MSC/M/35/2014

Adopted at MSC-36

Minutes

of the 35th meeting of the Member State Committee (MSC-35)

8-10 April 2014

I. Summary Record of the Proceedings

Item 1 - Welcome and apologies

The Chair of the Committee, Mr Watze de Wolf, opened the meeting and welcomed the participants to the 35th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

Item 2 - Adoption of the agenda

The Agenda was adopted as provided for the meeting by the MSC Secretariat without further changes (final Agenda is attached to these minutes).

Item 3 - Declarations of conflicts of interest to the items on the agenda

No potential conflicts of interests were declared by any members, experts or advisers with any item on the agenda of MSC-35. The Chair noted that in case the substance SEV-DE-009/2012 from the 34th meeting was to be discussed, an alternate chair would cover that specific part of the meeting.

Item 4 - Administrative issues

SECR informed the Committee of the upcoming web training on the OECD QSAR Toolbox that is to be held on 19 and 20 May 2014. The training is to be offered among others to the MSC members and accredited stakeholder observers.

SECR reminded the members of the ongoing testing of the new IT platform tool and encouraged all the members to test it and provide their feedback until 25 April 2014.

Item 5 – Adoption of the minutes of the MSC-34 meeting

The MSC Chair presented the MSC-34 draft minutes revised on the basis of the written comments received in advance of the meeting. The minutes were adopted without further changes. SECR would upload the final minutes on MSC CIRCABC and ECHA website.

Further, MSC-S presented some consolidated suggestions for members' consideration for streamlining the MSC minutes preparation. SECR will follow the outlined approach when preparing minutes of this meeting and members are invited to share the approach with their experts, and provide further comments and suggestions, if considered necessary, with the review of the minutes.

Item 6 – Substance evaluation

a. Introduction to and preliminary discussion on a draft decision on substance evaluation after MS-CA/ECHA reactions (Session 1, open)

b. Seeking agreement on one draft decision when amendments were proposed by MS's/ECHA (Session 2, closed)

SEV-FR-017/2012 Octocrilene (EC No. 228-250-8)

Session 1 (open)

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

The evaluating Member State Competent Authority (eMSCA) expert from French CA (FR CA) presented the outcome of substance evaluation (SEV) of the above-mentioned substance performed on the basis of the initial grounds for concern: environment/ suspected PBT/vPvB (Persistent, Bioaccumulative, Toxic / very Persistent, very Bioaccumulative); exposure/ wide dispersive use and high aggregated tonnage. Additional concerns were identified during the evaluation process: data gap on fertility; suspected endocrine disrupting (ED) properties; incomplete environmental risk characterisation; published studies suggest occurrence in rivers/ lakes.

During the presentation of the case eMSCA explained that DD was modified for the meeting based of the proposals for amendment (PfAs) received. eMSCA accepted and incorporated in the DD most of the PfAs received with as notable exceptions those PfAs related to Extended One Generation Reproductive Toxicity study (EOGRTS), the *in vivo* mechanistic study, and the Amphibian Metamorphosis Assay (AMA). Hence the discussion focused on the PfAs related to those information requirements.

Description of the PfAs discussed

In DD sent to MSCAs for PfAs, eMSCA requested an *in vivo* mechanistic study in rat in order to demonstrate specific thyroid toxicity mode of action via liver enzyme induction and a separate two-generation reproduction toxicity study. Four MSCAs did not agree with the request for the two-generation study and preferred an EOGRTS with DIT/DNT cohorts without F2 generation instead. Another MSCA proposed to consider extending the pre-mating exposure schedule in EOGRTS to 10 weeks. This was supported by one MSCA. However, another MSCA was of the view to use the default option of 2 weeks pre-mating exposure. In addition, two MSCAs proposed to include the mechanistic study in the EOGRTS protocol by measuring serum T4 and TSH levels, thyroid weight, enzymatic activity and histopathology in P and F1 generation. On the other hand a different PfA rejected the request for the mechanistic study since according to that MSCA this request was associated with the carcinogenicity of the substance or refinement of NOAEL. This PfA stated that even though the MSCA acknowledges that there is an information gap for fertility, yet they questioned that there is a concern for endocrine disruption that justifies a level 5 test according to the OECD Conceptual Framework, to be filled by a two-generation study (or EOGRTS). If on the other hand further testing is needed to fill in the fertility gap they proposed EOGRTS without F2 generation. Another PfA for the *in vivo* mechanistic study proposed to give more detail to the requested study to ensure better understanding by the registrants. Regarding the two-generation reproductive toxicity study an editorial change was proposed.

Regarding the amphibian metamorphosis assay a PfA proposed to await the outcome of the EOGRTS and in the follow-up to the substance evaluation decision decide whether or not there would be a need for further testing. A different MSCA made an editorial proposal to include mention of this test in the conclusion of DD. A third MSCA proposed two amendments 1) to further justify the need for this test 2) to subject this test to a tiered testing strategy because the results of the other tests may make the amphibian test unnecessary (if ED-effects in fish or humans or PBT/vPvB properties are confirmed).

Registrant's comments on PfAs of CAs and discussion

The registrants provided written comments on the PfAs submitted and highlighted some of those comments in the discussion in the meeting.

Firstly the registrants reiterated their written comments on their concerns on the linkages between the REACH Regulation and the Regulation (EC) No 1223/2009 on cosmetic products (the "Cosmetics Regulation"). They stated that the Commission Communication (2013) 135 on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics is not legally binding and expressed the view that conflicts between different regulations will need to be resolved by the European Court of Justice. The registrants pointed out that a case addressing the interpretation and validity of Article 18 of the Cosmetics Regulation is currently pending before the English

High court. They thus requested for the final decision to be postponed until a legally binding interpretation of Article 18 of the Cosmetics Regulation has been given or alternatively to take the final decision without requesting the registrants to conduct tests risking incompliance with provisions of the Cosmetics Regulation.

Regarding the reproduction toxicity endpoint, the registrants' representatives explained that the repeated dose toxicity studies, ED mechanistic studies and a developmental toxicity study were used in a weight of evidence approach. Hence they considered the reasoning made by eMSCA not to be robust enough to justify further testing for this endpoint. Regarding EOGRTS the registrants did not see a sound scientific rationale to request for the DIT/DNT cohorts. Furthermore, the inclusion of additional parameters would result in logistic difficulties while performing the EOGRTS, and mentioned it would be easier to incorporate these additional parameters in a dose-range finding study.

Regarding bioaccumulation in fish, the registrants' representatives pointed out that the concentrations of octocrilene quoted in DD are not a proper reflection of the concentrations quoted in the overview paper by Gago-Ferrero *et al*. 2012, which is being referred to in DD. The registrants' representatives argued that all fish BCF values cited by Gago-Ferrero *et al.* 2012 either were incorrectly presented or the average values were below the values obtained during the BCF fish study according to OECD 305. The registrants' representatives concluded that, taking into account the scientific based arguments by the registrants and the correct evaluation of the fish monitoring data, it could be concluded that the available fish study results were reliable using the unfiltered water samples as a basis for BCF calculation. The registrants' representatives strongly suggested to revise the necessity of BCF calculations based on the filtered water samples.

Some clarifying questions from MSC members were addressed by the Registrant's representatives. The Chairman thanked them for their interventions, and explained that the comments would be further considered during the closed session deliberations of MSC.

Session 2 (closed)

The discussion focused on whether to request AMA and on the design of EOGRTS.

Regarding AMA the MSC experts representing the MSCAs submitting the PfAs repeated the arguments of their PfAs. The eMSCA expert explained that this test is best fitted for assessing chemicals activity on thyroid and thyroid hormones system (hypothalamic-pituitary-endocrine axis) of vertebrates during their development. Thus, it allows identifying *in vivo* both a mechanistic effect and a developmental effect (potentially adverse). It is especially suited to assess substances that affect the rate of circulating T4 hormone and the production of thyroid hormones in tissues under development (which is the suspected mode of action of octocrilene). It is also complementary to studies on rats in order to cover various vertebrates with different sensibilities. Given that there is not much data available on octocrilene, they decided to request this test which is a level 3 test according to the OECD framework. Without the AMA test the weight of evidence for the assessment of environmental ED properties would be weak. If on the other hand, the outcome of the EOGRTS had to be awaited, eMSCA might then need to ask for a different test, and even have to ask for a level 5 test based on the OECD framework. Some members were questioning the need for AMA when there is also the request for the Androgenised Female Stickleback (AFS) screen. The eMSCA expert however explained that even if the AFS screen would be positive, this would only show that there are anti-androgenic mode of endocrine disruption effects in fish, but it would not provide information on e.g. the thyroid mode of action. On the other hand, another MSC member stated that even AMA does not determine the "mode of action" but rather aims at identifying a developmental effect that may occur from an endocrine activity of the substance e.g. on the thyroid, to which the eMSCA expert agreed.

Regarding EOGRTS and its design, there was consensus to request for EOGRTS with DNT cohort, although one member expressed reservations that the thyroid effect was rat

specific hence not being fully convinced that the request for the DNT cohort seemed justified.

Regarding the incorporation of the additional parameters instead of a separate *in vivo* mechanistic study one member explained that this combination would not be compatible since the animals used for those additional parameters need to be fasted and blood needs to be taken on specific days and at specific times. If such animals will then be used for EOGRTS, the results from these animals will not be viable for EOGRTS. Hence it would not be feasible to combine the tests.

The other options discussed were to either conduct the mechanistic study separately, as originally proposed by eMSCA in DD, or else to include the additional parameters in the range dose finding study, as proposed by the registrants, or to conduct the separate mechanistic study separately and use it as a dose range-finder for EOGRTS. The MSC agreed to a request for the *in vivo* mechanistic study, indicating to the Registrant he may be able to use this as dose range-finder.

Regarding whether to request the F2 generation in EOGRTS, some members stated that octocriline would have fitted the hazard information profile for such request. However, considering that much of the consumer uses seem to be covered by the Cosmetics Regulation, whereas on the other hand there is a need to clarify the concern for non-cosmetic product uses and for the environment, MSC members agreed to request EOGRTS without extending cohort 1B to the F2 generation. If the Registrant decides prior to testing there is significant exposure of the substance to the workers, professionals and consumers Cohort 1B may be extended.

Regarding the pre-mating period the MSC expert representing the MSCA submitting the PfA on keeping the premating period to 2 weeks stated that for this particular case he would agree with the 10-week premating period.

Based on the above considerations, MSC agreed unanimously to further amend the DD that was modified for the meeting and to replace the Two-Generation Reproduction Toxicity Study, oral route (OECD 416) with EOGRTS in rats, oral route (OECD 443) with the DNT cohort and a 10-weeks pre-mating period; to keep the request for *in vivo* mechanistic study in rat; to remove the request for Amphibian Metamorphosis Assay on *Xenopus laevis* and follow a testing strategy by awaiting first for the outcome of EOGRTS before deciding which further tests to perform to tackle the environmental ED concern*;* to add some further clarifications in Section III, statement of reasons on the rationale for requesting the information.

In addition, the MSC members agreed to clarify the concentrations of octocrilene quoted in DD as pointed out by the registrants for the bioaccumulation endpoint and to remove the requests for QSAR justifications on the (Q)SAR models used to predict the log Pow, the hydrolysis and the log Koc, since the actual tests are also requested.

MSC unanimously agreed on this SEV DD as modified at the meeting.

c. CoRAP and substance evaluation

SECR provided a short overview on the CoRAP 2014-2016 update that was published on 26 March, the next steps for the substances evaluated from CoRAP 2013, the published final SEV decisions from CoRAP 2012, and information on the substance evaluation (SEV) workshop to be held on 26-28 May 2014.

During the discussion it was asked whether the substance managers for the substances on CoRAP for evaluation in 2014 were identified. SECR reminded that this information was present in the email sent to the MSCAs on 26 March 2014. Regarding whether SECR will give feedback to eMSCA on the SEV report, SECR explained that it will give feedback, if any. However, eMSCA should already prepare the conclusion document for those cases that have been concluded. Then SECR will later on look at both documents for consistency. It is up to eMSCA to decide whether the conclusion document is circulated with the other

MSCAs. Following a question whether ECHA will send information to eMSCA on updates of the registration dossiers of those substances from CoRAP 2012 whose final decision has been sent to the registrants, SECR explained that the organisation of the follow-up on substance evaluation decisions will be one of the topics discussed at the SEV workshop.

Item 7 – Dossier evaluation

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

SECR gave a report on the outcome of the written procedure (WP) for agreement seeking on two dossier evaluation cases (see Section V for more detailed identification of the cases). WP was launched on 13 March 2014 and closed on 24 March 2014. For the two cases the draft decisions (DD) were split thus resulting in two DDs for each case and overall four DDs for the two cases. By the closing date, responses to WP were received from 23 members with voting rights and from the Norwegian member. Unanimous agreement was reached on two DDs. For the other two DDs MSC did not find unanimous agreement due to divergent opinions on the appropriate test method to fulfil the two-generation reproductive toxicity endpoint, and these cases will be referred to the Commission to be dealt with in accordance with the procedure referred to in Article 133(3) of REACH Regulation.

b. Update on appeal cases

SECR provided MSC with feedback from the appeal cases on dossier evaluation decisions.

c. General topics - Status report on on-going evaluation work

SECR gave detailed statistics and update on the status of dossier evaluation work. The Committee was also informed of the potential workload for the forthcoming MSC meetings, and the Workshop on Compliance Check 2014-2018 held on March 30-April 1 2014, including draft recommendations and conclusions. MSC took note of the report.

Item 8 – Authorisation process - Prioritisation of Candidate List substances for inclusion in Annex XIV

- Discussion on the prioritisation results of the selected substances for the next recommendation for inclusion of substances in Annex XIV (1st discussion)

Session 1 (open)

SECR presented the work carried out in assessing 101 substances currently on the Candidate List, and not yet recommended in the previous rounds, using the agreed, revised prioritisation approach. Besides the general approach also some examples were provided to exemplify how the approach was implemented and how the prioritisation works in practice in specific situations. Some further considerations for possible selection of substances for the 6th draft recommendation for inclusion in Annex XIV were shared by SECR, such as grouping of substances when potential substitution with candidate list substances for some uses may potentially be possible, or if there are on-going regulatory risk management activities under REACH. It was reiterated that over time all substances on the Candidate list are for inclusion in Annex XIV. The discussion was then opened on the topic.

In the discussion MSC generally appreciated how the revised prioritisation approach seems to work in practice, and the work done by ECHA when applying for the first time this revised approach. It was noted that the derivation of the scores was now more transparent. Proper opportunity to discuss on which substances will be included in the draft recommendation for the public consultation was welcomed. Some members noted that lead compounds are of high priority, some had reservations for prioritising them.

Besides lead compounds only few substances were specifically discussed. For example MSC indicated both support and resistance to the suggestion to put aside NMP and DecaBDE at this stage as proposed by ECHA due to uncertainty in potential impact of the restriction proposals on use and tonnage within the scope of authorisation and potential confusion caused by two parallel processes under REACH.

A member requested ECHA to clarify how many substances were expected to be part of this prioritisation round. ECHA clarified that that the number of substances was difficult to predict due to varying workloads between substances, it would in the end be the same order of magnitude of registered substances as in the previous recommendations (i.e. between 5 and 13).

In responding to a question SECR reiterated that registration dossiers are not the only source of information but a fundamental starting point for the prioritisation work, together with all other REACH/CLP related data, such as comments received during the public consultation in the SVHC identification phase and DU-report information, as is described in the prioritisation approach-document. Lack of RMOA for some substances was raised as an omission and a concern by several speakers, although this view was not shared by one observer. In particular, one member requested ECHA to clarify if a RMOA had been carried out for Hydrazine. One member asked whether uses derogated from Annex XVII restrictions should be taken into account in priority assessment. SECR clarified that in principle as those are not generally exempted from authorisation they should be considered at the prioritisation stage – considerations on whether such uses could be exempted based on Art. 58(2) are relevant at a later stage. It was noted that the public consultation on the draft recommendation is in particular on needs for such an exemption. Another MSC observer in his intervention indicated appreciation to the voluminous work carried out. He expressed also concerns that were mostly related to the interpretation and use of registration data (e.g., if only one of the member registrations has a use, should it be counted in the same way as information in the lead registration dossier), and to the grouping arguments used for some substances. ECHA recalled that updates to the registration dossiers until 25 April would be taken into account.

Session 2 (closed)

A closed session was held to allow sharing of and discussion on detailed use and tonnage information from registration dossiers on several lead substances on the candidate list. MSC discussed possibilities to group lead substances according to uses. Lead in batteries seemed to several members as well-regulated by other pieces of legislation, e.g. the ELV Directive covers most automotive batteries. They noted that the exemption under the ELV Directive for lead in automotive batteries is to be reviewed in 2015 and that if lead substances are prioritised in this round, this might be relevant when considering exemptions according to Art. 58(2). Some further points were raised in the discussion noting that lower volume applications can still have significant risk and how different types (industrial, automotive) of batteries may not be covered in a similar manner by existing measures.

A Commission observer reflected on some aspects of the authorisation process and the COM discussion on lead compounds. Discussion is ongoing in the COM regarding the functioning of the authorisation process as a whole and therefore COM observer advised that in 2014 they will not amend Annex XIV following ECHA's 5th recommendation. It was further explained that the Commission is considering an additional consultation on substances to be proposed for inclusion in Annex XIV as COM considers that there are two distinctive sets of information that are to be considered, on the one hand by ECHA (based on prioritisation criteria set out in Art 58(3)) and on the other by the Commission (e.g., economic consequences of the authorisation requirement). SECR took note of the comments and concerns of the members on these COM reflections.

Session 3 (open)

The Chair reported briefly in the open session to the accredited stakeholders on the discussions held in the closed session. SECR noted that based on the discussion they further consider grouping the lead substances. Furthermore SECR raised a question whether it would be useful to have a short to medium term planning for prioritisation and inclusion of substances in future draft Recommendations. COM shortly introduced the room document.

In closing the discussion further comments were invited to be submitted in writing by 25th April. These comments will be considered in preparation for the 6th Draft recommendation with a selection of substances which will be discussed during MSC-36.

Item 9 – MSC Manual of Decisions - Inclusion of possible new items

SECR introduced MSC with two topics proposed for inclusion in the MSC Manual of Decisions (MoD) based on the MSC work in 2013 on dossier evaluation, as indicated in document ECHA/MSC-35/2014/005. MSC concluded that the topics proposed to be included in MoD may not yet be mature enough to be decided and some further discussion would probably be needed in the following MSC meetings before the topics would be ready for MoD inclusion.

Members were encouraged to review the MSC minutes from the past years, to identify additional topics for potential inclusion in MoD and submit them to the MSC-S for further Committee's consideration and decision at the MSC meeting in September 2014.

Item 10 –Endocrine disrupting substances – Information sharing

- EU - current state of play and plans
- OECD framework - brief introduction of the assessment framework
- JRC - activities on identification and assessment of endocrine disruptors
- ECHA - Endocrine Disruptor Expert Group – mandate and report from the first meeting

Presentations by representatives of the organisations mentioned, or their backup, were provided. Due to a meeting held concurrently by OECD no representative from OECD was available, and only a high-level overview presentation on the OECD framework was provided by ECHA. MSC members appreciated the information sharing session on ED substances.

During the discussion, regarding the current state of play and plans, the MSC members were informed that the Commission is developing a questionnaire to be published for public consultation as part of the impact assessment for the development of criteria for the identification of EDs. Furthermore, MSC members expressed concern that considering that the criteria have not been developed yet, the target set out by the 7th Environmental Action Program to ensure by 2020 that all relevant substance with endocrine-disrupting properties are placed on the REACH candidate list, seems not to be realistic.

Regarding the OECD framework and the request from the Chairman whether MSC members would like a more in depth introduction to the test guidelines (TG) in a later meeting, an MSC member pointed out that having the information on TG without established ED criteria is not ideal; one needs the criteria to be able to apply TG to the REACH Regulation.

Regarding the Endocrine Disruptor Expert Group (ED EG), the MSC members showed interest to receive further updates what approach the ED EG will propose to identify EDs among others for CoRAP screening of substances, recognising it is not always easy to identify EDs based on the content of the dossiers.

Item 11 – Updates to MSC working procedures

a. Technical corrections to MSC working procedures under authorisation process

SECR presented a proposal for some technical corrections to the MSC working procedures on the SVHC identification and on providing opinion on ECHA's draft recommendations for priority substances for inclusion in Annex XIV. A Commission observer expressed concerns as regards the SECR's proposal how to engage third party expertise in the Committee's work.

A MSC industry observer responded on behalf of CEFIC and Eurometaux to this issue recognising the importance of bringing the expertise to the MSC meeting. He clarified that no problems have been identified up to the moment and both organisations follow the line to represent also other industry's interests, and upon request can invite to the meetings (industry) experts even if they are not members of these organisations.

In conclusion, MSC agreed unanimously to the proposed technical corrections and requested the MSC-S to introduce them to the Committee's authorisation working procedures.

b. Collection of feedback on MSC working procedures on evaluation for next updates

SECR gave a presentation on MSC working procedures on evaluation and possibilities for streamlining them. The MSC agreed that MSC-S would prepare a list of files and other items for feedback, which would be uploaded with the presentation on evaluation to MSC CIRCABC. Members are to provide feedback by 5 May 2014.

Item 12 – Report from other ECHA bodies and activities

The Chairman of the Committee for Risk Assessment (RAC) presented the RAC work programme for 2014. In particular, he informed on the increase of cases solved in previous meetings and the actions established for future meetings of current year. MSC members discussed the contribution of expert groups to the RAC activities.

Item 13 – Any other business

Note from the Chair on Rapporteurship and membership in MSC Working Group on the next recommendation for Annex XIV

The MSC Chairman strongly encouraged the members to consider volunteering for (co-) rapporteurship or membership in a MSC WG for developing the MSC opinion on the 6th ECHA's draft recommendation that are to be appointed by MSC in June meeting. Members were invited to consider the request, to discuss it with their MSCAs and to express their interest in response to the call that the SECR will launch in the following weeks.

Item 14 – Adoption of conclusions and action points

The conclusions and action points of the meeting were adopted in written procedure after the meeting (see Annex IV).

SIGNED

Watze de Wolf

Chairman of the Member State Committee

II. List of attendees

Members/Alternate members	**ECHA staff**
ALMEIDA, Inês (PT)	AJAO, Charmaine
ANDRIJEWSKI, Michal (PL)	ANDERSSON, Niklas
BASTIJANCIC-KOKIC, Biserka (HR)	BOWMER, Tim
BELVEZE, Corinne (FR)	BROERE, William
COSGRAVE, Majella (IE)	CARLON, Claudio
DEIM, Szilvia (HU)	CARTON DE TOURNAI, Laure-Anne
DOUGHERTY, Gary (UK)	DE WOLF, Watze
DUNAUSKIENE, Lina (LT)	DREVE, Simina
FINDENEGG, Helene (DE)	FEEHAN, Margaret
GAIDUKOVS, Sergejs (LV)	HUUSKONEN, Hannele
HUMAR-JURIC, Tatjana (SI)	JOHANSSON, Matti
KULHANKOVA, Pavlina(CZ)	KARHU, Elina
LUNDBERGH, Ivar (SE)	KORJUS, Pia
LULEVA, Parvoleta (BG)	LEPPER, Peter
MARTÍN, Esther (ES)	MELZER, Kai
MIHALCEA UDREA, Mariana (RO)	NAUR, Liina
PEDERSEN, Finn (DK)	RODRIGUEZ IGLESIAS, Pilar
PISTOLESE, Pietro (IT)	RÖNTY, Kaisu
REIERSON, Linda (NO)	SCHÖNING, Gabriele
STESSEL, Helmut (AT)	SOBANSKA, Marta
TALASNIEMI, Petteri (FI)	UOTILA, Elina
VANDERSTEEN, Kelly (BE)	VAHTERISTO, Liisa
VESKIMÄE, Enda (EE)	VASILEVA, Katya
WIJMENGA, Jan (NL)	
Representatives of the Commission	
BERTATO, Valentina (DG ENTR)	
SCHUTTE, Katrin (DG ENV)	
VAN DER JAGT, Katinka (DG ENV)	
Observers	
ANNYS, Erwin (CEFIC)	
DEL CASTILLO, Francisco (CONCAWE)	
LEROY, Didier (CEPE)	
MUSU, Tony (ETUC)	
SANTOS, Tatiana (EEB)	
STAIRS, Kevin (Greenpeace)	
TAYLOR, Katy (ECEAE)	
WAETERSCHOOT, Hugo (Eurometaux)	

Proxies:

- KULHANKOVA, Pavlina (CZ) also acting as proxy of RUSNAK, Peter (SK)
- LULEVA, Parvoleta (BG) also acting as proxy of KOUTSODIMOU, Aglaia (EL)
- LULEVA, Parvoleta (BG) also acting as proxy of KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
- PISTOLESE, Pietro (IT) also acting as proxy of BUSUTTIL, Ingrid (MT)

Experts and advisers to MSC members:

ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
DRAGUSANU, Mihaela (RO) (expert to MIHALCEA UDREA, Mariana)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
LINDBERG, Vibeke (NO) (expert to REIERSON, Linda)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
LØFSTEDT, Magnus (DK) (expert to PEDERSEN, Finn)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBRGH, Ivar)
MAXIMILIEN, Elisabeth (FR) (adviser to BELVEZE, Corinne)
MENDONÇA, Elsa (PT) (expert to ALMEIDA, Inês)

MOLDOV, Raili (EE) (expert to VESKIMÄE, Enda)
NYITRAI, Viktor (expert to DEIM, Szilvia)
IRSFELD, Brigitte (DE) (adviser to FINDNEGG, Helene)
SADOINE, Margaux (FR) (expert to BELVEZE, Corinne)
TRAAS, Theo (NL) (expert to WIJMENGA, Jan)
VILNISKE, Lina (LT) (expert to DUNAUSKIENE, Lina)

MSCA Expert for SEV case:
LAGRIFFOUL, Arnaud (FR)

By WEBEX-phone connection:
During agenda item 6: Ian DOYLE (UK), Enrique GARCÍA-JOHN (EC)
During agenda item 8 from the European Commission: Enrique GARCÍA-JOHN, Mariana FERNANDES DE BARROS, Georg STRECK, Giuseppina LUVARA, Jacek ROZWADOWSKI, Anna BORRAS HERRERO and Temenuzhka POPOVA

Case owners:
Representatives of the Registrants were attending under agenda item 6b for SEV-FR-017/2012

Apologies:
BUSUTTIL, Ingrid (MT)
DRUGEON, Sylvie (FR)
KOUTSODIMOU, Aglaia (EL)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
RUSNAK, Peter (SK)
TYLE, Henrik (DK)
WAGENER, Alex (LU)

III. Final Agenda

ECHA/MSC-35/2014/A/35

Agenda
35th meeting of the Member State Committee

8-10 April 2014
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

8 April: **starts at 16:00**
10 April: **ends at 16:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/035/2014
For adoption

Item 3 – Declarations of conflicts of interest to items on the Agenda

Item 4 – Administrative issues

For information

Item 5 – Adoption of draft minutes of MSC-34

- Adoption of draft minutes of MSC-34

MSC/M/34/2014
For adoption

Item 6 – Substance evaluation

Closed session for 6b
Indicative time plan for 6a is Day 1

a. **Introduction to and preliminary discussion on a draft decision on substance evaluation after MS-CA/ECHA reactions *(Session 1, tentatively open session)***

ECHA/MSC-35/2014/001

- **SEV-FR-017/2012** **Octocrilene** (EC No. 228-250-8)

ECHA/MSC-35/2014/002-003
For discussion

b. Seeking agreement on one draft decision when amendments were proposed by MS's/ECHA *(Session 2, closed)*

For agreement

c. CoRAP and substance evaluation

- Short general update by the secretariat

For information

Item 7 – Dossier evaluation

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

ECHA/MSC-35/2014/004
For information

b. Update on appeal cases

For information

c. General topics

- Status report on on-going evaluation work

For information

Item 8 – Authorisation process - Prioritisation of Candidate List substances for inclusion in Annex XIV

Partly closed session

- Discussion on the prioritisation results of the selected substances for the next recommendation for inclusion of substances in Annex XIV (1st discussion)

ECHA/MSC-35/2014/008
For discussion

Item 9 – MSC MoD

- Inclusion of possible new items to the Manual of decisions of MSC

ECHA/MSC-35/2014/005
For discussion and possible decision

Item 10 –Endocrine disrupting substances – Information sharing

Indicative time plan for item 10 is Day 3

- EU - current state of play and plans
- OECD framework - brief introduction of the assessment framework
- JRC - activities on identification and assessment of endocrine disruptors
- ECHA - Endocrine Disruptor Expert Group – mandate and report from the first meeting

For information

Item 11 – Updates to MSC Working procedures

a) Technical corrections to MSC working procedures

ECHA/MSC-35/2014/007
For decision

b) Collection of feedback on MSC working procedures on evaluation for next updates

For discussion

Item 12 – Report from other ECHA bodies and activities

For information

Item 13 – Any other business

- Note from the Chair on Rapporteurship and membership in MSC Working Group on the next recommendation for Annex XIV

ECHA/MSC-35-/2014/006

For information

- Suggestions from members

For information

Item 14 – Adoption of conclusions and action points

- Table with conclusions and action points from MSC-35

For adoption

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-35, 8-10 April 2014
(adopted at the meeting on **10 April 2014**)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 - Administrative issues	
MSC took note on the following announcements: **a.** Web training on QSAR on 19-20 May 2014 for members and stakeholders; **b.** 25 Mar–25 April 2014: testing of a new IT platform tool.	**Members** to participate in training and testing, as appropriate.
Item 5 – Adoption of draft minutes of MSC-34	
MSC adopted the revised draft minutes of MSC-34 without changes done in the meeting. MSC agreed that SECR will follow the presented proposal on streamlining the MSC minutes and members will provide further comments, if considered necessary, within the review of the MSC-35 minutes.	**MSC-S** to upload final version of the minutes on MSC CIRCABC and ECHA website by 15 April 2014. **MSC-S** to follow the presented line when preparing MSC-35 minutes.
Item 6 - Substance evaluation b. **Introduction to and preliminary discussion on a draft decision on substance evaluation after MS-CA/ECHA reactions (*Session 1, open)*** c. **Seeking agreement on one draft decision when amendments were proposed by MS's/ECHA *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decision as modified in the meeting : **SEV-FR-017/2012 Octocrilene** (EC No. 228-250-8)	**MSC-S** to upload on MSC CIRCABC the final ECHA decision/cover letter of the agreed case.
Item 7 – Dossier evaluation **a. Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the report.	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions agreed in written procedure, as indicated in document ECHA/MSC-35/2014/004. **MSC-S** to provide COM for further decision making with documents (DD, RCOM, outcome of the vote, justifications for NO votes) of cases on which MSC did not reach agreement, as indicated in document ECHA/MSC-34/2014/004.
Item 8 – Authorisation process - Prioritisation of Candidate List substances for inclusion in Annex XIV	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
• Discussion on the prioritisation results of the selected substances for the next recommendation for inclusion of substances in Annex XIV (1st discussion)	
MSC took note of the work carried out for the 6th draft recommendation for inclusion of priority substances in Annex XIV. MSC generally appreciated how the revised prioritisation approach works in practice, the work done by ECHA when applying for the first time this revised approach, in particular the transparency provided, and how the results were presented leaving more room for discussion on which substances will be included in the draft recommendation for the public consultation. MSC took note of a room document by the Commission reflecting some aspects of the authorisation process provided at the meeting. SECR took note of the oral comments for further consideration.	**MSC** to provide to SECR further written comments by 25 April on document ECHA/MSC-34/2014/008. **SECR** to consider the comments when preparing the draft recommendation for discussion at MSC-36.
Item 9 – MSC MoD • Inclusion of possible new items to the Manual of decisions of MSC	
MSC took note of the SECR's proposal for inclusion of two new topics in the MSC MoD and decided not to include any of them at this point in time, as the topics are still open for further discussion.	**Members** to review MSC meeting minutes from past years, consider appropriate topics for potential inclusion in the MSC MoD, and to submit their suggestions to the MSC-S after the meeting.
Item 10 – Endocrine disrupting substances – Information sharing • EU - current state of play and plans • OECD framework - brief introduction of the assessment framework • JRC - activities on identification and assessment of endocrine disruptors • ECHA - Endocrine Disruptor Expert Group – mandate and report from the first meeting	
	Members to provide MSC-S with suggestions for future information sharing/capacity building topics of interest to them. **MSC-S** to consider possibility to include such capacity building topics in future meeting agendas.
Item 11 – Updates to MSC Working procedures a) Technical corrections to MSC working procedures under authorisation process b) Collection of feedback on MSC working procedures on evaluation for next updates	
MSC agreed with the SECR proposal for the technical corrections to the MSC working procedures on identification of SVHCs and on developing opinion on the ECHA's draft recommendation for inclusion of substances in Annex XIV. MSC agreed to provide feedback on items on the working procedures on evaluation specified by MSC-S.	**MSC-S** to make the necessary corrections, as agreed, and to upload the updated MSC authorisation working procedures in MSC CIRCABC and on ECHA website by 30 April 2014 **MSC-S** to prepare a list of files and other items for feedback, to be uploaded with the presentation on evaluation. **Members** to provide feedback on MSC working procedures on

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	evaluation by 5 May 2014.
Item 13 – Any other business • Note from the Chair on Rapporteurship and membership in MSC Working Group on the next recommendation for Annex XIV • CoRAP 2014 Substance Managers • Suggestions from members	
MSC took note of the Note from the Chair (ECHA/MSC-35/2014/006)	**MSC Chair** to send invitation for volunteers by email after the plenary. **Members** to consider and volunteer for rapporteurship or working group membership by 12 May 2014 (or, end of May at latest). **Members** to check the email of 26 March 2014 from REACH substance evaluation mailbox on substance managers.
Item 14 – Adoption of conclusions and action points	
MSC adopted the main conclusions and action points of MSC-35.	**MSC-S** to upload the main conclusions and action points on MSC CIRCABC by 11 April 2014.

V. Dossier evaluation cases addressed for MSC agreement seeking in written procedure (WP):

Draft decisions unanimously agreed by MSC in WP:

MSC ID number	Substance name used in draft decision	EC No
TPE-001**B**/2014	6-phenyl-1,3,5-triazine-2,4-diyldiamine	202-095-6
CCH-018**B**/2014	dodecamethylcyclohexasiloxane	208-762-8

Draft decisions for which no unanimous agreement was reached by MSC in WP and which are to be referred to COM:

MSC ID number	Substance name used in draft decision	EC No
TPE-001**A**/2014	6-phenyl-1,3,5-triazine-2,4-diyldiamine	202-095-6
CCH-018**A**/2014	dodecamethylcyclohexasiloxane	208-762-8