MSC/M/02/2008 Final
(adopted on 03/09/2008)

Final Minutes

Minutes of the 2nd Meeting of the Member State Committee (MSC-2) 24-25 June 2008

I. Summary Record of the Proceeding

Item 1 - Welcome and Apologies

The Chair of the Committee, Ms Anna-Liisa Sundquist, welcomed the participants to the second meeting of the Member State Committee (MSC). New member appointed by Romania was welcomed in particular to her first meeting.

For this second meeting, apologies were received from three members. The list of attendees is given in Part II of the minutes. Two members of the committee prevented from participating in the meeting had notified their proxies. United Kingdom and Spain have given there proxies to Ireland and France respectively.

The Chair welcomed the representative from Norway as an EEA-EFTA representative and as an observer to the meeting, following the general invitation from ECHA to the EEA-EFTA states to participate in the work of the Agency. The EEA Joint Committee Decision 25/2008 on REACH entered into force on 5 June 2008, and it was recognised that the Secretariat's will now invite EEA-EFTA Countries in writing to appoint non-voting members to the MSC.

Item 2 - Adoption of the Agenda

The Agenda, revision 1, was adopted without changes. The final agenda is attached to these minutes.

Item 3 - Declarations of conflicts of interest

No conflicts of interest were declared specific to any agenda point of the meeting.

Item 4 - Adoption of the draft minutes of the MSC-1

The draft minutes from MSC-1 including the comments received from members in advance of the meeting were adopted without further modifications. The Chair reminded the MSC that its final minutes would be published on ECHA's website.

All action points from the last meeting had been dealt with. On action point 3b the Secretariat gave orally examples on how personal relationships might need to be included in the declarations of Conflict of Interest. In various ways it is a question of good judgement and it should be ensured by the members that their personal relationships can not be considered to influence their decisions in the MSC.

Item 5 - Administrative Issues

5a Reimbursement rules

- The Secretariat informed the MSC that the Management Board (MB) of ECHA has agreed on a minor revision of the general rules on reimbursement of travel expenses that will also apply to the MSC.

The Chair also advised members and experts to clearly fill in the reimbursement form together with the IBAN-code in order to ensure reimbursement.

5b Annual declarations

The Chair advised in accordance with Rules of Procedure (RoP) that all members should hand over the completed and signed annual Declaration of Commitment, the annual Declaration of Interests and the Declaration of Confidentiality during the meeting.

Members not present will be asked to send the completed declarations to the Secretariat within two weeks. The Chair reminded MSC that the Secretariat will place declarations of interests on ECHA website.

The Chair asked non-members to complete and sign the Declaration of Confidentiality.

5c Curriculum vitae for web publication

The Secretariat thanked the members for providing the short CVs and informed the members that all the received CVs were now placed on the website in line with Article 88(1) of the REACH Regulation.

Item 6 - Rules of Procedure (RoPs)

The Secretariat presented the outcome of the discussion on the proposed Rules of Procedure (RoPs) at the MB meeting on 23-24 April, (RoP document MB/20/2008 final).

The draft RoPs for the MSC were presented together with the three other draft rules of the other Committees and the Forum to the MB for its approval. After a discussion in the MB, the Board approved the RoPs with one change concerning observers that applies to all four sets of RoPs, and in particular article 6, paragraph 10 for MSC regarding exclusion of observers upon a request by a single member. This provision was replaced by referring to the right of the Chair to hold a close session.

The Board furthermore requested the Secretariat and the Committees and the Forum to ensure a maximum degree of harmonisation when the rules of procedure are revised for the first time.

The Board was also asked to give its views on the possibility to appoint alternates for the Committee/Forum members. The Board found it useful to first test the use of proxies. The Board expressed its view that alternates could only be introduced if the system of proxies was then repealed. The need for alternates should be reconsidered after one year - in the light of practical experience - and by taking into account the legal requirements of the REACH Regulation.

The Chair added that the Secretariat will provide a draft proposal for revised RoPs in the fall due to the changes necessitated by the entry into force of the EEA-EFTA agreement on REACH. At the same time the RoPs can be streamlined as requested by the Board. The final RoPs will be made available on the ECHA website.

The Secretariat concluded that it will prepare a review of the MSC RoPs within one year based on the experience of application in the MSC.

Item 7 - Stakeholder participation

Follow-up of the public call for expression of interest,

The Secretariat gave an introduction to the subject by emphasising that it is important to ensure transparency of the work of ECHA Committees and referring to Article 85(4) of the REACH, which stipulates that stakeholders may be invited as observers to the meetings of the Committees The MB had authorised the Executive Director to launch an open call for expression of interest for the stakeholder organisations to participate in the work of the Agency. The result of the call was presented to the Board at its meeting in 18-19 June 2008.

By 30 April 2008 61 organisations had expressed their interest by registering through the ECHA website, *(*http://echa.europa.eu/opportunities/stakeholdercall_en.asp*).* An eligibility assessment was performed by the Secretariat on the basis of the information submitted in the registration phase. Of the 61 organisations, the Board had regarded 32 to fulfil the criteria laid down by the Board. The Board recommended to the Committees and the Forum to use this list when selecting stakeholder observers. The call for expression of interest is continuing, and new organisations may register later on.

The Chair then opened the floor for discussion by emphasizing that it was now up to the MSC to select and invite observers to the MSC. The MB will be informed about the outcome of this decision. It was further highlighted by the Chair that it is important for the work in the MSC that invited stakeholders represents all relevant interests in a balanced way.

In the discussion following the presentation it was agreed that the MSC should indeed invite stakeholders that have expressed their interest in the work of the MSC. The invited stakeholders should represent all relevant interests and, in particular organisations representing industry, “academic world”, workers, consumers, health, animal welfare and environment. The observers were considered to be able to provide relevant information to the discussions in MSC, ease communication and function as mediators between concerned and relevant partners in specific cases as well as expand confidence among stakeholders, members and the Secretariat.

In the discussion some members were concerned that no representatives of small and medium sized enterprises have indicated their interest to participate in MSC as an observer. The Chair responded by emphasising that the MSC could invite stakeholder organisations from all the lists including organisations considered to represent particular interest relevant for the committee. One organisation (UEAPME) can be considered to represent SME’s.

Some members stressed that representatives of stakeholder organisations should not represent case-holders who would have a direct interest in an issue under discussion but they should in general be able to provide scientific and factual input to Committee’s work representing views of the whole stakeholder group.

Some members considered that it could be advisable to invite case-owners as observers sometimes when their cases are discussed at the Committee. The Secretariat pointed out that the case holders are already consulted during earlier phases of the process but did not exclude this option. Some members sensed that it could be useful in some situations if case-holders were present during certain items on the agenda related to specific substances.

After discussion the Chair concluded that the issue of case owners should not be included in the discussion of inviting stakeholder organisations as observers, but should rather be discussed in the context of working procedures of the MSC.

After the discussion it was agreed by the MSC that the total number of stakeholder observers should not in principle exceed 15 and the following organisations were concluded to fulfil the purpose of a balanced approach.

- BEUC (*Bureau Européen des Unions de Consommateurs, Business Europe*),
- The Confederation of European Business,
- CEFIC *(European Chemical Industry Council),*
- CONCAWE *(The oil companies' European organisation for environment, health and safety),*
- Eurometaux (*European Association of the Metals Industry),*
- ECEAE *(European Coalition to End Animal Experiments*),
- European Trade Union Confederation (ETUC),
- Health and Environmental Alliance,
- FEEC (*European Association of Chemical Distributors),*
- Friends of the Earth Europe,
- Greenpeace International,
- WWF European Policy Office,
- ECETOC (*European Centre for Ecotoxicology and Toxicology of Chemicals),*
- EUROTOX (*Federation of European Toxicologists & European Societies of Toxicology),*
- UEAPME *European Association of Craft, Small and Medium-sized Enterprises.*

It was agreed that the MSC will review the situation in 6 months time considering possible new candidates that have registered their interests in the meantime. The review will be based on keeping the balanced approach for observer participation and the number of observers proportionate to the number of members of the Committee. Furthermore, it was agreed that rotation of invited organisations will be considered if there are more interested parties than seats available.

In was further agreed that the Secretariat should send a general invitation to the selected stakeholder organisations by the end of July 2008 and ask them to nominate one person as the observer for the MSC meetings. The invitation should also indicate that the MSC will consider a possible rotation and review of the decision in 6 months. It was agreed that the stakeholder organisations could be invited first time to MSC-4 in October.

Code of conduct

To ensure that the presence of observers is not adversely affecting the work of the Committee, a Code of Conduct is proposed. The Secretariat had prepared elements for such a code and a first draft was presented by the Secretariat.

The majority of the members supported the importance of a positive and constructive approach to observers and also stressed the urgency in finalising the Code of Conduct so that observers could receive the code before observers are invited to take part in MSC meetings. The members also underlined that stakeholder organisations normally represent certain interests and this should be acknowledged in the Code of Conduct. Furthermore the confidentiality concept should be clarified in the text in particular regarding the rights of representatives of stakeholder organisations to report back to their constituencies. The possibility for MSC to have closed sessions should also be explicitly mentioned in the Code of Conduct.

Some members also asked to clarify in the Code of Conduct what is the role of stakeholder organisations, how distribution of stakeholder documents should be arranged and how observers' access to meeting documents can be properly organised. It was pointed out that a stakeholder organisation representative should not be simultaneously a case-owner.

The Chair concluded that the Secretariat will prepare a new version on Code of Conduct after the discussion in the Committee for Risk Assessment (RAC) meeting in early July with the aim of developing one common Code of Conduct for all ECHA bodies. The Secretariat will incorporate remarks and provide the Committee the Code of Conduct for comments in written procedure with a deadline in mid-August. The Code of Conduct will be brought for MSC endorsement in the September meeting unless agreed via written procedure.

Item 8 - Feedback from other ECHA bodies

The Secretariat informed shortly about the RAC-2 meeting and about the coming RAC-3 meeting on 1 to 4 July 2008. The issues of current relevance were the following:

RAC is going to discuss code of conduct for stakeholder observers, procedures for appointment of rapporteur and co-rapporteur and working procedures for C&L Annex XV dossiers.

Item 9 - Role and tasks of different bodies in REACH implementation

The Chair gave an introduction to the different roles of Committees, Competent Authorities (CA), REACH CA meeting and further explained the ways of communication between the secretariat and the members.

In the presentation it was emphasised that Committees are essential bodies of ECHA and before dossiers are addressed in the MSC the MS-CAs and third parties are normally consulted by the ECHA Secretariat. The ECHA Secretariat will communicate with MS-CA's via CIRCA MS-CA interest group. If comments are provided, the dos-

sier will be addressed in the MSC and the MSC Secretariat will communicate with the members via CIRCA MSC interest group. It is MS-CAs that will make proposals for Annex XV dossiers. REACH CA-meetings are supposed to discuss joint approaches regarding Annex XV dossiers.

Item 10 - Working Procedures

Standard Operating Procedures (SOPs) related to the work of the MSC

Accordance check

The Secretariat gave a brief presentation explaining the key background for an accordance check. For the Annex XV dossiers proposing an identification of substances of very high concern (SVHC) Articles 59(2) and (3) require the dossiers to be in accordance with Annex XV. Thus, the aim of the accordance check is to ensure that an Annex XV dossier for SVHC includes the information specified in section 2 of Annex XV. It is vital for the whole decision making procedure that a dossier is in accordance with Annex XV because that will facilitate the process of identification of SVHC substances including MSC involvements in the process.

The Secretariat highlighted that there is no 'formal' accordance check foreseen in REACH compared to what is required under the conformity check for Annex XV dossiers submitted in case of restrictions. The aim of the accordance check is to facilitate work of the MSC and it is not an evaluation of the quality of data but only to make sure the dossiers include all the necessary information specified in Annex XV.

As accordance check will concern the dossiers prepared by the MS-CA's the Chair rounded up the discussion by saying that the character of accordance check will be further discussed in CA meetings.

Processes related to the Identification of Substances of Very High Concern

The Secretariat presented the way it envisages the process on identification of SVHC and the preparation of the first recommendation of priority substances to be included in the Annex XIV as well as the embedded timing needs linked to it.

The presentation highlighted that all the documentation to the members will be made available on the designated CIRCA site for the MSC. Until the IT-tools are more developed to allow access to the full dossiers using REACH-IT, an export file of the IUCLID file will be placed on the CIRCA site at the time when comments on Annex XV dossiers are received and there is a need to address the issue in the Committee.

Receipt following the finalised accordance check will begin the process of identification of SVHC and the time lines of the different steps of the process will start running.

The Secretariat underlined that the MS-CA submitting the dossier will have to prepare in co-operation with the ECHA Secretariat the Response to comments-document (RCOM) and transform the Annex XV report to Support Document based on the received comments. These two documents are provided to the Secretariat by the dossier submitter. As soon as any comments are received the MSC is made aware that the substance needs to be addressed by it.

The referral of Annex XV dossier to MSC triggers the 30 day period within which the MSC must seek unanimous agreement on the identification. The Response to comments document prepared by the dossier submitter and the Support Document (i.e., the Annex XV dossier updated and modified as necessary) will be made available to the members via CIRCA as soon as available. The draft agreement referring to Support Document on identification of the SVHC will be discussed at the meeting of the MSC if written procedure cannot be applied for finding the agreement.

Discussion
In the following discussion MSC supported in principle the process as developed and presented. Some issues were raised on accordance check. However, the Chair noted that such discussion should take place in REACH-CA meeting. Some members pointed out, that only comments contradicting identification of SVHC should be brought up in the MSC and not the comments which are meant to support the identification.

A majority of members supported this approach and the Chair then concluded that the MSC should only address real comments and not comments like “I agree” or “I support the dossier”. The Chair furthermore underlined that all comments, also those from third parties against the identification of SVHC will also be taken up in the MSC.

Some members pointed out that the MSC should avoid using unnecessary time in obvious cases, and move directly to written procedure on some proposals for SVHC identification (e.g. CMRs in Annex I of Dir. 67/548).

Responding to a question about the status of RCOM, support document and draft agreement the Chair clarified that RCOM is only supposed to be background information to the MSC, whereas the support document will be used as justification for the agreement. The Support Document is supposed to be adopted by the MSC together with the agreement.

One member expressed concern if comments on exposure and uses could influence the agreement on identification of SVHC. The Chair responded that it will be clarified that comments on exposure and uses will not be considered for the agreement on identification of SVHC but only later on the process for possible priority setting and for the reparation of the draft recommendations of substances to be included on Annex XIV.

The Chair pursued the discussion by saying that the Secretariat will draft working procedures for MSC for the September meeting focusing on:

- Specifying the basis for MSC agreement (The draft agreement and Support Document will be based on Annex XV dossier and comments provided during the process. The members are not expected to raise new comments when seeking the agreement),
- Setting up the right procedures to make sure MSC meetings are efficient in seeking agreements,
- Clarifying when to apply written procedure,
- Clarifying which type of comments should not be considered,

- Set up a Manual of Decisions to record principles used for decisions – to help MSC members to track important principals,
- Efficient ways to facilitate finding agreements: teleconferences as one example
- Considering invitation of case-owners for certain agenda points as necessary.

The Chair closed the item by recommending MSC members to provide suggestions for any desired procedures or elements to be included in the working procedure by mid-August.

To complete the picture for identification of SVHC the Secretariat will prepare a document for September meeting how to apply PBT/vPvB criteria in the identification process. Discussion on the PBT/vPvB criteria should take place before SVHC dossiers are addressed in the October meeting.

Processes related to handling of testing proposals and decision making

The Secretariat gave an elaborated presentation on the processes related to the examination of testing proposals as carried out by the Secretariat and the involvement of the MSC, including the timeframes foreseen to be applicable for the MSC.

The Secretariat highlighted that MSC involvement becomes necessary when proposals of amendments are provided by MS-CA(s) on the draft decision of the Agency on a testing proposal.

Taking into account the strict deadlines for the process it is essential that the members are well prepared for finding an agreement on a draft decision at the meeting. The draft decision will be the basis for the Committee's discussion. It will be prepared by the Secretariat and the related Statement of Reasons should shortly justify the proposed actions.

Procedure

If proposals of amendments are received the item is tentatively added to the draft agenda. Written procedure would be preferred for finding the agreement, however, this will be considered based on the type of proposed tests and amendments. Seeking of unanimous agreement takes place in the MSC meeting (or via written procedure), after the consultation period of 30 days with registrants/DU's on amendments of MS-CA's has expired.

The draft decision with the reasoning is discussed and amended if needed at the meeting of the MSC, in particular for taking into account as necessary comments of registrants/DU's after referral of the draft agreement to the MSC. Unanimous agreement of the members present on the draft decision is required. Written procedure may also be used when seeking agreement on the draft decision.

Discussion

Following the presentation and as a respond to a question from a member the Chair highlighted that the use of written procedure should be maximized as the 60 days deadline for agreement would allow a meeting after written procedure if no agreement is reached in the written procedure. This approach was supported by the MSC.

The Chair also envisaged that further criteria and potential practices (working procedures) should be developed to be able to decide in advance on the use of written procedure.

Item 11 - Planning of the work for 2008

a) Information on Annex XV dossiers – Intentions for proposals for the identification of substances of very high concern (SVHC) and early estimates related to the opinion on the recommendation of priority substances to be included in the Annex XIV (list of substances subject to authorisation).

The Secretariat informed that 17 dossiers have been received by early June 2008, and that after the accordance check the Annex XV reports will be published on the website of ECHA for public commenting (target date as Monday 30 June), and full dossiers for MSs will be available on the designated CIRCA site.

The Agency shall make its first recommendation of priority substances to be included in Annex XIV (substances subject to authorisation) by 1 June 2009 (Article 58 (3)). In order to be able to meet this deadline the Secretariat has made a detailed planning for the different steps that need to be followed in line with the procedures defined in Articles 58 and 59 of the REACH Regulation.

As a consequence of the process, a major workload for the MSC is foreseen on the identification of SVHC for the October meeting, and subsequently in December on providing the MSC opinion on the draft recommendation for inclusion of substances in Annex XIV before the public consultation phase starts.

Following the intervention of the Commission Services it was underlined that this planning will only hold for those substances for which the MSC has reached unanimous agreement on their identification at its meeting in October 2008. This would then mean in practice that it will not be possible to include those substances for which the Commission will ask the Agency to make Annex XV, in the first recommendation of the Agency.

The Chair noted that since the submitted SVHC Annex XV dossiers only include substances already identified as CMR's in Annex I of Directive 67/548/EEC or PBT's/vPvB's identified by MS's as such earlier the Secretariat does not foresee major obstacles.

The Chair concluded that a main milestone for the MSC this year is seeking of agreement for the proposals received by ECHA for identification of SVHC and to provide an opinion on the first recommendation of priority substances in December.

b) Dossier evaluation - Overview on draft decisions on testing proposals and compliance check

The Secretariat presented preliminary estimates of the workload under dossier and substance evaluation in the period 2008-2012, with particular regard to those activities that will involve the Committee. It presented rough estimates in terms of minimum and maximum numbers that are expected to be refined in the following months along with the beginning of the registration and evaluation process.

It was emphasized that there are still major uncertainties about the number of registrations and testing proposals that will be submitted, and in particular about the number of early registrations of phase-in substances in the years 2008 and 2009. Moreover, it is difficult to predict the number of cases in which the MS-CAs will propose amendments on the draft decisions and hence trigger the involvement of the MSC.

The Secretariat has to make the compliance check for a relevant quota of submitted dossiers (at least 5% per tonnage band) to verify whether the information in the technical dossier and in the Chemical Safety Report is adequate and corresponds to the legal requirements. However, an intense compliance check activity in the first years could play a strategic role to improve the quality of registrations. A part of the compliance check includes checking dossiers which include waiving statements and QSAR calculations.

It is expected that a gradually increasing number of draft decisions relating to the compliance check of registration dossiers have to be examined by the MSC from 2009 to 2012. Initial activities in the MSC linked to substance evaluation are expected to start in 2012.

The Chair closed the item by assuming that no testing proposal draft decisions or compliance check draft decisions will reach the MSC before early 2009.

Item - 12 Preparing for the MSC tasks under REACH

With two experts, Dr. Ursula Gundert-Remy (Bundesinstitut Für Risikobewertung) and Dr. Etje Hulzebos (RIVM), specifically invited for this agenda item the workshop session was started by giving a general introduction to risk assessment paradigm, testing for different endpoint and test requirements under REACH in order to prepare the MSC for their future tasks under REACH. Also differences between the old legislation and REACH Regulation were underlined.

Following the presentations the meeting participants were divided into two groups to learn about the experiences from evaluation and processing of testing needs used under the new substances regime under Directive 67/548/EEC and to discuss the example documents prepared by the Secretariat for the draft agreement testing proposal and draft agreement, Support Document and RCOM for the identification of SVHC.

Following the workshop each group reported back to plenary about the outcome of their discussions. The main conclusions were:

Testing proposals

- Correct application/interpretation of the legal text of REACH and its Annexes IX-XI is essential when testing proposals are discussed and concluded by the MSC.
- On scientific issues there is usually some room for manoeuvre but the limited time means that as many difficult issues as possible should be identified and solved in advance to the extent possible.
- Recording of the decisions is important in order to ensure consistency.
- More difficult waiving cases would often require support from specialised experts before the meetings; time constraints of concern in this respect.

- Legal interpretation issues (e.g. what is an intermediate) will also need to be clarified but this is usually easier based on the extensive, already available guidance.

SVHC (PBT) assessment

- Draft agreement, being a legal document, should be as concise as possible; however some Members were of the view that coherent presentation of the underlying argumentation is needed in the draft agreement.
- The underlying argumentation should be taken from the Support Document summary or conclusion part and any new summary text for the agreement should be avoided.
- Also chronology of key events should be included in the draft agreement in order to provide clear evidence that all the legal deadlines and steps were followed;
- If the case has already been discussed and agreed at EU level (in particular if the agreement is formalised by voting in the Article 15 committee of Reg. 793/93), reopening of the earlier case should be avoided unless new contradicting information has been submitted.
- All relevant scientific information in one consolidated Support Document is regarded helpful and transparent; the Support Document should however focus on the relevant hazard endpoints for identification of SVHC. It is assumed that the discussion in the MSC should concentrate on issues which were subject to comments on identification of SVHC.

The Chair summarised the workshop session by saying that the cases the members have been working on through the day very well illustrate the complexity of future tasks for the MSC and the responsibilities for the members. It is critical in order to ensure the functionality of the MSC that members are well prepared before the meetings and it is important that the Secretariat and members already now start identifying problematic issues where discussion may be needed. In cases where answers already can be found from existing guidance documents it should be brought to the attention of the members.

The Chair concluded that the Secretariat will take all the constructive conclusions into consideration when revising the draft agreement and the Secretariat will provide revised version of the draft agreement for the MSC-3 meeting.

Item 13 - AOB

Next meetings

Tentative meeting dates for 2008 were presented as

- 3-4 September
- 7-10 October
- 4-6 November
- 16-18 December (start pm of the 16th).

The Chair highlighted that in the September meeting important issues to be covered will be the discussion on criteria for identification of PBT/vPvB-substances for the candidate list, working procedures of the MSC and endorsement of code of conduct.

Feedback from the REACH Competent Authorities meeting

A short debriefing from the meeting of the REACH CAs was provided by the Chair on issues of relevance to the MSC. To complement the information on identification of SVHC the MSC was informed that the Commission has asked ECHA to prepare five Annex XV dossiers for PBTs. These substances will only be included in the identification process for SVHCs once the Commission has made its formal request to ECHA identifying the substances for which Annex XV dossiers are to be prepared. These substances will not be ready for discussion in MSC October meeting.

The Secretariat will consider developing a document for later in the autumn (November meeting) on principles for making a recommendation and prioritising substances for Annex XIV.

The Commission is reviewing Annex XI.3 (so called exposure based waiving) and Annex XIII of REACH. Reviews are supposed to be finalised by 1 December 2008. Outcome of both reviews will have relevance for MSC work.

Invitation of OECD

The Secretariat informed that the OECD Secretariat have asked for observer status in MSC. As OECD is an international organisation it can be invited to Committee meetings according to article 107 of REACH. MB has expressed a positive view on invitation of OECD to participate in Committees work as an observer.

It was agreed that the Secretariat should invite OECD as observer to MSC meetings. The Secretariat will prepare a general invitation to OECD Secretariat to this end.

Item 14 - Adoption of conclusions and action points

The conclusions and action points of the meeting as drafted by the Secretariat were adopted after discussion.

II List of attendees

Members
BÖHLEN Elmar (DE)
CAMILLERI Tristan (MT)
COSGRAVE Majella (IE)
DEIM Szilvia (HU)
DUNAUSKIENE Lina (LT)
FAJFAR Simona (SI)
FERREIRA MARQUES Jeanine (BE)
FLODSTRÖM Sten (SE)
GEUSS Erik (CZ)
KORENROMP René (NL)
LARSEN Henrik Søren (DK)
LUDBORZS Arnis (LV)
LULEVA Parvoleta Angelova (BG)
MAJKA Jerzy (PL)
MOREAU Emmanuel (FR)
MIHALCEA-UDREA Mariana (RO)
PALMA, Maria do Carmo Ramalho Figueira (PT)
PISTOLESE Pietro (IT)
RAUTALAHTI Katariina (FI)
RUSNAK Peter (SK)
STESSEL Helmut (AT)
VESKIMÄE Enda (EE)
WELFRING Joëlle (LU)

Representatives of the Commission
SOKULL-KLÜTTGEN Birgit (JRC)
VAN HAELST Anniek (ENV)
ROZWADOWSKI Jacek (DG ENTR)
Observers
HALLINGSTAD Trygve (NO)
ECHA staff
ALT-ANTSKOG Natalie
BALOGH Attila
BRAUNSCHWEILER Hannu
BROERE William
CARLON Claudio
DE BRUIJN Jack
KORJUS Pia
KOSKINEN Majo
KREYSA Joachim
LEBSANFT Joerg
MUNN Sharon
PEDERSEN Finn
PETERSEN Kim
POPESCU Raluca
RASMUSSEN Kirsten
SUNDQUIST Anna-Liisa
TISSIER Chrystele
VAHTERISTO Liisa
VASILEVA Katya
YLÄ-MONONEN Leena

Replacements
SANCHEZ, Pablo replacing MARTIN, Ester (ES)
NORTHAGE, Christine replacing FAIRHURST, Steve (UK)

Proxy's
COSGRAVE Majella (IE) also acting as proxy of FAIRHURST, Steve (UK)
MOREAU Emmanuel (FR) also acting as proxy of MARTIN, Ester (ES)

Experts and advisers to MSC members
HEISKANEN, Jaana (adviser to RAUTALAHTI, K.)
SCIMONELLI, Luigia (adviser to PISTOLESE, P.)
LEONELLO, Attias (adviser to PISTOLESE, P.)
TRAAS, Theo (adviser to R. Korenromp)
LUNDBERGH, Ivar (expert to FLODSTRÖM, Sten)
KOZMIKOVA, Jana (expert to GEUSS, Erik)

Invited experts
GUNDERT-REMY, Ursula (invited expert)
HULZEBOS, Etje (invited expert)

Apologies:
ANGELOPOULOU, Ioanna (GR)
FAIRHURST, Steve (UK)
MARTIN, Ester (ES)
KYPRIANIDOU-LEODIDOU Tasoula (CY)

III Final agenda

12 June, 2008
ECHA/MSC-2/2008/A/02 DRAFT Agenda-Rev. 1

Draft Agenda

Second meeting of the Member State Committee

24-25 June 2008
Helsinki, Finland
24 June: starts at 9:00
25 June: ends at 17:30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/02/2008
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the draft minutes of the MSC-1

MSC/M/01/2008/revised draft
For adoption

Item 5 – Administrative Issues

a) Reimbursements – revised rules
b) Annual declarations
c) Curriculum vitae for web publication

ECHA/MSC-2/2008/10

For information

Item 6 – Rules of Procedure (ROPs)

Feedback from the Management Board meeting

ECHA/MSC-2/2008/11

For information

Item 7 – Stakeholder participation

Follow-up procedures following the public invitation

ECHA/MSC-2/2008/12

For discussion and decision

Item 8 – Feedback from other ECHA bodies

Committee for Risk Assessment meeting (March 11-13)

For information

Item 9 – Role and tasks of different bodies in REACH implementation

- Explanation of role of Committees, Competent Authorities (CA) and REACH CA meeting
- Communication tools

For discussion

Item 10 – Working Procedures

Standard Operating Procedures (SOPs) related to the work of the MSC

- Processes related to the Identification of Substances of Very High Concern
- Processes related to handling of testing proposals and decision making

ECHA/MSC-2/2008/13 and ECHA/MSC-2/2008/14 and ECHA/MSC-2/2008/17

For discussion

Item 11 – Planning of the work for 2008

Workload of the MSC in 2008

a) Information on Annex XV dossiers – Intentions for proposals for the identification of substances of very high concern (SVHC) and

Early estimates related to the opinion on the recommendation of priority substances to be included in the Annex XIV (list of substances subject to authorisation)

b) Dossier evaluation - Overview on draft decisions on testing proposals and compliance check

ECHA/MSC-2/2008/15 and ECHA/MSC-2/2008/18
For discussion

Item 12 – Preparing for the MSC tasks under REACH

a) Dossier evaluation

- Examples of testing needs under the Directive 67/548/EEC for new substances
  - Human health aspects
  - Environmental aspects

b) Identification of Substances of Very High Concern

- Examples of agreement process on PBT substances

Test cases for documents

- Annex XV dossier
- Support Document
- Agreement

ECHA/MSC-2/2008/16
For discussion

Item 13 – AOB

Next meetings
Feedback from the REACH Competent Authorities meeting

Item 14 – Adoption of conclusions and action points

IV Main conclusions and action points

MSC-2 MAIN CONCLUSIONS & ACTION POINTS – 24-25th June 2008
(adopted at the MSC-2 meeting)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
4. Draft minutes	• Draft minutes were adopted	• Minutes will be placed on the ECHA website (SECR /after the meeting)
5.b) administrative issues (annual declarations)		• Declarations (three forms annexed to the RoPs) to be filled in and returned to the secretariat (all members / within 2 weeks) • Publication of the declarations of conflicts of interest (SECR / ASAP)
6. MSC Rules of Procedure	• Revision of the RoPs will be prepared to take account of the EEA-EFTA agreement on REACH and the streamlining need indicated by the MB in April • Review of ROPs based on experience of application in one year's time (alternates)	• Final RoPs to be made available on the ECHA website and CIRCA (SECR/after the meeting) • Secretariat to provide a proposal for revised RoPs in the fall • SECR to prepare a review to the MSC within one year
7. Stakeholder participation	• MSC decided to invite the following 15 stakeholder organisations to send an observer on a regular basis to the MSC-meetings from MSC-4 onwards: BEUC - Bureau Européen des Unions de Consommateurs, BusinessEurope - The Confederation of European Business, CEFIC, CONCAWE, Eurometaux (*European Association of the Metals Industry), European Coalition to End Animal Experiments* (ECEAE), European Trade Union Confederation (ETUC), Health and Environmental Alliance, FEEC (*European Association of Chemical Distributors)*, Friends of the Earth Europe, Greenpeace International, WWF European Policy Office, ECETOC, EUROTOX (*Federation of European Toxicologists & European*	• Send a general invitation to the selected stakeholder organisations (SECR/by end of July) indicating possible rotation and review of the decision in 6 months time

	Societies of Toxicology), UEAPME *European Association of Craft, Small and Medium-sized Enterprises* • Agreement was based on the balanced representation and total number of organisations. In general, 14-15 was regarded as appropriate number of stakeholder observers. • MSC will review the list of invited organisations within 6 months time based on the new indications of interest by stakeholder organisations (in particular SME and DU representatives). The review will be based on number of relevant interested organisations and balanced representation. • Rotation of invited organisations will be considered if there are more interested parties than seats available.	
7. Code of Conduct	Discussion on elements for Code of Conduct; Attention should be paid to the following: • Stakeholders represent certain interests and that should be taken into account in the document • Confidentiality concept should be clarified in the text in particular regarding the rights of representatives of stakeholder organisations to report back to their constituencies, closed sessions should be referred to • Role of stakeholder organisations should be clarified in the code of conduct • Distribution of documents by stakeholders should be clarified • Stakeholders access to documents should be clarified • More positive tone preferable • Stakeholder organisation representative should not be simultaneously a case-owner	• The Secretariat will prepare a new version on code of conduct after the discussion of RAC next week with the aim of agreeing on one code of conduct for all ECHA bodies • Code of conduct will be provided to the MSC for comments in written procedure with a deadline in mid-August • The Code of Conduct will be brought for MSC endorsement in the September meeting unless it can be agreed in the written procedure
8. Feedback from other ECHA bodies		• SECR to report back from other ECHA bodies always when the issue touches/relates to MSC work
9. Role and tasks of different bodies	• Committees are part of ECHA • Before the dossiers are addressed in the Committee the MS-CAs and third parties are normally consulted by the ECHA secretariat	

	• If comments are provided, the dossier will be addressed in the MSC and the MSC secretariat will communicate with the members via Circa interest group • MS-CAs will make proposals for Annex XV dossiers • REACH CA-meeting will discuss joint approaches regarding Annex XV dossiers	
10. Working Procedures - Identification of Substances of Very High Concern	SVHC process • No firm conclusions but the MSC understands the usefulness of the accordance check which would facilitate work of the MSC • The accordance check is not an evaluation of the data • The RCOM is provided as background information to the MSC • Draft agreement is prepared by the secretariat and it should be in line with the support document • Some agreement was indicated for the proposed justification for using written procedure on some proposals for SVHC identification (e.g. CMRs in Annex I of Dir. 67/548 or when no comments from the MS-CAs are received) • Comments on exposure and uses will not be considered for the agreement on identification of SVHC • It will be clarified what shall be considered as a comment to be taken into consideration in the process • MSC supported in principle the process as developed and presented	SECR to develop further considerations to facilitate agreement seeking prior to October meeting: • Discussion on PBT/vPvB criteria SECR to propose a draft for MSC working procedures for the September meeting: • Specify the basis for MSC agreement (Annex XV dossier and comments provided) • The members will not express new comments at the meeting but are seeking the agreement • Write down when to apply written procedure • Which type of comments should not be considered • Manual of Decisions to record principles used for decisions • How to facilitate finding the agreement: teleconferences • Consider invitation of case-owners to meetings. MSC members to provide suggestions for any desired procedures or elements to be included in the working procedure (by mid-August)
10. Working Procedures - testing proposals and decision making	Testing proposal procedures • MSC agreed that use of written procedure should be maximized as 60 days deadline for agreement would allow a meeting after written procedure if necessary	• Considerations for working procedures as above on relevant aspects

	• Written procedure would be launched after the comments of registrants' on amendments of MS-CAs have been received • Further criteria and potential practices should be developed to be able to decide in advance on the use of written procedure • MSC supported in principle the process as developed and presented	
11. Planning of the work	Main milestones for the MSC this year are • seeking of agreement for the app. 17 proposals received by ECHA for the identification of SVHC in October • to provide an opinion on the first recommendation of priority substances in December The assumption is that no testing proposal draft decisions or compliance check draft decisions will reach the MSC this year but only early 2009	• The procedure and considerations to be developed (first draft by SECR) on how to develop the opinion on recommendation of priority substances; for November meeting • For testing proposals and their efficient processing in the MSC further development by both SECR and the MSC members is needed.
12. Preparing for the MSC tasks under REACH	Testing proposals • Correct application of the legal text of REACH and its Annexes IX-XI is essential when testing proposals are discussed and concluded by the MSC • On scientific issues there is usually some room for manoeuvre but the limited time means that as many difficult issues as possible should be identified and solved in advance to the extent possible • Recording of the decisions to the MoD is important in order to ensure consistency • More difficult waiving cases would often require support from specialised experts before the meetings; time constraints of concern in this respect • Legal interpretation issues (e.g. what is an intermediate) will also need to be clarified but this is usually easier based on the extensive, already available guidance SVHC (PBT) assessment • Draft Agreement, being a legal document, should be as concise as possible; however some Members were of the view that co-	• SECR and Members to identify problematic issues where discussion may be needed; where answers can already be found from existing guidance documents, this is to be brought to the attention of the members

	herent presentation of the underlying argumentation (including key numerical values) is needed in the DA • The underlying argumentation should be taken from the SD summary or conclusion part and any new summary text for the agreement should be avoided. • Also chronology of key events should be included in the draft agreement in order to provide clear evidence that all the legal deadlines and steps were followed; • If the case has already been discussed and agreed at EU level (in particular if the agreement is formalised by voting in the Article 15 committee of Reg. 793/93), re-opening of the earlier case should be avoided unless new information has been submitted. • All relevant scientific information in one consolidated Support Document is regarded helpful and transparent; the SD should however focus on the relevant hazard endpoints for identification of SVHC. It is assumed that the discussion in the MSC should concentrate on issues which were subject to comments.	• SECR to consider the conclusions when revising the DA and SD templates for MSC-3 • SECR to provide revised versions of examples for MSC-3.
13. AOB	Tentative meeting dates for 2008 • 3-4 September • 7-10 October • 4-6 November • 16-18 December (start pm of the 16th) OECD Secretariat to be invited as observer to the MSC meetings	• MSC SECR invite OECD to meetings
General		• all presentations and room documents on Circa (SECR /by 27/6/08) • conclusions and action points (= this doc) to be uploaded to Circa (SECR /by 27/6/08) • remaining mini-CV to be published by SECR