MSC/M/49/2016
(adopted at MSC-50)

Minutes
of the 49th Meeting of the Member State Committee (MSC-49)
13 September 2016

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 49th 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 modified by the MSC Secretariat with addition of an item to the AOB on the progress made in Read-Across Assessment Framework (RAAF) for environmental endpoints and with addition of an item to the Administrative issues on the planned update of the Working Procedures of the MSC for dossier evaluation decision making process (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-49.

Item 4 - Administrative issues

- **Outlook for MSC-50**

The Chairman presented an outlook on the potential length of the next meeting using best available estimates on key parameters from dossier and substance evaluation, as well as CoRAP and SVHC identification. Acknowledging the existing uncertainties, the October meeting is expected to require at least 3 plenary days. The Chairman also presented an early stage estimation for the MSC-51 meeting in December which is expected to last at least 5 plenary days. The Chairman also indicated that there may be a need for additional preparatory meetings due to the high number of dossier evaluation, substance evaluation and SVHC cases.

- **Written procedure voting**

The Chairman informed MSC of the possible changes to the format of the written procedure excel sheets to improve on its clarity, and invited the members to provide any further suggestions for improvements and to share their experience on enhancing the usability of the system.

- **MSC Evaluation Working Procedures**

The Chairman indicated to MSC that SECR is considering updating the Working Procedure of MSC for dossier evaluation decision making due to a need to harmonise the applied practice in substance and dossier evaluation decisions for case-owner attendance.

Item 5 – Adoption of the minutes of the MSC-48 meeting

The minutes of MSC-48 were adopted as modified at the meeting.

Item 6 – Substance evaluation

a. Written procedure report on seeking agreement on a draft decision on substance evaluation

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on one substance evaluation case with one draft decision (DD) (see Part V for more case-identifier information). WP was launched on 18 August 2016 and closed on 29 August 2016. By the closing date, unanimous agreement was reached on this draft decision.

b. General topics

- **Status report on on-going substance evaluation work**

MSC took note of the SEv report given by SECR. Amongst others, SECR announced plans of earlier interactions between the evaluating Member State Competent Authorities (eMSCA) and Substance Managers in ECHA and gave an overview of the pilot project on the verification step of the DD after receiving the first Registrants' comments on the first DD. In this regards, it was recognised that the need for the consistency screening and the verification step could be reduced if early interactions take place. An industry representative showed support for the verification step, however, raised a note of caution that this could potentially mean less decisions going for agreement seeking in MSC, thus reducing the learning for industry.

The link between compliance check (CCH) and SEv was also discussed where it was explained that since each substance on the CoRAP undergoes CCH before the initiation of SEv, some eMSCAs may end up having to evaluate only one substance in a year because the outcome of the CCH can take several years. SECR explained that the outcome of CCH could also lead to a decision to go straight to risk management instead of SEv. However, there could also be situations where both CCH and SEv will runn in parallel covering different endpoints.

The Chairman reiterated the message given in the presentation to submit good quality justification documents for the substances proposed to be included in the draft annual update of the Community Rolling Action plan (CoRAP), and make full use of ECHA's support. In his view it is not the role of MSC to do the quality assurance for these documents. Instead, a poor quality justification document might lead to a recommendation from MSC not to include the substance in the CoRAP. He asked the MSC members to pass this message across to the eMSCAs.

- **Appeals update**

SECR gave an overview of the status of recent appeals on dossier and substance evaluation submitted to the Board of Appeal of ECHA (BoA). MSC took note of the information received.

Item 7 – Dossier evaluation

Decision making process - General topics

- **Appeals update**

See item 6.b.

Item 8 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2017-2019)

Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update and for Working Group membership

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

MSC agreed on the tasks of the rapporteur and the co-rapporteur in drafting the MSC opinion on the draft update of the CoRAP for 2017-2019. The Committee also appointed two of its members as a rapporteur and a co-rapporteur for this opinion preparation.

The Chairman asked the MSC to consider not accepting the substance to go to the CoRAP update if its justification document is not of good quality.

b) Discussion and possible establishment of a MSC Working Group to support the Rapporteur

MSC agreed on the mandate of a working group to support the MSC rapporteur in drafting the MSC opinion on the draft update of the CoRAP for 2017-2019. Further, MSC appointed four volunteering MSC members and three member's expert as the working group members to support the rapporteurs in the opinion development.

Item 9 – Opinion of MSC on ECHA's draft 7th recommendation of priority substances to be included in Annex XIV

a) Update by SECR on further work done on the 7th recommendation

SECR explained the changes introduced in its documentation regarding the process information for all substances, responses to the requests for exemptions under Art. 58(2) (on lead substances) and other background documentation. SECR also reflected on the impact of and potential changes to the final recommendation of substances due to updated registration data and comments received during the public consultation. Those were firstly the slight decrease in priority for the sensitizers HHPA/MHHPA lowering further the relative priority of these substances having lowest priority among substances in this round. SECR also noted that the amendment of Annex XIV based on ECHA's 5th and 6th recommendation had not proceeded in the time foreseen in the beginning of the work on the 7th recommendation. This has led to a situation where a relatively high number of recommended substances are pending the inclusion in Annex XIV and for workload reasons it is not foreseeable that the Commission can include them all immediately. Therefore, to keep the time within which the substances can move from the recommendations to Annex XIV reasonable and by that support transparency, predictability and functioning of the whole authorisation process, SECR indicated it is considering to reduce the number of substances recommended this time. Secondly, the possibility of splitting the latest application date (LAD) of the lead group (24 months) into two: 24 months for lead sulphates and 27 months for lead oxides. SECR anticipated that after receipt of the MSC opinion it will be able to finalise the 7th recommendation to be sent to the Commission around end of October.

Some MSC member's provided their views following this update (item 9a) which are included in the summary of the discussion under item 9b. The Chairman concluded this update by reiterating that the decision about inclusion of substances and their specific annex entries in the 7th recommendation will only be taken after the MSC discussions and after SECR receives the opinion of MSC.

b) MSC opinion on ECHA's Draft 7th recommendation of priority substances to be included in Annex XIV

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

The Chairman opened this item by thanking the Committee for providing the necessary feedback to the rapporteur to allow her to finalise the draft opinion for adoption in this meeting. The Rapporteur presented a slightly revised draft MSC opinion on the draft 7th recommendation of ECHA for inclusion of substances in Annex XIV as compared to the document shared before the meeting. MSC discussed the draft opinion which supported recommending the 11 substances submitted for public consultation for their inclusion in Annex XIV: two phthalates (1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear; Dihexyl phthalate), four lead compounds (Orange lead (lead tetroxide); Lead monoxide (lead oxide); Pentalead tetraoxide sulphate; Tetralead trioxide sulphate, trixylylphosphate), two anhydrides (HHPA = Cyclohexane-1,2-dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane-1,2-dicarboxylic anhydride [3]; MHHPA = Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-

methylphthalic anhydride [4]), trixylyl phosphate (TXP) and two perborates (Sodium perborate; perboric acid, sodium salt; Sodium peroxometaborate). The opinion is based on the draft recommendation of ECHA which was submitted for public consultation in November 2015.

MSC discussed the priority of the anhydrides where the score for one of the anhydrides (HHPA) had been reduced following updates in registration data and comments received in the public consultation. The overall score decreased from 20 to 18 for HHPA. The score of MHHPA, the other anhydride grouped with HHPA, remained unchanged (18). This lowered score is below (one substance with score 19) or similar to other substances that were not included in the 7th draft recommendation. Several members expressed a concern that the slight decrease in score is not a reason to leave these substances out from the current recommendation. In their view the Commission needs to keep up with the work on inclusion of substances into Annex XIV and it cannot be predicted whether the Commission will put on hold certain substances from the 7th recommendation as was done for the previous recommendations, and ECHA should not in this round be slowing down this step of the authorisation process by recommending less substances for inclusion than initially submitted for public consultation. Two members indicated that for them the reduction in priority score is sufficient grounds to recommend to ECHA that the two anhydrides are dropped now. They indicated that they would submit a statement to the minutes to document their view. One of them highlighted that in reality dropping them now means only a postponement. Other members considered that the overall reduction was slight, and that this was not a sufficient argument to justify leaving them out from the current recommendation, and to restart the process with their inclusion in the 8th draft recommendation due to their still high score. Also, two stakeholder observers, from an NGO and Trade Unions representative, expressed clear support in keeping the two sensitizers in the current recommendation whereas another one from industry expressed clear support for dropping them. SECR in responding reassured MSC that the ongoing court cases on anhydrides have no impact on the current recommendation process, and even if the actual score of certain substances change, one should not be solely looking on the relative priority but also the role of the recommendation in the authorisation process. According to SECR the predictability for the industry as well as overall good functioning of the authorisation process are important factors, and inclusion of a substance into Annex XIV in a reasonable timeframe after ECHA's recommendation will add overall clarity to the system.

As regards exemptions, MSC was of the opinion that for an exemption for a use the existing EU legislation must properly control the risk from that use of the substance specifically. Generally, the legislation should refer to the substance. Furthermore, the existing EU legislation must impose minimum requirements for the control of risks for the use in question, covering all life cycle stages, and these minimum requirements must be binding and enforceable. In the context of the lead group the exact wording to be used in the opinion was discussed and agreed upon after the rapporteur's clarifications. Some members wished to include a statement to the minutes regarding any exemptions for leads (see below). Finally, for other substances in the recommendation MSC considered that no information was submitted that would form the basis for an exemption of uses.

An expert to an industry stakeholder observer questioned the proportionality and regulatory effectiveness of including the lead compounds in Annex XIV and flagged what he considered as weaknesses in the MSC draft opinion, in particular as regards lack of proper reflection as to whether the existing lead-specific legislation (not only ELV and RoHS) when evaluated holistically properly controls the risks to human health and/or the environment from the use of the substances in battery manufacturing. He further questioned the relevance of ELV and RoHS for battery manufacturing use of the lead substances now under discussion as they are chemically transformed during the manufacturing process and are not present in the final product. He also emphasised that if including a provision for substitution in existing legislation is a requirement for granting a REACH Article 58(2) exemption, then the ELV Directive does provide a similar level of protection as REACH as it is a restriction/ban on use of lead batteries in automotive applications based upon technical availability of alternatives and that this is reviewed

periodically by Commission (e.g. every five years). However, this argumentation was not followed by MSC. Another stakeholder observer from industry was challenging the wording used in the opinion as regards experience of industry on the authorisation process to justify a shortening of the LAD compared to previous cases (chromates) and advised to consult e.g. the SEAC about its experience so far. He also expressed concern about different LADs for the leads as they are all used in the same applications. Non-aligned LADs would require multiple submissions for the same use. As regards the sensitizers, a representative from a sectoral stakeholder observer organisation drew MSC's attention to the importance of sufficient RMMs, and the improvements the sector introduced in this regard since 90's the time in which the scientific evidence that forms the basis of the annex XV dossiers was generated. He clarified that there have been no cases of adverse health effects in recent history. He pointed out the commitment of the sector to monitor and further improve upon any conditions leading to exposure, as a precautionary approach.

Referring to the leads one stakeholder observer was doubting the enforceability of biological limit values. This was counterbalanced by an industry expert's view on enforceability of these values as in the case of lead it is binding for Member States and is supported by a mandatory requirement for companies to conduct health surveillance in exposed populations through requirements of the Chemicals Agents Directive. The EU wide biological limit value established by DG Employment, under advice from SCOEL, also undergoes revision process. In this context several members considered it necessary to conduct an analysis of the basis on how these values have been set.

After introduction of few editorial changes MSC adopted the opinion by consensus albeit with abstentions from four members. One member abstained indicating that he cannot support prioritisation of the lead group due to the uses of these substances in automotive batteries where actually no alternatives are available and due to the low expected regulatory effects this route would bring in terms of human health and the environment. He also referred to potential recycling problems this might bring due to the presence of these substances in imported articles but acknowledged that the existing legislation does not cover all regulatory requirements. Five members provided a statement to be included in the minutes as regards their countries objection to inclusion of any of the lead substances in Annex XIV due to reasons of regulatory effectiveness and overall proportionality similar to the statement to the MSC-42 minutes in the 6th recommendation round). Another five members made a statement to the meeting minutes to flag that any exemption of leads from authorisation should be preceded by a proper analysis of the basis on which the binding OELs were set. One member expressed support for that statement to the minutes at the meeting, however, had to reconsider and withdrew shortly thereafter. Also two members provided a statement to be included in the minutes as regards the inclusion of the two anhydrides in ECHA's recommendation. (See Section VI for the statements.)

Following adoption of the MSC opinion on the draft ECHA 7th Recommendation for inclusion of priority substances in Annex XIV, the Rapporteur and her working group were thanked and discharged from their duties.

Item 10 – Update of stakeholder observers' participation at MSC

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

MSC thoroughly considered the ASO participation in the past year in line with the MSC General approach[1] for admission of observers from accredited stakeholder organisations (ASO). MSC took note as well on the feedback received from the regular ASO observers in this regard, the expressions of interest in MSC work of new ASOs and the expressed preferences of some of the ASOs for withdrawal or change of their observer status (from regular to occasional observers).

[1] http://echa.europa.eu/documents/10162/13578/general_approach_aso_in_msc_work_en.pdf

Members discussed the possible scenarios for a) keeping unchanged the total number of ASO observers' seats as divided in the 'Industry' and 'NGOs and Trade Unions' quotas of 7 each, or b) potentially reducing the seats in both quotas by one or by two in order to better reflect the reality. MSC recognised the importance of ensuring the proper balance of ASO interests at the MSC meetings, the ASO areas of interests in different aspects of the MSC work and the envisaged workload under the MSC processes in the next one year. Taking further into consideration the importance of proper representation of different interests and the good contributions made by the MSC ASO observers, the Committee decided to keep unchanged the total number of ASO observers' seats.

As regards the ASO admission as MSC permanent observers in different quotas, MSC decided to reconfirm, within 'NGOs and Trade union' quota[2], the MSC regular observer status of: ETUC; the seven ENV & HH NGOs (ChemSec, Client Earth, EEB, Greenpeace, HEAL, Health Care without harm Europe and Women in Europe for Common Future) to share four seats[3] when participating in MSC plenary meetings within their rotation group; the four "Animal Welfare NGOs" (ECEAE, Eurogroup for Animals, HSI and PISC) to share two seats[4] when participating in MSC plenary meetings within their group. Further, MSC revoked the MSC regular observer status of CHEM Trust due to a notified withdrawal of their interest to the MSC activities.

Within the 'Industry' quota[5] MSC decided to re-confirm the regular observer status of Cefic, CONCAWE, Eurometaux, ORO, and of CEPE and FECC (the latter two to share one seat[6] within their rotation group when participating in MSC plenary meetings). Members also reconfirmed the regular observer status of UEAPME (acknowledging the collaboration agreement of this ASO with the MSC observer from Cefic) with possible occasional participation in MSC meetings. Finally, MSC decided to change the status of the European DIY Retail Association (EDRA) from a regular to an occasional MSC observer upon their request.

As regards the admission of ASOs as MSC occasional observers, MSC decided to re-confirm the occasional observer status of the remaining ASOs interested in MSC work (mainly sectorial ones). They are invited to follow the MSC work as sector-specific observers and participate in MSC plenary meetings on an occasional basis, in accordance with MSC General approach on the ASO admission to the MSC work at the discretion of the MSC Chair's decision. The Committee also agreed on admission of one new ASOs (TIE) as an MSC occasional observer.

In addition, members discussed the suggestion of the four Animal Welfare NGOs for considering more open session discussions on substance and dossier evaluation cases that may allow more active ASO involvement in these MSC processes. In conclusion, MSC requested the MSC-S to further clarify with the NGOs what are the grounds for the issue raised - a generic transparency issue and/or a logistical issue of the organisation of open/closed sessions placed throughout the MSC meeting. Furthermore, MSC requested the MSC-S to prepare for an MSC discussion in order to align between members what items require confidential discussions and which may be held in open session.

The MSC Chair thanked MSC for the decisions taken and pointed out that MSC-S will inform ASOs concerned of these MSC decisions and will update the list of the MSC ASO observers[7] on ECHA's website after the meeting.

Item 11 – MSC Manual of decisions (MoD)

SECR presented proposals for entries for inclusion in the Manual of Decisions and Opinions (MoD). They comprised, firstly, to include one item on selecting tissues for comet assay,

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

and, secondly, standardized text on the approach of sequential testing of repeat dose toxicity study (the 90-day sub-chronic toxicity study) and the extended one-generation reproductive toxicity study (EOGRTS). The latter was for initial discussion only, noting that the text had been revised and clarified after MSC-48 with several editorial suggestions.

MSC agreed with the proposal on the tissues in the comet assay. It specifies the tissues to be examined to be "liver, glandular stomach and duodenum". In addition, it agreed to include further reasoning on different sensitivities of these tissues. The decision will apply to both dossier and substance evaluation.

MSC discussed the proposal on sequential testing. It agreed that the clarification on new available information, as agreed in the MSC-48 minutes, would be considered in the proposal.

In conclusion, MSC agreed to include one entry (under both 3.1.8 and 4.1.2), in the MoD, as revised at the meeting. Further, MSC agreed to consider the SECR's proposals for potential inclusion of one entry (tentatively 3.1.9) at the next meeting, for which MSC members were invited to send their suggestions for modification to SECR by 30 of September 2016. MSC-S will take them into account when preparing the revised proposal for MSC consideration and decision at MSC-50 in October 2016.

Item 12 – Any other business

- Tentative MSC meeting dates in 2017

The Chairman informed MSC about the availability of MSC meeting dates for 2017 which includes tentative dates for 6 plenaries available in S-CIRCABC as well as on the website. MSC was also informed on the timelines for evaluation process (SEv) related to each of those meetings which have been made available in S-CIRCABC. MSC Chairman asked MSC members for future reflection and suggestions on the feasibility of planning for 5 meetings in 2018 taking into account the expected workload for that year.

Additionally the Chairman informed MSC that progress was made in Read-Across Assessment Framework (RAAF) for environmental endpoints. MSC was informed that the draft documentation is available for the MSCAs commenting until 30 September.

- Suggestions from members

One MSC member suggested for a possibility to format text in the PfA submission webform to ease the readability.

Item 13 – Adoption of conclusions and action points

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

II. List of attendees

Members/Alternate members	**ECHA staff**
ALMEIDA, Inês (PT)	AJAO, Charmaine
ANDRIJEWSKI, Michal (PL)	BROERE, William
ATTIAS, Leonello (IT)	DE BACKER, Liisi
COCKSHOTT, Amanda (UK)	DE WOLF, Watze
COPOIU, Oana (RO)	DREVE, Simina
COSGRAVE, Majella (IE)	HERBATSCHEK, Nicolas
DIMCHEVA, Tsvetanka (BG)	JAAGUS, Triin
DUNAUSKIENE, Lina (LT)	JOHANSSON, Matti
FINDENEGG, Helene (DE)	KARHU, Elina
FRANZ, Michel (FR)	MÜLLER, Birgit
HERMES, Joe (LU)	NAUR, Liina
HUMAR-JURIC, Tatjana (SI)	RÖNTY, Kaisu
JANTONE, Anta (LV)	SOBANSKA, Marta
KREKOVIĆ, Dubravka Marija (HR)	VAHTERISTO, Liisa
KULHANKOVA, Pavlína(CZ)	VASILEVA, Katya
LONDESBOROUGH, Susan (FI)	
LUNDBERGH, Ivar (SE)	
MARTÍN, Esther (ES)	
REIERSON, Linda (NO)	
SPETSERIS, Nikolaos (EL)	
STESSEL, Helmut (AT)	
TYLE, Henrik (DK)	
VANDERSTEEN, Kelly (BE)	
VESKIMÄE, Enda (EE)	
WIJMENGA, Jan (NL)	
Observers	
ANNYS, Erwin (Cefic)	
BINKS, Steve (Int. Lead Association)	
DE KORT, Patrick (EuPC)	
DROHMANN, Dieter (ORO)	
FAβBENDER, Christopher (PISC)	
HÖK, Frida (ChemSec)	
KERÄNEN, Hannu (CONCAWE)	
MUSU, Tony (ETUC)	
WAETERSCHOOT, Hugo (Eurometaux)	

Proxies
- ATTIAS, Leonello (IT) also acting as proxy of BORG, Ingrid (MT)
- COSGRAVE, Majella (IE) also acting as proxy of DEIM, Szilvia (HU)
- SPETSERIS, Nikolaos (EL) also acting as proxy of PALEOMILITOU, Maria (CY)

Experts and advisers to MSC members
BARTHELEMY-BERNERON, Johanna (FR) (expert to FRANZ, Michel)
DOBRAK-VAN BERLO, Agnieszka (BE) (expert to VANDERSTEEN, Kelly)
JANONYTE, Agne (LT) (expert to DUNAUSKIENE, Lina)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
NYGREEN, Beryl. C. (NO) (adviser to REIERSON, Linda)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
RISSANEN, Eeva (FI) (adviser to LONDESBOROUGH, Susan)
TERENDIJ, Carline (FR) (adviser to FRANZ, Michel)

By WEBEX/phone connection:
During the agenda items 6-8 and 11: Maila PUOLAMAA (DG GROW)
During the agenda item 9: Joop DE KNECHT (NL) and Valentina BERTATO (DG GROW)

During the whole meeting: Enrique GARCÍA-JOHN (DG GROW)

Apologies:
BORG, Ingrid (MT)
DEIM, Szilvia (HU)
KOUTSODIMOU, Aglaia (EL)
MIHALCEA UDREA, Mariana (RO)
PALEOMILITOU, Maria (CY)
PISTOLESE, Pietro (IT)
RUSNAK, Peter (SK)
WAGENER, Alex (LU)

III. Final Agenda

ECHA/MSC-49/2016/A/49

Final Agenda

49th meeting of the Member State Committee

13 September 2016
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

13 September: starts at 9 am
13 September: ends at 4 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/049/2016
For adoption

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

Item 4 – Administrative issues

- Outlook for MSC-50
- Update of the Working Procedures of the MSC for dossier evaluation decision making process

For information

Item 5 – Minutes of the MSC-48

- Draft minutes of MSC-48

MSC/M/48/2016
For adoption

Item 6 – Substance evaluation
Partly closed session for 6d

Decision making process

a. Written procedure report on seeking agreement on a draft decision on substance evaluation

ECHA/MSC-49/2016/001
For information

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

For discussion followed by agreement seeking under 6c:

No cases

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

No cases

d. General topics

- Status report on on-going substance evaluation work
- Appeals update[8]

For information

Item 7 – Dossier evaluation

Partly closed session

***Decision making process* - General topics**

- Appeals update[2]

For information

Item 8 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2017-2019)

Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update and for Working Group membership

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

ECHA/MSC-49/2016/002
For discussion and decision

b) Discussion and possible establishment of a MSC Working Group to support the Rapporteur

ECHA/MSC-49/2016/003
For discussion and possible decision

Item 9 – Opinion of MSC on ECHA's draft 7th recommendation of priority substances to be included in Annex XIV

a) Update by SECR on further work done on the 7th recommendation

ECHA/MSC-49/2016/008-012
For information

b) MSC opinion on ECHA's Draft 7th recommendation of priority substances to be included in Annex XIV
   - Discussion on the draft MSC opinion

ECHA/MSC-49/2016/004-005

[8] A combination of Appeal updates for Substance and Dossier Evaluation may be introduced, if appropriate.

- Adoption of MSC opinion

For discussion and adoption

Item 10 – Update of stakeholder observers' participation at MSC

Closed session

Discussion and update of the MSC decision about the invited organisations

ECHA/MSC-49/2016/006
(For members only)

For discussion and decision

Item 11 – MSC Manual of decisions (MoD)

Suggestion for possible new entries to the MoD

ECHA/MSC-49/2016/007

For discussion and possible decision

Item 12 – Any other business

- Tentative MSC meeting dates in 2017

ECHA/MSC-49/2016/013

For information

- Progress made in Read-Across Assessment Framework (RAAF)

For information

- Suggestions from members

For information

Item 13 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-49

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

- *Introduction of EU-ToxRisk to MSC and invitation for co-operation (ECHA/MSC/I/2016/023)*
- *Status report on on-going dossier evaluation work (presentation slides)*
- *Report from other ECHA bodies (ECHA/MSC/I/2016/024)*

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-49, 13 September 2016
(adopted at MSC-49)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 5 – Minutes of the MSC-48	
MSC adopted the draft minutes as provided and amended at the meeting.	**MSC-S** to upload final version of the minutes on MSC S-CIRCABC by 14 September 2016 and on ECHA website without undue delay.
Item 6 - Substance evaluation **Decision making process** **a. Written procedure report on seeking agreement on a draft decision on substance evaluation**	
MSC took note of the written procedure report.	**MSC-S** to upload on MSC S-CIRCABC the final ECHA decision agreed in written procedure.
Item 8 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2017-2019) Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update and for Working Group membership a) Draft terms of Reference and possible appointment of the Rapporteur and Co-Rapporteur b) Discussion and possible establishment of a MSC Working Group to support the Rapporteur	
MSC adopted the mandate and the tasks of the rapporteur, and appointed one member as a Rapporteur and another member as a Co-Rapporteur for drafting the MSC opinion on the draft annual CoRAP update. MSC established a working group to support the Rapporteur and appointed volunteering members to it.	**MSC-S** to send the appointment letters to the Rapporteur and the Co-Rapporteur.
Item 9 – Opinion of MSC on ECHA's draft 7th recommendation of priority substances to be included in Annex XIV a) Update by SECR on further work done on the 7th recommendation b) MSC opinion on ECHA's Draft 7th recommendation of priority substances to be included in Annex XIV • Discussion on the draft MSC opinion • Adoption of MSC opinion	
MSC discussed the 7th ECHA's draft recommendation for inclusion of priority substances in Annex XIV. MSC in its opinion supported recommending the 11 substances for inclusion in Annex XIV as had been submitted for public consultation. Some members provided a statement to be included in the minutes as regards the inclusion of any of the lead substances in ECHA's recommendation. Some members provided a statement to be included in the minutes as regards the inclusion of any of the anhydride substances in ECHA's recommendation. Some members provided a statement to be included in the minutes to flag that any exemption of leads from authorisation should be preceeded	**Members** with statements to the minutes to submit them to SECR in writing by 19 September 2016 in the finalised form (if not yet done). **SECR** to take into account the MSC opinion and discussion at MSC-49 when finalising ECHA's 7th recommendation for inclusion of substances in Annex XIV and to submit it to the Commission. **MSC-S** to publish the final MSC opinion on MSC S-CIRCABC and on ECHA

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
by a proper analysis of the basis on which the binding OELs were set. MSC adopted the opinion on ECHA's 7th draft recommendation.	website after the meeting.
Item 10 – Update of stakeholder observers' participation at MSC • Discussion and update of the MSC decision about the invited organisations	
MSC took note of the update of the ASO observers' participation in the MSC work and took the following decisions: 1. With regard to the balance of interests and allocation of seats in different quotas, MSC decided to: • keep unchanged the total number of ASO observers' seats as divided in two quotas of 7 each[9], • keep unchanged the allocated one seat to the trade unions within the 'NGOs & trade union' quota, • mandate the MSC-S to monitor the ASO participation in the coming year and to ensure that the balance of interests is kept. 2.With regard to the admission of ASOs as MSC permanent observers in different quotas, MSC decided to: • reconfirm the MSC regular observer status of: ➢ seven Environmental and Health Care NGOs (ChemSec, Client Earth, EEB, Greenpeace, HEAL, Health Care without harm Europe and Women in Europe for Common Future) within their rotation group to share four seats when participating in MSC plenary meetings (to be physically present per meeting), ➢ four "Animal Welfare NGOs" (ECEAE, Eurogroup for Animals, HSI and PISC) within their group to share two seats when participating in MSC plenary meetings (to be physically present per meeting), ➢ ETUC, Cefic, Concawe, Eurometaux and ORO, ➢ CEPE and FECC within a rotation group to share one seat when participating in MSC plenary meetings (as agreed between themselves who to be physically present per meeting). • keep the regular observer status of UEAPME who will be represented on a regular basis by the MSC observer from Cefic and will participate in the MSC meetings on occasional basis, • change the status of EDRA from regular to occasional MSC observer, • revoke the MSC regular observer status of CHEM Trust. 3. With regard to the admission of ASOs as MSC occasional observers, MSC desided to: • re-confirm the occasional observer status of the remaining stakeholder organisations (mainly sectorial ones) previously invited to follow the MSC work as sector-specific observers on an occasional basis, in accordance with MSC General approach on the ASO admission to the MSC work at the discretion of the MSC	**MSC** to review ASO participation in its work in one year's time **MSC-S** to inform ASOs concerned of outcome of MSC decisions taken and update the list of the MSC ASO observers on ECHA's website ater the meeting **MSC-S** to invite the Animal Welfare NGOs representatives for discussion in the remit of MSC-50 plenary in order to clarify where/how they could provide better input to the MSC evaluation work **MSC-S** to prepare for a discussion on aspects that require confidentiality and which should not be addressed in the open sessions for evaluation process decision making for further MSC consideration at MSC-50

[9] Seven seats are assigned to the 'Industry' quota and seven seats are assigned to the 'NGOs & trade union' quota.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Chair's decision, • agree on admission of TIE as an MSC occasional observer. Further, MSC discussed the suggestion of the Animal Welfare NGOs for opening up more sessions to ASOs and requested the MSC-S to further clarify with these NGOs whether the raised concern is really a generic transparency issue and/or a logistical issue of the organisation of open/closed sessions placed throughout the MSC meeting. Furthermore, MSC requested the MSC-S to consider possible organisational improvements when structuring the open sessions for evaluation cases and prepare a proposal in this regard for further MSC consideration.	
Item 11 – MSC Manual of decisions (MoD) Suggestion for possible new entries to the MoD	
MSC agreed to include one existing entry (under both 3.1.8 and 4.1.2), in the MSC Manual of Decisions and Opinions (MoD), as revised at the meeting. Further, MSC agreed to consider the SECR's proposals for potential inclusion of one new entry (tentatively 3.1.9) at the next meeting.	**MSC-S** to update on MSC CIRCABC the MoD as revised by 19 September 2016 **MSC** to send their suggestions for modification of MoD entry (tentatively 3.1.9) to the Secretariat by 30 September 2016.
Item 12 – Any other business • Tentative MSC meeting dates in 2017 • Suggestions from members	
MSC was informed on MSC meeting dates for 2017 with tentative dates for 6 plenaries and on the availability of timelines for evaluation process (SEv) for each of those meetings. Additionally MSC was informed about progress made in Read-Across Assessment Framework (RAAF) for environmental endpoints. For that, documentation is available on Evaluation CIRCABC for commenting. A MSC member requested for a possibility to format text in the PfA submission webform to ease the readability.	**MSC-S** to inform MSC members on updates of the meeting dates timely if/as necessary. **MSCAs** to send to SECR their comments to RAAF documents by 30 September 2016. **SECR** to provide further information on this request.
Item 13 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-49 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC S-CIRCABC by 14 September 2016.

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

Draft decision unanimously agreed by MSC in WP

MSC ID number	Substance name used in draft decision	EC number
SEV-BE-005/2014	S-(tricyclo[5.2.1.0 2,6]deca-3-en-8(or 9)-yl) O-isopropyl or isobutyl or 2-ethylhexyl) O-(isopropyl or isobutyl or 2-ethylhexyl)phosphorodithioate	401-850-9

VI. Statements as regards agenda item 9 'Opinion of MSC on ECHA's draft 7th recommendation of priority substances to be included in Annex XIV'

Statement to the minutes of Germany, Italy, Czech Republic, Spain and Poland on the inclusion of four lead substances into the 7th ECHA recommendation

The representatives on the MSC for the countries named above do not support the inclusion of the substances Orange lead (lead tetroxide), Lead monoxide (lead oxide), Tetralead trioxide sulphate and Pentalead tetroxide sulphate into Annex XIV.

We doubt about the proportionality and the regulatory effectiveness of inclusion of these lead substances into Annex XIV. Lead substances are already highly regulated in various legislative acts (e.g. Battery Directive (2006/66/EG), End of Life Vehicle (ELV) Directive (2000/53/EC), RoHS Directive (2011/65/EU)). Further regulation of the lead substances by listing them in Annex XIV should be reflected in the light of climate protection efforts: promoting of batteries for storing renewable energy.

Regarding this we request ECHA to further analyse the benefits of prioritising these already regulated substances for Annex XIV inclusion at the current stage. Based on the results of this analysis the best way forward should be discussed.

Statement to the minutes

The representatives of the MSC for Belgium, Finland, France, Slovenia and Norway support the inclusion of the 4 lead substances in Annex XIV as the prioritisation criteria are fulfilled.

In the MSC opinion and its annex, reference is made to possible exemptions under article 58(2) due to the existing minimum requirement (BOEL) for inorganic lead and its compounds set down under Directive 98/24/EC for the protection of worker health. We strongly encourage further verification of the basis under which this limit value was set out and whether it would indeed meet the conditions of article 58(2) of REACH, namely that the risk for workers is properly controlled by applying this limit value.
It is noted that there seems to be no general methodology for the establishments of BOELs and that socio-economic considerations seem to be taken into account in this process. The BOEL for inorganic lead and its compounds (Directive 98/24/EC) is 150 µg/m^3 corresponding with a binding biological limit value of 70 µg Pb/100 ml blood, while in 2002, the SCOEL[1] proposed an OEL of 100 µg/m^3 consistent with a BLV of 30 µg/100 ml. In addition, the following is indicated in the SCOEL opinion:

Page 12: ''There is considerable uncertainty concerning impairment of reproductive function by lead. For males, there are valid indications that only PbB levels above 40 µg/dl are connected with impairment of fertility. In females, however, it is relevant that cognitive deficits of the offspring are dose-dependently associated with lead exposure. The question of reversibility of such deficits is not yet satisfactorily resolved. On the basis of the present data no definite NOAEL can be deduced, which calls for a minimization of exposure.''

Page 13:
''It should be kept in mind that the recommended BLV is not seen as being entirely protective of the offspring of working women. No threshold for potential central nervous system effects in new born and infants can be identified at present. The exposure of fertile women to lead should therefore be minimised.''

[1] Recommendation from the Scientific Committee on Occupational Exposure Limits for lead and its inorganic compounds; SCOEL/SUM/83 (January 2002)

According to the workers protection legislation, irrespective of the fact whether a BOEL exists for a substance or not, the first risk management measure is always substitution of that dangerous substance by a less dangerous one if technically possible and worker exposure to a dangerous substance always has to be minimized as much as technically possible.

[1] Recommendation from the Scientific Committee on Occupational Exposure Limits for lead and its inorganic compounds; SCOEL/SUM/83 (January 2002)

Statement to the minutes of Italy and UK on the inclusion of two anhydrides HPPA and MHPPA into the 7th ECHA recommendation

The representatives on the MSC for the countries named above support the proposal by ECHA to drop these two substances from the current recommendation.

Decreasing the prioritisation score for HHPA on the basis of information received during the public consultation means there are now other substances of similar priority that are not included in this recommendation. In addition there remain other uncertainties regarding their prioritisation at this time; there is still uncertainty on the intermediate status of relevant volume manufactured or imported. Moreover two court appeal cases are still open for the two substances concerning their identification as SVHC according to Article 57(f). We agree that actions before the European Court of Justice have no suspensive effect, however in consideration of the other arguments reported above, in our opinion the prioritisation should be reconsidered against similarly scoring substances in the next round.

Regarding this we request ECHA to further consider not prioritising these substances for Annex XIV inclusion at the current stage.