MSC/M/09/2009 Final
Adopted at MSC-10, 2 December 2009

Final Minutes

Minutes of the 9th Meeting of the Member State Committee (MSC-9)
27-28 October 2009

I. Summary Record of the Proceedings

Item 1 - Welcome and Apologies

The Chair of the Committee, Ms Anna-Liisa Sundquist, opened the meeting and welcomed the participants to the 9th meeting of the Member State Committee (MSC).

For this 9th meeting, apologies were received from two MSC members. They had notified the Chair as to their proxies (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 proposed by the Secretariat. The final Agenda is attached to these minutes.

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

No conflicts of interest were declared in respect to any Agenda point of the meeting.

Item 4 – Minutes of the MSC-8

The Secretariat (SECR) explained that written comments on the draft minutes of MSC-8 received from MSC members had been taken into account. The minutes had been adopted via written procedure on 12 September 2009 and made available on CIRCA and on the ECHA website on 2 October 2009. The adopted minutes were slightly amended in the meeting as proposed by one MSC member. The MSC Secretariat will re-upload the minutes on CIRCA and on the ECHA website.

The action points from the MSC-8 meeting were referred to by the SECR. All points had either been carried out or were to be covered at this meeting.

Item 5 - Administrative Issues

The Chair informed the meeting that the revised reimbursement rules which were adopted by the Management Board (MB) at its meeting in September 2009 are available on ECHA website and had also been uploaded to CIRCA.

The Chair asked those meeting participants who had not already handed in their declarations on confidentiality to return the signed declaration to the SECR as soon as possible during the meeting. She reminded the participants to respect the rules for confidentiality particularly because of the closed sessions of the meeting discussing confidential documents.

Item 6 - Review of the Stakeholder participation in the MSC meetings (closed session)

MSC-S reported on the closed session of the meeting. The MSC had discussed the topic and concluded to continue the current practice of stakeholder participation in those MSC meetings where identification of SVHCs and adoption of an opinion on ECHA's recommendation of substances to be included in Annex XIV are on the Agenda. SECR will continue ensuring that confidential information will be deleted from the documents that are distributed to the stakeholder observers.

Regarding discussions of draft evaluation decisions, stakeholders can continue participating on discussions of general matters. ECHA is currently not in the position to give a definite answer whether stakeholder observers can be present at discussions of documents containing company specific information.

When concluding on this issue SECR will take into account the special status of the nominated stakeholder observers and their nominating organisations which were identified as eligible by the MB to take part in the work of ECHA's Committees and the fact that these observers have signed a declaration of confidentiality and agreed to respect the Code of Conduct for stakeholder observers.

ECHA will come up with a policy decision how stakeholder observers can be involved in discussions of company specific information in ECHA's Committees. As long as such decision is not taken, the MSC will discuss all evaluation cases in closed sessions and inform the stakeholder observers about these cases appropriately.

Item 7 – Prioritisation and grouping of SVHCs for the authorisation procedure (closed session)

Feedback from the MS Workshop on prioritisation and grouping of SVHCs relevant for the authorisation procedure

A participant of the meeting reported on the closed session.
The main aim of the workshop was to screen potential SVHCs and identify those substances which should be given priority in proposing them for inclusion in the Candidate List. Annex I of Directive 67/548/EEC and the list of identified PBT/vPvB substances (478 substances) were screened. Identifying new potential SVHCs was not the purpose of the work.

Identified substances were ranked and grouped. Ranking scores were based on available information and simple indicators while grouping was mainly based on chemical structural similarities. Due to incomplete data, no final conclusions were drawn as to whether an Annex XV dossier for these substances will be prepared at last.

Several MSs expressed their initial interest to consider and to prepare an analysis of Risk Management Options (RMO) for the identified substances.

The project was a useful tool to share workload and avoid duplication of work. It also initiated an early involvement of both MSCAs and Commission in the authorisation process.

Publication of the results is not foreseen. It is at the individual Member States discretion whether and how to share the results with their stakeholders.

Item 8 – Evaluation work

a) Reporting from the Evaluation workshop - held at ECHA on 22-23 September 2009

SECR gave a presentation on findings and conclusions of the Workshop.

ECHA's view on the aim of compliance check was presented. It was highlighted that to focus the compliance check on key parameters relevant for the safe use is essential to achieve high throughput. Compliance check is not a prerequisite to start a substance evaluation although in certain cases findings of the compliance check can be very useful for substance evaluation. ECHA's findings and shortcomings identified in the dossiers during compliance check including communication letters and draft decisions will be communicated to MSs to facilitate their work.

Use of Article 36(1) of REACH instead of draft decisions under compliance checks to request submission of already available information (e.g. full study reports) was also discussed in the Workshop and should be further investigated. Based on the experience so far, registrants need more guidance to prepare robust study summaries and study summaries of sufficient quality to avoid ECHA asking too frequently for full study reports.

A written report of the Workshop will be prepared and made available later on. Criteria for targeting compliance checks will be developed by ECHA in 2010. Discussions with MSs will be continued in further workshops in 2010 with special regard to substance evaluation.

The Chair highlighted the importance of having a common understanding between ECHA and MSCAs on the principles used by ECHA for compliance check. Without this common understanding many draft decisions are likely to be commented on by MSCAs and end up in the MSC for it to find a unanimous agreement upon.

b) Information on ongoing draft decisions (closed session)

1) Reporting on the status of ongoing work

By September 2009, ECHA has received 136 registration dossiers, 21 of which have been subject to compliance check. So far three compliance checks were concluded with a communication letter to the registrant and one without any further action.

Regarding testing proposals, three registration dossiers for non-phase-in substances were received one of which was already referred to the MSC and two of which are still in earlier stages of the process. Two examinations were started on testing proposals of phase-in substances. The deadline for these examinations is 1 June 2016.

(2) Introduction to the first draft decision on testing proposals

SECR explained that the tests proposed by the registrant were for viscosity, dissociation constant and long-term toxicity. None of these were vertebrate tests so no avail-

able information was requested from the third parties by ECHA on its website. ECHA checked in detail all Annex IX and X endpoints and screened all Annex VII and VIII endpoints. The justification given by the registrant to read-across for developmental toxicity and repeated dose toxicity from another substance was found insufficient by ECHA. Data for these endpoints could not be found in major databases including OECD Toolbox. Therefore, a draft decision approving the three tests proposed by the registrant and requesting tests for the two other endpoints mentioned was sent to the registrant for comments. The registrant provided more argumentation (but no data) for the endpoints in question within the 30-day commenting period. However, registrant's comments were insufficient in ECHA's view. ECHA did not change the draft decision but sent it to MSCAs which have the right to propose amendments. Two MSCAs supported ECHA's position while one MSCA supported the registrant's position regarding read-across. One MSCA proposed a refinement of the draft decision and one MSCA considered that the testing for dissociation constant and long-term toxicity was not necessary. After careful consideration of these contributions, ECHA replied to these comments without changing the essence of the draft decision. The draft decision was referred to the MSC on the 26 October and will be discussed in the MSC-10 meeting on 2-4 December 2009 for finding unanimous agreement.

3) Information about transitional dossiers (NONS)

SECR gave a presentation on the situation of transitional dossiers. Under the Directive 67/548/EEC (NONS Directive), 8433 notifications were submitted for 5287 substances until May 2008. These notifications shall be regarded as registrations under REACH according to Article 24(1) of REACH. There are two different types of pending evaluation activities related to these notifications:
- requests of further information made by MSCAs under the NONS Directive are regarded as ECHA decisions under REACH (Article 135). The information has to be submitted to ECHA and will be evaluated by ECHA or the requesting MSCA depending on the legal basis of the original decision. It concerns about 270 dossiers but do not imply any MSC involvement, because the decision was already taken by MSCAs in an earlier stage of the process.

In the second case, where MSCAs could not finalise the evaluation process pursuant to Article 7(2) of the NONS Directive, the dossier evaluation still needs to be carried out by ECHA. The number of these cases is 120. All notifications above 100tpa (60 dossiers) and some below 100tpa will be evaluated by ECHA.

Following its action plan, ECHA has already invited 61 notifiers to voluntarily submit testing proposals by 30 November 2009 to bring their registrations into compliance with REACH. If the testing proposal(s) are submitted, they will be subject to examination in accordance with Article 40 of REACH. If no testing proposals are submitted, ECHA will prioritise the dossier for compliance check.

Registration dossiers submitted as notifications under the NONS Directive can be evaluated only for information which was required under the NONS Directive at the time of the notification (until they reach the next tonnage threshold under REACH).

The MSC will be involved in the process only if MSCAs comment the draft decision of ECHA. The first 20 draft decisions are likely to be finalised by early 2010 so the possible MSC involvement is expected not sooner than June 2010. Close collabora-

tion of ECHA Secretariat with the MSCAs (mostly of UK and Germany) might reduce the workload of MSC.

4) Draft working procedures for the MSC for compliance check and testing proposal draft decisions

The working procedures were adopted with one minor change. They will be posted on the MSC CIRCA site and also ECHA's website.

SECR gave a short presentation explaining the structure and content of the draft decisions on testing proposals and compliance checks with model examples.

Item 9 – Revision of the MSC Rules of Procedure (RoP)

SECR informed the meeting about the changes introduced in the revised version of RoP either upon proposals of MSC members or based on the need of maximum harmonisation between the RoPs of different ECHA Committees.

Regarding the most important new element of having alternates for MSC members, *option 2* for Article 5 of the RoP gained broad support from the MSC. According to this, in addition to the possibility of giving their proxy to another MSC member, members (with a voting right) can have an alternate appointed by the MSs. Alternates shall be appointed by the same procedure as the ordinary members and will have the same rights and obligations as members except for (Co)-Rapporteurship.

The concept of invited experts will not be changed. Article 11 concerning transparency was discussed but no changes were made. It was however concluded that the names of those members expressing minority opinions will be mentioned.

The MSC endorsed the RoP with the proposed changes. The revised draft RoP will be placed on CIRCA and submitted to MB for approval at a later stage most likely for its meeting in February 2010.

Item 10 – Work related to prioritisation and inclusion of substances in Annex XIV

a) ***ECHA's first recommendation for inclusion of priority substances in Annex XIV***

ECHA gave a report on finalisation of ECHA's recommendation of priority substances to be included in Annex XIV after the MSC had provided its opinion on the draft recommendation.

1. ECHA pointed out that after taking account of the opinion of the MSC regarding the change of the recommendation in some points, it amended the proposed exemptions from the authorisation requirement for the following substances *diaminodiphenylmethane (MDA),bis(2-ethylhexyl)phthalate (DEHP), benzyl butyl phthalate (BBP) and dibutylphtalate (DBP).* For these substances, the original proposal to exempt "*Placing on the market in preparation for supply to the general public for the use in artists' paints which are covered by directive 1999/45/EC"*has been withdrawn from the final version of the Recommendation.

2. The request of the MSC to raise at the next CARACAL meeting that a considerable amount of emissions of SCCP are through the use of MCCP was followed up (CARACAL-2, June 2009). MSs or COM may now take this into account in their considerations regarding the development of Annex XV dossiers for SVHC identification or for restriction.

3. Although not a priority for the moment, ECHA has began to follow MSC's request to consider the possible risks of phthalates, SCCP and HBCDD in articles (Art. 69(2)) by supporting the Commission in the review of existing specific restrictions on certain phthalates in toys and childcare articles (entries n°51 and 52 of Annex XVII of REACH).

4. MSC's request to ECHA to raise at CARACAL the issue of preparing an overview of the relevant arsenic and dichromate salts suitable for replacement of substances on the candidate list has been followed. At CARACAL-2 in June 2009 it was pointed out that ECHA has no further information on this issue than what was provided in the background documentation to the Recommendation. Given that specific data collection and investigations will need to be undertaken to obtain a sufficient overview of the potential members of a group that are related in terms of their hazard properties as well as in terms of their suitability and compatibility for certain uses, it was suggested that this analysis is carried out by the MSs or the Commission that want to bring additional arsenates or chromates to the candidate list. Norway has notified its intention to prepare an SVHC Annex XV dossier for arsenic acid and its salts.

5. MSC's request to ECHA to propose at CARACAL discussion on the issue of assessment of combined or cumulative effects in the context of REACH and potential application of an approach considering cumulative effects resulted in the conclusion that ECHA and the experts of the Commission shall develop a paper scoping the legal, scientific and technical boundaries as input for further discussion. This paper is still under development.

The Commission representative gave an overview on the timeline for preparation of Annex XIV. It was explained that inter-service consultation in the Commission on the draft Annex XIV takes ten days. Then, the World Trade Organisation has to be notified allowing 60 days to third countries to submit their comments concerning trade barriers. Translation into all the Community languages will be done in the meantime. The draft Annex XIV has to be submitted to the MSs 20 days in advance of the REACH (comitology) committee meeting. Taking these timeframes into account, the earliest REACH committee meeting which could deal with the draft Annex XIV would take place at the end of April 2010. After reaching qualified majority in the REACH committee, the European Parliament has three months to examine and propose modifications to the draft Annex XIV before it can be adopted by the Commission and enter into force.

b) Reflections from the MSC on lessons learned from the prioritisation approach for future application

Written comments of two MSC members were briefly introduced by the submitters. The Chair pointed out that the MSC had generally supported the prioritisation approach of ECHA at the MSC-8 meeting in May 2009, only some adjustment was considered necessary.

In the discussion, broad support was expressed for the use of a score-based ranking system and increased transparency. Workload for ECHA could also be considered for future prioritisations. There was a general agreement that the discussion on ECHA's prioritisation approach should be continued later in a more systematic and structured way. The Chair invited the MSC to submit further comments to MSC-S by 6 November 2009 and to inform MSC-S if they want to participate with the ECHA Secretariat in preparation of the discussion on this topic for MSC-10 in December 2010.

SECR outlined the further steps in the development of the prioritisation approach. First, ECHA will consider all the comments received and the first discussion on the revision of the approach will take place in the MSC-10 meeting. Based on the results of that discussion, the prioritisation approach can be further refined by ECHA and a further discussion on the prioritisation approach will follow in the MSC meeting in April 2010.

Regarding the 15 new substances proposed for inclusion in the Candidate List, ECHA will analyse all the available information, identify the data gaps for prioritisation and preparation of Annex XIV entries and identify the potential priority substances for Annex XIV. However, how, when and by whom the lacking information will be gathered is still unclear as ECHA's resources are insufficient to tackle this task without external support.

c) Outcome of written procedure for the MSC working procedure on providing an opinion on the draft recommendation

SECR informed the MSC that the revised working procedure was adopted via written procedure in September 2009 and that it will upload the adopted working procedure to CIRCA and to ECHA's website.

Item 11– First discussion on Annex XV dossiers for identification of SVHCs

a) Introduction to the process ahead

SECR gave a brief presentation on the different steps and deadlines of the process.

b) Brief introduction of the new Annex XV dossiers for SVHCs

SECR gave an overview on the second set of 15 substances proposed to be identified as a SVHC and on the comments received on them in the public consultation that closed on 30 October 2009.

Regarding comments challenging the harmonised classification of substances SECR pointed out that ECHA is not in the position to take these comments into account in the authorisation procedure. If industry would like to change the classification of a substance, they can initiate the process via a MS which can make a proposal for harmonised classification and labelling (CLH). This would then be addressed by RAC which would give its opinion on the proposal to COM.

Replying to a question SECR explained that although the relevant parts of the 1st ATP of CLP will be effective from 1 December 2010, the formal agreement on the harmo-

nised classification of substances included in it was already reached. In accordance with Article 57 a)-c) of REACH, a substance has to meet the criteria for classification as CMR. When a substance is included in the 1st ATP of CLP it is a clear indication that the substance meets the criteria for classification as CMR and such a substance can be identified as SVHC.

Mechanisms to de-list substances from the Candidate List should be probably found in the future if existing harmonised classification were deleted for a substance included in the Candidate List.

c) Selection of dossiers for identification of SVHCs in a written procedure

Comments either on exposure and use of a substance or challenging harmonised classification or proposing changes which can be easily introduced by the submitting MS in the Annex XV proposals and in the support documents were considered by SECR as comments that would not trigger a meeting discussion. Therefore, SECR proposed that six CMR substances would be addressed in a written procedure starting on 17 and closing on 27 November 2009. It was noted that the comments on substance identity of the two proposed Refractory Ceramic Fibers (Carcinogenic cat. 2) would not allow addressing these substances in a written procedure.

Lead chromate for which no relevant comments on intrinsic hazardous properties were received will be placed on the Candidate List without involvement of the MSC.

If the responses or modifications of the support document given by the MSCAs would give a reason not to start a written procedure on some of the six substances, MSC-S can postpone the discussion of these substances for the MSC-10 meeting in 2-4 December 2009, where also the eight other substances will be addressed.

The MSC unanimously supported the proposed way forward.

Item 12 – Planning of the work for 2009 and 2010

a) Update of the MSC work plan based on both the Registry of Intentions and ECHA's work plan

SECR briefly reviewed the main upcoming issues and their implications for the future work of MSC particularly the six substances being currently on the SVHC Registry of Intentions and the tasks originating from dossier evaluation of transitional dossiers on new notified substances. Work on dossier evaluation is continuing and may result in addressing some draft decisions in the MSC.

b) Provisional meeting calendar for 2010

SECR briefly presented the dates and main topics to be addressed in the MSC meetings planned for 2010.

c) Preparation of the Manual of Decisions

SECR presented the first draft model of the Manual of Decisions of the MSC. It's legal basis, scope, purpose and considerations taken into account during the preparation

were briefly reviewed. The way to maintain and update the document was outlined as well.

In the discussion, the MSC broadly supported the structure and provisional content of the document. Some items were initially proposed to be modified or deleted.

The Chair asked to submit written comments, including any items to be added or deleted, by 15 December 2009. SECR will then revise the document which will be discussed in-depth at the MSC meeting in April 2010. New updates for the document would also be invited taking into account finalization of some MSC processes in the meantime.

Item 13 – CLP Regulation

Classification - issues relevant to the work of the MSC

SECR gave a detailed overview on the role of harmonised classification in different REACH processes. Parts of the Community legislation including among others Article 57 of REACH are to be replaced by the CLP Regulation from 1 December 2010 were pointed out. Until 1 December 2010 the "old classifications" will serve as the basis of identification of SVHC's.

The process for proposals for harmonised classification and labelling and transitional provisions was reviewed in details. New elements regarding classification criteria, hazard and precautionary statements were briefly explained. ECHA activities on the relevant guidance to industry and CAs were also mentioned.

Item 14 – Role of the Committees in the process for guidance updates

SECR gave a presentation on the steps of preparing and updating guidance documents the aim of which is to provide industry and authorities with the commonly agreed view of REACH implementation. Special attention was drawn to the consultation procedure of guidance where also the MSC has a role to play. The MSC will be consulted on a new or modified guidance that is affecting its tasks. Individual members of the MSC can provide feedback to ECHA via a web form on ECHAs website. The MSC as such can raise issues gaps or failures in the present guidance with an impact on the MSC's work via the ECHA Secretariat. ECHA will assess these issues and inform the MSC about the feasibility and timeframe of the guidance update if the update proves necessary.

The Chair reminded the meeting that the same item was also on the Agenda of meetings of the other ECHA Committees and asked the MSC to consider the consultation process on guidance provided in the relevant meeting document.

Item 15 – Co-operation with other Community bodies

Draft Rules of Procedure (Article 110(2) and (4) of REACH) for co-operation with European Food Safety Authority and Advisory Committee of Safety and Health at Work

SECR gave a status report on the work related to the draft RoPs which were also available to the MSC for comments. After the written commenting round of the ECHA Committees, EFSA and the Advisory Committee of Safety and Health at Work, the revised documents will be submitted to MB for adoption. One comment had been received from a participant of the MSC meetings by the end of the commenting period.

Item 16 - Feedback from ECHA

a) Feedback from other ECHA bodies

The Chair of SEAC (in office since May 2009) and RAC (in office since August 2009) introduced themselves and the ongoing activities of SEAC and RAC. The MSC welcomed the new Chairs.

b) Short progress report on data security issues - MSCAs' and MSC's access to confidential data

SECR gave a brief report on ECHA's current efforts to further develop its security policy and improve its data security with special regard to documents including confidential business information. As ECHA's Committees enter into a phase when more confidential information need to be distributed via CIRCA, it seemed necessary to establish precise rules for activities related to these tasks. In this context, ECHA had prepared a draft document describing, on one hand, rules for the Committee secretariats, rapporteurs and other members to apply when uploading confidential documents to CIRCA. On the other hand, security provisions were laid down in the Annex of the document also for Committee members to receive and handle confidential information.

As it has implications for the work of Committee members, the document was distributed to the MSC (and also to RAC and SEAC) for comments. After possible revision of the document based on the comments, its adoption by the Executive Director of ECHA is foreseen and the Annex will be distributed in paper copy to all members of the ECHA Committees for their further work concerning confidential documents.

Current discussions of MB on a problem in some MSs concerning public access to confidential information will be taken into account in the final version of the document. The MSC took note of the document presented.

Item 17 – AOB

Introducing the topic, SECR gave an overview on the status and recent history of the co-operation between EU Member States and OECD on the field of chemicals (reference was made to a document presented on the CARACAL meeting in June 2009). Aim of this co-operation was to use synergies between OECD's HPV program and EU's existing chemicals program. The CARACAL meeting in June this year had supported the future co-operation although some MSs had expressed their concerns regarding lack of their resources to contribute.

Reporting from OECD on activities of interest to the MSC:

- **Future Existing Chemicals programme at OECD and assessments for SVHC**

OECD gave a presentation on the revision of its HPV Chemicals Programme.

The scope of the revised Programme will cover not only HPV but also non-HPV chemicals. In terms of outputs, the full initial hazard assessments continue to be the core of the Programme. Ways how to keep track and how to incorporate hazard assessments elaborated in national, regional and industry programmes most efficiently into these should be investigated.

Elaboration of targeted hazard assessments not covering all endpoints and of targeted chemical categories focusing on some endpoints should also be examined.

EU's potential contribution to the Programme could be the Chemical Safety Reports, Annex XV dossier for restrictions and for SVHC identification and dossiers for harmonised classification and labelling. OECD Secretariat would keep member countries informed about ECHA's public consultations on different Annex XV dossiers giving to other countries a possibility for timely comments. The submitting MSs could submit dossiers to OECD after they have passed ECHA's Committees.
In the discussion it was clarified, that the definition of targeted hazard assessments is still open. Similarly, how the information in CSRs could be best fed in the Programme still remains to be seen. ECHA would like to act as an interface between OECD and the dossier owners (i.e. MSCAs and industry) to fully utilize the opportunities offered by parallel discussions. In line with this role, ECHA will encourage industry and MSCAs to contribute to OECD's work. CEFIC and Eurometaux expressed their willingness to do so.

- **Development of the OECD QSAR Application Toolbox**

OECD gave a detailed presentation on the main features of the Toolbox, the aim of which is to facilitate the regulatory acceptance of QSAR methodology by applying computational methods in forming chemical categories, profiling chemicals and filling data gaps. The main structural parts of the Toolbox are databases and profiler tools. Version 2.0 is under development its release is foreseen in October 2010.

The results of using this Toolbox might come up in the work of the MSC in the processing of draft decisions under dossier evaluation.

Item 18 - Adoption of conclusions and action points

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

II. List of attendees

Members
BÖHLER, Elmar (DE)
CAMILLERI, Tristan (MT)
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)
FAJFAR, Simona (SI)
FLODSTRÖM, Sten (SE)
GEUSS, Erik (CZ)
HEISKANEN, Jana (FI)
KORENROMP, René (NL)
KYPRIANIDOU-LEODIDOU, Tasoula (CY)
LUDBORZS, Arnis (LV)
LULEVA, Parvoleta (BG)
MAJKA, Jerzy (PL)
MARTIN, Esther (ES)
MIHALCEA-UDREA, Mariana (RO)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TYLE, Hendrik (DK)
WELFRING, Joëlle (LU)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)

Representatives of the Commission
BORRAS HERRERO, Anna (DG ENTR)
VAN DER JAGT, Katinka (DG ENTR)
Observers
ANNYS, Erwyn - CEFIC
DIDERICH, Bob - OECD
LEENAERS, Joeri - EUROMETAUX
MUSU, Tony - ETUC
TAYLOR, Kathy - ECEAE
ECHA staff
AJAO, Charmaine
BALOGH, Attila
BRAUNSCHWEILER, Hannu
BROERE, William
CARLON, Claudio
DE BRUIJN, Jack
GRADZKA, Agnieszka
KARHU, Elina
KNIGHT, Derek
KORJUS, Pia
KOSKINEN, Marjo
LEBSANFT, Jörg
LEPPER, Peter
LEFEVRE, Remi
LUOTAMO, Marita
MALM, Jukka
NAUR, Liina
SUNDQUIST, Anna-Liisa
TARAZONA, Jose
THUVANDER, Ann
VAHTERISTO, Liisa
YLÄ-MONONEN, Leena

Replacements
NUNEZ, Maria do Céu (PT) replacing PALMA, Maria do Carmo Ramalho Figueira (PT)

Proxy's
KYPRIANIDOU-LEODIDOU, Tasoula (CY), also acting as proxy of ANGELOPOULOU, Ioanna (EL)
MARTIN, Esther (ES), also acting as proxy of PALMA, Maria do Carmo Ramalho Figueira (PT)

Experts and advisers to MSC members
ARTUS, Hannela (expert to VESKIMÄE Enda).
BIWER, Arno (expert to WELFRING, Joëlle).
KOZMIKOVA, Jana (expert to GEUSS, Erik)
LAGRIFFOUL, Arnaud (adviser to DRUGEON, Sylvie)
LEONELLO, Attias (expert to PISTOLESE, Pietro)
LUOMAHAARA, Sirpa (adviser to HEISKANEN, Jana)
LUNDBERGH, Ivar (expert to FLODSTRÖM, Sten)
PECZKOWSKA, Beata (expert to MAJKA, Jerzy)

RÁCZ, Éva (expert to DEIM, Szilvia)
SCIMONELLI, Luigia (adviser to PISTOLESE, Pietro)
TRAAS, Theo (adviser to KORENROMP, René)

Apologies:
ANGELOPOULOU, Ioanna (EL)
PALMA, Maria do Carmo Ramalho Figueira (PT)

III Final agenda

27 October, 2009
Final Agenda

Final Agenda

Ninth meeting of the Member State Committee

27-28 October 2009
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

27 October**: starts at 9:30**
28 October**: ends at 18:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/09/2009
For adoption

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

Item 4 – Minutes of the MSC-8

MSC/M/08/2009
For information

Item 5 – Administrative Issues

For information

Item 6 – Review of the Stakeholder participation in the MSC meetings

Closed session

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

ECHA/MSC-9/2009/056

For discussion and decision

- Discussion on the need of closed sessions for the MSC evaluation tasks

For discussion and decision

Item 7 –Prioritisation and grouping of SVHCs for the authorisation procedure

Closed session

- Feedback from the MS Workshop on prioritisation and grouping of SVHCs relevant for the authorisation procedure

For information and discussion

Item 8 – Evaluation work

Closed sessions for 8a and b

a) Reporting from the Evaluation workshop held at ECHA 22-23 September 2009

For information

b) Information on ongoing draft decisions

1) Reporting on the status of ongoing work

2) Introduction to the first draft decision on testing proposals

For information

c) Information about transitional dossiers (NONS)

For information

d) Draft working procedures for the MSC for compliance check and testing proposal draft decisions

ECHA/MSC-9/2009/063 and ECHA/MSC-8/2009/018

For adoption

Item 9 – Revision of the MSC Rules of Procedure

ECHA/MSC-9/2009/057 and 058

For discussion and possible endorsement

Item 10 – Work related to prioritisation and inclusion of substances in Annex XIV

a) ECHA's first recommendation for inclusion of priority substances in Annex XIV

b) Reflections from the MSC on lessons learnt from the prioritisation approach for future application

c) Outcome of written procedure for the MSC working procedure on providing an opinion on the draft recommendation

ECHA/MSC-9/2009/059, 060 and 061

For information and discussion

Item 11– First discussion on Annex XV dossiers for identification of SVHC[1]

a) Introduction to the process ahead

b) Brief introduction of the new Annex XV dossiers for SVHCs

For information and discussion

c) Selection of dossiers for identification of SVHCs in a written procedure

ECHA/MSC-9/2009/062

For discussion and decision

Item 12 – Planning of the work for 2009 and 2010

a) Update of the MSC work plan based on both the Registry of Intentions and ECHA's workplan

For information

b) Provisional meeting calendar for 2010

ECHA/MSC-9/2009/064

For information

c) Preparation of the Manual of Decisions

ECHA/MSC-9/2009/065

For information and discussion

Item 13 – CLP Regulation

- Classification - issues relevant to the work of the MSC

For information

Item 14 – Role of the Committees in the process for guidance updates

ECHA/MSC-9/2009/066

For information and discussion

Item 15 – Co-operation with other Community bodies

- Draft Rules of Procedure (Article 110(2) and (4) of REACH) for co-operation with European Food Safety Authority and Advisory Committee of Safety and Health at Work

[1] Annex XV dossiers for the identification of SVHCs and respective comments received are available in MSC CIRCA under 03. SVHC identification

For information

Item 16 – Feedback from ECHA

a) Feedback from other ECHA bodies

b) Short progress report on data security issues - MSCAs' and MSC's access to confidential data

For information

Item 17 – AOB

Reporting from OECD on activities of interest to the MSC:

- Future Existing Chemicals programme at OECD and assessments for SVHC
- Development of the OECD QSAR Application Toolbox

For information

Item 18 – Adoption of conclusions and action points

- Table with action points and decisions from MSC-9

For adoption

IV Main conclusions and action points

MSC-9 MAIN CONCLUSIONS & ACTION POINTS -27-28 October 2009
(Adopted at the MSC-9 meeting)

Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/action/by when)
4. Minutes of the MSC-8	
Pg 9 of the MSC-8 minutes to be amended slightly as proposed by one of the members after the expiration of the deadline.	MSC-S to re-upload the minutes on the ECHA web-site.
6. Review of the Stakeholder participation in the MSC meetings (closed session) Discussion and review of the MSC decision about the invited organisations	
MSC supports to keep the original list of 15 stakeholder organisations as agreed upon on MSC-2.	MSC-S will inform the original 15 stakeholder through a separate letter and reply to DUCC request soon after the meeting.
DUCC will be invited and MSC accepted their proposal to invite CEPE as their representative. They have the possibility to rotate the participation amongst the members of DUCC.	
A committee member or the Chair could propose to invite a sector organisation for the participation in the MSC meeting based on the agenda.	
The stakeholder participation will be reviewed in a year's time.	MSC-S should raise the review for discussion in late 2010.
• **Discussion on the need of closed sessions for the MSC evaluation tasks (closed session)**	
At this point in time ECHA is not in a position to give a final answer whether stakeholder observers could be allowed to follow the discussions when company related dossiers will be discussed.	
Until a decision has been taken, the MSC discussions on company related documents will be carried out in closed sessions.	Since ECHA is currently discussing internally whether to have closed sessions when company related documents are discussed, the MSC-S will inform the MSC on the outcome of such discussions, as soon as available.
8. Evaluation work	
c) Information about transitional dossiers (NONS)	
No cases on draft decision for NONs are expected to come to the MSC in 2009. If cases will come to the MSC based on the comments received from the MSCAs, the earliest will be June 2010.	
d) Draft working procedures for the MSC for compliance check and testing proposal draft decisions	
Working procedures were adopted with a slight change on pg3.	MSC-S to place on the ECHA website the adopted working procedures soon after the meeting.

Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/action/by when)
9. Revision of the MSC Rules of Procedure (RoPs)	
It was agreed that the members with the right to vote may have an alternate. The appointment of an alternate is not obligatory and each member with the right to vote can still vote by proxy.	MSC-S will upload the endorsed version of the RoPs on CIRCA and will also send them to the MB for adoption.
10. Work related to prioritisation and inclusion of substances in Annex XIV	
b) Reflections from the MSC on lessons learnt from the prioritisation approach for future application	
MSC will discuss the prioritisation approach in a more structured and detailed way in December 2009.	Members to provide written input on the reflections already provided by other members, by 6 November, if they wish to be included in the December meeting document.
The document on the prioritisation approach will then be modified after the discussion in December which will then be sent for written comments to the MSC in January. Document will then be further amended if necessary so as to provide it for the April 2010 meeting for the final discussion and possible endorsement.	MSC-S to post on CIRCA the contributions made by the members, as soon as they are received.
	Members should inform the MSC-S if they want to participate in the preparation of the discussion for the December meeting on the prioritisation approach.
First draft proposal of prioritised substances will be provided in the June 2010 meeting, with the MSC having the possibility to comment on this proposal.	
The discussion held under this agenda item will be reflected in the minutes.	
c) Outcome of written procedure for the MSC working procedure on providing an opinion on the draft recommendation	
	MSC-S will upload on CIRCA the newly adopted working procedure to replace the one that is currently on CIRCA.
11. First discussion on Annex XV dossiers for identification of SVHC	
b) Brief introduction of the new Annex XV dossiers for SVHC's	
MSC agreed on the following: - the comments received on classification do not challenge the classification of the substances since the classification is already harmonised. For the classification to be changed, a member state needs to submit an Annex XV dossier on C&L to RAC to provide an opinion on. - Substances as classified in the 1st ATP of	

Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/action/by when)
the CLP Regulation meet the criteria for classification as CMR as specified in Article 57 of REACH. This classification can be applied before the entry into effect of the same ATP (i.e. 1 December 2010). - Lead chromate will automatically be listed in the candidate list since the comments received in the public consultation do not trigger the involvement of the MSC because they were not challenging the intrinsic properties.	
c) Selection of dossiers for identification of SVHC's in a written procedure	
MSC agreed with the proposal made by the MSC-S. The 6 CMR substances proposed for written procedure were accepted.	MSC-S to start the written procedure on 17 November.
MSC gave a mandate to the MSC-S to proceed as proposed and to move any of the 6 substances proposed for written procedure to the meeting, in case the responses and the Support Document provided by the MSCAs leave room for doubt.	
12. Planning of the work for 2009 and 2010	
c) Preparation of the Manual of Decisions	
	MSC to provide comments in writing to the MSC-S by 15 December 2009.
MSC-S will change the document based on the comments received and will decide whether a written commenting round should be started before the April meeting, when it will be discussed during the meeting.	
16. Feedback from ECHA	
b) Short progress report on data security issues - MSCAs' and MSC's access to confidential data	
	MSC to provide the MSC-S with written comments on the draft ED decision.
18. Adoption of conclusions and action points	
	MSC-S will upload the conclusions and action points on CIRCA together with the presentations delivered at the meeting by 30 October.