANN, Dieter (ORO)	
FAßBENDER, Christopher (PETA)	
FERNANDES DE BARROS, Mariana (Cefic)	
GRANGE, Emma (ECEAE)	
KERÄNEN, Hannu (CONCAWE)	
LOONEN, Helene (EEB)	
WAETERSCHOOT, Hugo (Eurometaux)	

Proxies

- ANDRIJEWSKI, Michal (PL) also acting as proxy of VANDERSTEEN, Kelly (BE)
- ATTIAS, Leonello (IT) also acting as proxy of ELLUL, Nathanael (MT)
- DE KNECHT, Joop (NL) 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)
BOLWIG, Asger (DK) (expert to HJORTH, Rune)
CIESLA, Jacek (PL) (expert to ANDRIJEWSKI, Michal)
EINOLA, Juha (FI) (adviser to RISSANEN, Eeva)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
KUROVA, Martina (SK) (expert to HORSKA, Alexandra)
LANDVIK, Nina (NO) (adviser to REIERSON, Linda)

MALKIEWICZ, Katarzyna (SE) (expert to LUNDBERGH, Ivar)
PEPPIN, Lindsay (UK) (expert to COCKSHOTT, Amanda)
ROSENTHAL, Esther (DE) (expert to FINDENEGG, Helene)
SPURIENE, Otilija (LT) (expert to DUNAUSKIENE, Lina)
TARNOCZAI, Timea (HU) (expert to DEIM, Szilvia)

MSCA experts for SEv cases:
DOYLE, Ian (UK)

Registered to the WEBEX-phone connection:
ARNING, Jürgen (DE)
BALLIAUW, Sharissa (BE)
BOEL, Els (BE)
BOISEN, Anne (DK)
BURGA, Karen (FR)
DANG, ZhiChao (NL)
DOBRAK-VAN BERLO, Agnieszka (BE)
FERNÁNDEZ SÁNCHEZ, Raquel (ES)
FRANZ, Michel (FR)
HORNEK-GAUSTERER, Romana (AT)
HÖLZL, Christine (AT)
KAARTINEN, Tomi (FI)
KINZL, Max (AT)
LOSERT, Annemarie (AT)
MENDONÇA, Elsa (PT)
MÜHLEGGER, Simone (AT)
PASQUIER, Elodie (FR)
RAITALA, Suvi (FI)
VANDERSTEEN, Kelly (BE)

Case owners:
Representatives of the Registrants were attending under the Agenda Item 6.2 for SEV-2-UK-037/2014 and under the Agenda Item 7.2 for CCH-153/2018

Apologies:
ELLUL, Nathanael (MT)
FRANZ, Michel (FR)
MIHALCEA UDREA, Mariana (RO)
PALEOMILITOU, Maria (CY)
VANDERSTEEN, Kelly (BE)
WAGENER, Alex (LU)
WIJMENGA, Jan (NL)

III. Final Agenda

MSC/A/063/2019

Agenda

63rd meeting of the Member State Committee

5-7 February 2019
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

5 February: starts at 9 am
7 February: ends at 12 pm (noon)

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/063/2019
For adoption

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

Item 4 – Administrative issues

- Outlook for MSC-64
- ECHA Organisation Chart
- MSC Meeting dates 2020

For information

Item 5 – Minutes of the MSC-62

- Draft minutes of MSC-62

MSC/M/62/2018
For adoption

Item 6 – Substance evaluation

Closed session for 6.3

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

   No cases

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

ECHA/MSC-63/2019/012

MSC code	Substance name	EC/List No.
SEV-2-UK-037/2014	Climbazole	253-775-4

ECHA/MSC-63/2019/013-014

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

Case as listed above under 6.2

For agreement

4. General topics

Status report on on-going substance evaluation work

For information

Use of the updated SEv RCOM template (*closed session*)

For discussion and possible agreement

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

ECHA/MSC-63/2019/001

For information

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

ECHA/MSC-63/2019/002

For information

For discussion followed by agreement seeking under 7.3:

<u>Compliance checks</u>

MSC code	Substance name	EC No. / Document
CCH-130/2018	Ethyl (z,z)-9,9-dioctyl-4,7,11-trioxo-3,8,10-trioxa-9-stannatetradeca-5,12-dien-14-oate	268-500-3
		ECHA/MSC-63/2019/003-4
CCH-145/2018	1-[(2-chloro-4-nitrophenyl)azo]-2-naphthol	220-562-2
		ECHA/MSC-63/2019/005-6
CCH-153/2018	1-(N,N-bis(2-hydroxyethyl)amino)propan-2-ol	229-764-5
		ECHA/MSC-63/2019/007-8
CCH-154/2018	C,C'-azodi(formamide)	204-650-8
		ECHA/MSC-63/2019/009-10

For discussion

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

Cases as listed above under 7.2

For agreement

4. General topics

1. Mutagenicity – status report on germ cell requests *(Closed session)*

For information

2. Regulatory challenges in compliance checks *(Closed session)*

For information

Item 8 – SVHC identification

Not relevant for this meeting

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

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

ECHA/MSC-63/2019/015

For discussion and adoption

Item 10 – 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

1. Highlights from the comments received in the public consultation - summary by the Secretariat
2. Brief report from the Rapporteur and Working Group

For information and discussion

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

- Discussion of tasks and appointment of Rapporteur for drafting MSC opinion

ECHA/MSC-63/2019/016

For discussion and decision

Item 11 – Any other business

Partly closed session

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

(Open session)

For information

2. Sterile controls in simulation test requests (OECD TGs 307, 308, and 309) under dossier and substance evaluation *(Closed session)*

ECHA/MSC-63/2019/017

For discussion

3. Consultation on deviation from test conditions in substance evaluation *(Closed session)*

For information

4. Announcement of report by EEB – Review of evaluation process under REACH

For information

Item 12 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-63

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 dossier evaluation work (presentation slides)
- 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)
- Report of MSC work in 2018 (presentation slides)

APPENDIX to the MSC-63 agenda:

List of evaluation cases agreed by MSC in written procedure in advance of the MSC-63 meeting:

Compliance checks

MSC code	Substance name	EC/List No.
CCH-123/2018	m-xylene	203-576-3
CCH-124/2018	p-xylene	203-396-5
CCH-125/2018	o-xylene	202-422-2
CCH-127/2018	1,3-diphenylguanidine	203-002-1
CCH-136/2018	Tetrabutylammonium bromide	216-699-2
CCH-137/2018	Propane-1,2,3-triyl 3,5,5-trimethylhexanoate	260-257-1
CCH-141/2018	6'-(dibutylamino)-3'-methyl-2'-(phenylamino)-spiro[isobenzofuran-1(3H),9-(9H)-xanthen]-3-one	403-830-5
CCH-151/2018	Reaction mass of 2-ethylpropane-1,3-diol and 5-ethyl-1,3-dioxane-5-methanol and propylidynetrimethanol	904-153-2

Testing proposal examinations

MSC code	Substance name	EC/List No.
TPE-114/2018	3,6-bis(4-chlorophenyl)-1H,2H,4H,5H-pyrrolo[3,4-c]pyrrole-1,4-dione	401-540-3
TPE-119/2018	Citral	226-394-6
TPE-120/2018	Tris[2-[2-(2-methoxyethoxy)ethoxy]ethyl]-orthoborate	250-418-4
TPE-122/2018	Magnesium, bis(2-hydroxybenzoato-O1,O2)-, ar,ar'-di-C14-18alkyl derivs.	931-371-5

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-63, 5-7 February2019
(adopted at MSC-63)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 5 – Minutes of the MSC-62	
MSC adopted the draft minutes as modified at the meeting.	**MSC-S** to upload final version of the minutes on MSC S-CIRCABC by 12 February 2019 and on ECHA website without undue delay.
Item 6 – Substance evaluation **3. Seeking agreement on draft decisions when amendments were proposed by MSCA's/ECHA**	
MSC reached unanimous agreement on the following ECHA draft decision (as modified in the meeting): SEV-2-UK-037/2014 Climbazole (EC No. 253-775-4)	**MSC-S** to upload on MSC S-CIRCABC the agreed decision in the respective case folder. **MSC member who made a statement** and **requested for its attachment to the minutes** to provide this statement in writing to MSC-S by 12 February 2019.
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.
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 provided for or modified at the meeting): **<u>Compliance checks (CCH)</u>** CCH-130/2018 Ethyl (z,z)-9,9-dioctyl-4,7,11-trioxo-3,8,10- trioxa-9-stannatetradeca-5,12-dien-14-oate (EC No. 268-500-3) CCH-145/2018 1-[(2-chloro-4-nitrophenyl)azo]-2-naphthol (EC No. 220-562-2) CCH-153/2018 1-(N,N-bis(2-hydroxyethyl)amino)propan-2-ol (EC No. 229-764-5) CCH-154/2018 C,C'-azodi(formamide) (EC No. 204-650-8)	**MSC-S** to upload on MSC S-CIRCABC the agreed decisions in the respective case folders.
4. General topics 1. Mutagenicity – status report on germ cell requests	
MSC took note of the status on mutagenicity.	**SECR** to prepare both scientific background and possibilities for practical implementation, in consultation with appropriate Member State experts, and present a document for discussion in MSC-64.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
4. General topics 2. Regulatory challenges in compliance checks	
MSC took note of the new CCH approaches envisaged.	**Members** to discuss the information with their CAs and to submit to ECHA their comments/ suggestions for further consideration by end of March 2019.
Item 9 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2019-2021) • Discussion on the draft MSC opinion • Adoption of the opinion	
MSC adopted by consensus the draft opinion and its Annex on the draft CoRAP update 2019-2021.	**MSC-S** to upload the MSC CoRAP opinion including its annex on MSC S-CIRCABC by 11 February 2019. **MSC Chair** to share the MSC CoRAP opinion with the ECHA's process owner once finalised. **SECR** to publish the opinion on the ECHA website together with the annual CoRAP update in March 2019.
Item 10 – 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 1. Highlights from the comments received in the public consultation - summary by the Secretariat 2. Brief report from the Rapporteur and Working Group 2) Draft recommendation to amend entries of DEHP, BBP, DBP, and DIBP in Annex XIV • Discussion of tasks and appointment of Rapporteur for drafting MSC opinion	
2) MSC adopted the mandate and the tasks of the (co-)rapporteur and appointed one of its members as a rapporteur and another member as a co-rapporteur.	**SECR** to provide post-public consultation documents to MSC by end of March 2019 for MSC's review. **MSC-S** to send the appointment letter to the Rapporteur and Co-Rapporteur after the meeting.
Item 11 – Any other business 2. Sterile controls in simulation test requests (OECD TGs 307, 308, and 309) under dossier and substance evaluation *(closed session)* 3. Consultation on deviation from test conditions in substance evaluation *(closed session)* 4. Use of the updated SEv RCOM template	
2) MSC agreed not to specify the use of sterile controls when requesting for OECD 309, to specify the use of sterile controls on a case by case basis when requesting for OECD 307 and to preferably have a technical discussion at the PBT EG on whether this needs to be specified when requesting for OECD 308. 3) MSC members exchanged views and made recommendations on the way forward with the presented SEv case where a deviation from requested test conditions have been identified. 4) MSC members agreed to ask eMSCAs to start using the updated SEv RCOM template.	**2) Members** are invited to share comments and observations via MSC FMB with the member initiating the consultation by end of February 2019. **2) MSC Chairman** to discuss and assess with the Chair of the PBT-EG if and when to have discussion on this topic in the PBT EG. **3) Members** are invited to share any experience on similar cases or comments for consideration via MSC FMB with the member initiating the consultation by end of February 2019. **4) SECR** to ask eMSCAs to start using the

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	updated SEv RCOM template. **4) MSC-S** to update the SEv timelines so as to include a second submission of the RCOM updated with the eMSCA assessment of the PfAs at WP or meeting stage.
Item 12 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-63 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC S-CIRCABC by 8 February 2019.

V. Statements as regards agenda item 6.3 'Seeking agreement on draft decisions when amendments were proposed by MSCA's/ECHA'

UK MSC member statement for the minutes for climbazole SEV case at MSC 63

In the interest of compromise and in respect of the MSC opinion, the UK decided not to contest this decision but instead to abstain. We remain unconvinced that the available data on environmental endocrine disruption for this substance justify a level 4 test in the OECD Conceptual Framework for Testing and Assessment of Endocrine Disrupters. For the UK this is particularly important given the large number of fish used in the requested Fish Sexual Development Test.

Based on the discussions at MSC 63, it remains unclear to us what type evidence MSC would consider trigger the lower OECD ED tests at levels 2 and 3 of the conceptual framework, rather than level 4. We think there would be benefit in the MSC seeking the advice of the ECHA ED EG on this issue.

Additionally, and different to the views expressed by Other Member States at the meeting, we consider that there are circumstances where negative results from valid in vitro studies performed according to OECD test guidelines can be used to conclude on an environmental ED concern.

UK MSC member
12.02.19