MSC/M/07/2009 Final
Adopted on MSC-8, 18/05/2009

Final Minutes

Minutes of the 7th Meeting of the Member State Committee (MSC-7)
1-2 April 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 7th meeting of the Member State Committee (MSC). She informed the participants that the meeting would be recorded solely for the purposes of taking the minutes and that the tape will be destroyed after the adoption of the minutes.

For this 7th meeting, apologies were received from four MSC members. The list of attendees is given in Part II of the minutes. Three members of the MSC who were unable to participate in the meeting had notified the Chair as to their proxies (for details see Part II of the minutes).

The Chair informed the meeting participants about the house keeping rules of the conference centre in ECHA.

Item 2 - Adoption of the Agenda

The Agenda was adopted with a slight change of order of Agenda sub items 7a and 7b. 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 – Final minutes of the MSC-6

4a Adoption of draft minutes

Written comments on the draft minutes of MSC-6 received from five MSC members had been taken into consideration. These comments were presented to the MSC for information. The minutes had been adopted by the written procedure on 10 March 2009. The Chair reminded the MSC that the final minutes had been published on ECHA's website in March 2009.

4b Action points

The action points from the last meeting were referred to by the Secretariat. All had been carried out or were to be covered at this meeting.

Item 5 - Administrative Issues

The Chair informed that the revised reimbursement rules which were adopted by the Management Board at its meeting in December 2008 are available on ECHA website and have also been uploaded to MSC CIRCA site.

According to the revised reimbursement rules, starting from this MSC meeting pre-paid tickets and pre-paid hotel arrangements would be provided to Committee members by the travel agency Kaleva Travel. Members can make their travel and hotel ar-

rangements via a special web page. The Chair asked for any feedback on the use and functionality of the system, so that any necessary improvements could be introduced later on if necessary.

The Secretariat (SECR) introduced the Decision of the Management Board made in December 2008 on the Remuneration of Co-opted Members and Experts Invited by the ECHA Committees or the Forum, and the logic behind. The Decision has been made available on ECHA website as well as on the MSC CIRCA site.

It was clarified that the legal basis for the Decision is Article 87(3) of REACH and Article 15 of the ECHA Fee Regulation. The scope of the remuneration rules covers the co-opted members and invited experts of the Committees and Forum. However, an important limitation was that employees of REACH competent authorities and enforcement authorities are not entitled to remuneration. It was also clarified that experts can be remunerated only if they are invited by the Committee; invitation by a Committee member is not sufficient for remuneration purposes.

The Chair asked those meeting participants who had not already handed in their declarations on confidentiality to return the signed declaration to the Secretariat as soon as possible during the meeting.

Annual declarations, if filled in and signed, should be returned to the Secretariat at the meeting. Otherwise annual declarations are expected to be provided by mail to the secretariat by 17th April 2009.

The Chair also informed that a new more secure MSC CIRCA platform was in place.

Item 6 – Rules of Procedure (RoP) of the MSC

SECR presented the current status of RoPs.

After all the Committees and Forum had discussed and endorsed the revision of their respective RoPs to take into account i.a. the status of members from the EEA-EFTA states, the revised RoPs had been put forward to the Management Board and were approved in the Management Board meeting in February 2009. The revised version had been uploaded to CIRCA and to the ECHA website. On CIRCA, a track changed version is also available.

SECR will initiate a survey well before MSC-9 addressed to all members (and observers) for suggestions and modifications on the current RoP which would then be used by SECR to present a proposal for a revised version.

Item 7 – Implications for the MSC of the outcome of the ECHA workshop on the Candidate List and Authorisation as Risk Management Instruments

a) Clarification of interrelationship between authorisation and restriction

As was agreed in the MSC-6 meeting, SECR gave a presentation on the topic. It was pointed out that although the decision for either of the processes has to be made by the REACH Member State Competent Authorities (MSCA) when preparing the Annex XV dossiers, many issues related to authorisation and restriction processes have implications on the MSC work. For example if the MSC supports the inclusion of a sub-

stance into Annex XIV and the substance is subsequently listed in Annex XIV, then a restriction process on the uses of the substance related to the intrinsic properties of the substance identified in Annex XIV is blocked. Differences between the two processes in particular regarding aim, scope, timelines and resources needed were reviewed.

b) Recommendation and conclusions of ECHA workshop

SECR briefly presented the concerns raised by MSC members since the start of the authorisation process with the aim of giving the MSC the possibility to analyse their concerns against the answers that the workshop provided.

Then a presentation on the conclusions and recommendations of the workshop organised by ECHA on 21-22 January 2009 on the topic Candidate list and Authorisation as Risk Management Instruments was given. The report on the workshop will be finalised and published on ECHA's website in April 2009. In response to a comment, it was also noted that the revised format of Annex XV dossier will be circulated to MSCAs for written consultation, if possible still in April 2009 and will probably be addressed at the next CARACAL meeting as well before being adopted.

In the discussion, SECR acknowledged that authorisation does not prevent the exposure to SVHCs originating from articles imported from outside of the EU and that restriction could be an appropriate tool to manage the risks from such articles. In line with article 69(2) ECHA will have to look at this issue after the relevant sunset dates have expired as to whether any more action is needed.

In relation to the grouping approach, one of the main issues of the workshop, it was pointed out by SECR that grouping of substances has to be done before and during preparation of Annex XV dossiers for identification of SVHCs and it cannot be done by the MSC on the substances of the candidate list.

Regarding the gathering of information on SVHCs in articles as an aim of the candidate list, some disagreement was expressed by some meeting participants stating that the mere listing of a substance on the candidate list may already cause commercial damage.

The Chair concluded that the MSC recognises the agreement of MSCAs on the conclusions and recommendations of the workshop. For the work of the MSC, the implementation of the conclusions and recommendations of the workshop would result in a more systematic approach to the preparation of Annex XV dossiers and in more information on the reasons explaining already at an early stage why a substance is being proposed for the authorisation route. It will also facilitate identification of substances for the candidate list and simplify the planning of the work of the MSC in the future. Furthermore, more information on uses, releases and exposure of substances will be available in Annex XV dossiers which will be necessary when the MSC is developing its opinion on whether a substance should or should not be prioritised for Annex XIV. Concerning the grouping of substances, there will be a closer cooperation between MSCAs when preparing Annex XV dossiers which will also help the work of the MSC.

The Chair drew the attention of the meeting participants to the fact that the CARACAL meeting also endorsed the timetable for submission dates of Annex XV dossiers

for 2009 and 2010 (the deadline for submission of Annex XV dossiers to be considered for the next recommendation is 3 August 2009). This timetable has practical implications to the work of MSC and that is why the MSC meetings in the second half of 2009 need to be rescheduled. The rearranged timetable with the new dates of the MSC meetings in 2009 will be presented at the next MSC in May 2009.

Item 8 - Draft recommendation for inclusion of priority substances in Annex XIV

SECR gave a presentation on what happened after the MSC-6 meeting regarding the development of the documentation and start of the consultation, as well the status of the consultation process on the priority setting for inclusion of substances for Annex XIV and the recommendation and draft Annex XIV entries for prioritised substances.
It was noted that very few comments, including five from MSCAs, were received prior to this meeting. Most of the comments concerned the prioritisation and only a few the draft recommendation (Annex XIV entries). It was pointed out that ECHA would be interested in getting more specific information, in particular on the uses requested to be exempted from authorisation, and that the final documents with ECHA's responses to comments (RCOM) will be prepared and provided to the MSC by 8 May 2009.

In the discussion, some concern was expressed that the use of two web-forms in the public consultation for commenting on the prioritisation and on the draft recommendation was confusing. The issue of better communication of the ongoing public consultation to the general public was also raised.

Concluding the item, the Chair emphasised that it is not enough for MSCAs or stakeholder organisations to provide comments only to the MSC, but such comments should be provided via the public consultation web-forms on the ECHA website. She encouraged MSC members to ask their CAs to submit their comments via the public consultation web-forms on the ECHA website as soon as possible. Comments of stakeholder organisations on the individual substances submitted via the web-form are also most welcome.

Item 9 - Preparations for the opinion on the draft recommendation of priority substances to be included in Annex XIV

a) Scope of the opinion – Implications of the MSC opinion on prioritisation of substances for the first and following draft recommendations

The Chair reviewed the sequence of events concerning the scope of the opinion and its implications following the MSC-6 meeting as an introduction to the item and specified the documents relevant to the discussion. SECR explained the process for the recommendation and clarified the different steps of the legal procedure.

As already highlighted in the meeting documents, it was emphasised again by SECR that no more substances can be added to the current recommendation, only deletions are possible. If the MSC considers that more substances should be prioritised, then this will be considered for the next recommendation.
It was pointed out that this situation was not clearly highlighted at MSC-6 by ECHA.

The Chair also pointed out that the relevant working procedures of the MSC agreed previously would need to be revisited, and referred to the meeting document for this item as a way forward to discuss different options on how the process could take place in the future. Then SECR introduced the five different options to start off the discussion as presented in the meeting documents for this agenda item.

In the discussion, there was a general agreement in the MSC that option a) which describes the current way of giving an opinion on the recommendation is not a real option for the future because it does not give the MSC the possibility to propose substances for inclusion in the ongoing recommendation. Option c) and d) were not recognised as an alternative way forward either. In option b), a formal opinion of MSC would be requested on both the prioritisation and the draft recommendation. Therefore, the difference between option b) and e) was solely considered by the meeting as the level of formality, with option e) being less formal.

There was a consensus in the MSC that the best suitable option is option e) which ensures the maximum level of transparency with a minimal level of formality. In this option, the MSC will be informally consulted on the prioritisation before the public consultation. The outcome of the informal consultation will be documented and ECHA's responses to the MSC view recorded. The formal opinion of MSC on the (amended) draft recommendation will be requested after the public consultation. Transparency was identified by numerous MSC members as a key issue in the process.

SECR re-emphasised that it is a mutual interest to take the views of the MSC on prioritisation into account to the highest possible degree.

The Chair concluded that a lot of support was garnered for option e) as a way forward for the future recommendation processes. She pointed out that this gives a good starting point to review the relevant working procedures which will be presented for discussion and adoption by SECR in the MSC-8 in May 2009.

b) Status report on development of the MSC opinion on draft recommendation for Annex XIV - Reporting back by the rapporteur

The rapporteur gave a presentation on the work of the working group up to now and on the preliminary view of the working group on the prioritisation and draft recommendation. He reported that three teleconferences and a working group meeting on 31 March 2009 have been held so far.

First, he reviewed the general issues which showed up in comments in the public consultation and as such were then discussed in-depth in the working group. These questions referred mainly to possible exemptions from authorisation due to

- analytical use and calibration,
- intermediate use (MDA and sodium dichromate),

coverage by other community legislation like the carcinogens directive, chemical agent directive, RoHS directive, legislation on waste and recycling and legislation on medicinal products and medical devices,

- to a possible need of the grouping of substances for the authorisation process and
- to the relation between the risk reduction and risk management measures adopted under the Existing Substances Regulation (ESR) and REACH.

In the discussion of this part of the presentation, the Czech member of the MSC drew the attention of the meeting to the fact that the use of phthalates (DBP and BBP) in medicines, therapeutic appliances and equipment as well as in materials coming into direct contact with foodstuffs is still allowed by Community legislation, and called for action from ECHA to start a process for reviewing the legislation. A room document on this statement was also circulated by the Czech MSC member in the meeting. SECR clarified that reviewing the existing Community legislation is in the competence of the Commission.

Regarding the grouping approach, several MSC members expressed their supporting views. As to when the grouping proposal (Annex XV dossier) should be done and whether single substances should be prioritised before Annex XV dossiers for the whole group is available was discussed but no final conclusion was drawn. Some members emphasised that placing single substances of a group one by one on Annex XIV would be a signal to the industry that the group is under scrutiny and other steps into the same direction will follow. This signal could be given also in the opinion of the MSC. Concerning sodium dichromate, there were different views on whether the prioritisation should happen alone or together with other substances of the group. As no substances can be added in the current recommendation, a proposal for grouping of similar substances (e.g. water soluble dichromates) could be done rather quickly thus encompassing the issue of prioritisation of sodium dichromate. In comments that had been submitted within the public consultation the question had been raised whether the use of sodium dichromate could be considered as an intermediate use.

Concluding this first part of the discussion, the Chair pointed out that most of the general issues presented here by the rapporteur would need more legal advice which will be given by ECHA in co-operation with the Commission, if necessary. One of the main issues was how to apply Article 58(2) of REACH for possible exemptions from authorisation. It was pointed out that regarding these legal issues, as well as other comments SECR will continue preparing and providing the MSC and the working group with clarifications and responses via the responses to comments (RCOM) tables.

The Chair also emphasised in line with the rapporteur that comments and any kind of input, even if they are not final opinions but indications of views, are more than welcomed from all MSC members during and after this meeting because they would help substantially the work of the rapporteur and the working group when drafting the opinion of the MSC.

Secondly, the rapporteur reviewed the issue of the general prioritisation approach. He explained that during the working group discussions, three prioritisation approaches were discussed in addition to the one of ECHA which is a weight-of-evidence approach taking into account all Article 58(3) criteria. One approach says that at least and at most 'X' number of substances should be prioritised while another one proposes to prioritise all substances fulfilling at least one Article 58(3) criterion. The third approach used a ranking system to decide which substances should be proposed for inclusion in Annex XIV. The third approach could be seen as a parallel approach to ECHA's prioritisation approach. It is not essentially different from ECHA's approach but giving scores to substances exceeding certain thresholds within the prioritisation criteria.

The preliminary view of the working group on this issue was that ECHA's approach is well documented and broadly accepted as a solid approach for the current round of

prioritisation. Other approaches are feasible as well and could lead to different outcomes. Parallel approaches could be useful to pinpoint difficult issues/ different options.

Then the rapporteur informed the members on the substance specific comments received and on major discussion points raised substance by substance. He highlighted three groups of substances on the current candidate list. All comments from MSCAs supported the prioritisation of the seven substances proposed for inclusion in Annex XIV by ECHA. In the case of five substances, some MSCA comments were in favour of the prioritisation whilst others were against. In the case of three substances, non-prioritisation was not argued by any of MSCAs.

In the discussion on this second part of the presentation, comments from stakeholder observers were received on phthalates saying that based on the new risk assessment report by the US National Academy of Sciences "Phthalates and cumulative risk assessment: The task ahead", a threshold cannot be established for these substances due to their additive effects and therefore, authorisation via the adequate control route should not be granted (as suggested in the draft recommendation). In one written comment, it was proposed on the basis of the same report that the cumulative risk assessment concept should be employed in any application for authorisation for certain uses of the three phthalates which are currently prioritised. On the other hand, it was also noted by an observer that based on this early study one should avoid drawing far-reaching conclusions for the cumulative exposure and additive effects of phthalates. SECR explained that the threshold issue could be dealt with in the MSC but giving an opinion on authorisation applications to the Commission for granting the authorisations is more an issue for the Committee for Risk Assessment.

Concerning diarsenic trioxide and diarsenic pentaoxide, some MSC members were arguing for prioritisation on the basis of carcinogenic cat. 1 hazards of these substances and on possible wide dispersive use for diarsenic trioxide and potential exposure to workers for arsenic oxides. More solid information for prioritisation would be needed on worker or citizen exposure to arsenic oxides. Although arsenic trioxide and arsenic pentaoxide cannot easily be replaced by other similar substances they can be replaced by arsenic acid.

SECR explained that they started drafting the response to comments, which will make available the earlier they can, with the latest date being 8 May. It was also agreed that the draft opinion will be ready by 14 May, i.e. 4 days before the MSC-8 meeting. This can be modified during the meeting to be finalised and adopted in MSC-8.

The Chair and the rapporteur concluded the item: concerning the prioritisation approach and the list of prioritised substances several members had expressed their general support for ECHA's proposal, but majority of the members had not yet expressed any position. Some members supported the prioritisation of some other substances such as diarsenic trioxide and diarsenic pentoxide, PBTs (TBTO and anthracene) in general and sodium dichromate. MSCAs and stakeholders were again encouraged to submit their comments to ECHA using the web-forms on ECHA's website as soon as possible.

Item 10 - Process and work plan for evaluation work

a) Information about transitional dossiers

The Chair pointed out that SECR had promised in response to a question in MSC-6 to explain the whole process on evaluation of transitional dossiers of existing substances and the role of MSC in this process.

In this context, SECR first gave a presentation on the guidance on transitional measures for the evaluation of existing substances (the same guidance on notified substances is not yet finalised). The scope and the legal basis - Article 136(1) and (2) - of the guidance was reviewed and then an overview on the different possible scenarios and on their outcome was given.

Hence the actions described in the relevant meeting document would take place between ECHA and MSCAs, and the chance for the MSC getting involved in these activities is rather low. The MSC involvement is possible as the indirect consequence of the risk assessment : in case an Annex XV for SVHC identification is prepared or in case industry did not submit the requested data for the substance and the substance is subjected to a compliance check or to substance evaluation, after inclusion in Community RAP-list.

The Chair pointed out that the process has been sufficiently clarified and it mainly relates to MSCAs, so the MSC involvement is unlikely.

b) Role of the MSC in the compliance check of registration dossiers

SECR gave a presentation on the topic outlining the legal basis, possible outcomes, role of MSCAs and the MSC and the key steps in the process of a compliance check. Pursuant to Article 41 (5) of the REACH Regulation in the selection of dossiers for compliance check priority shall be given, but not exclusively, to dossiers meeting at least one of the following criteria: 1) dossiers for substances on the CRAP list, 2) dossiers where registrants opted out from the joint submission and 3) dossiers for substances manufactured in quantities of one tonne or more per year not meeting the requirements of Annex VII applying under Article 12(1)(a) or (b). Otherwise Article 41 of REACH gives a large margin of discretion to ECHA to decide which dossiers are selected and which information in a dossier is examined. The REACH Regulation specifies that a minimum of 5% of the dossiers in each tonnage band should be examined, but there is no timeframe given for this provision.

The outcome of the compliance check can be that due to non-compliance with REACH (Article 41(3)) a decision is taken which requests the registrant to provide the missing information. The draft decisions elaborated by the ECHA Secretariat are sent to the registrant and for possible proposals for amendment to MSCAs and, in case the MSCAs propose amendments, to the MSC (see below). Decisions are enforceable and subject to an appeal.

In other cases, the ECHA Secretariat may decide to send a communication letter to the registrant and, for information, to MSCAs. Three main cases could be identified as a reason for sending a communication letter

1. Further information which should already be in the possession of the registrant should be provided by the registrant.

2. There are (minor) information shortcomings in the dossier which do not justify a formal decision-making procedure.
3. There are deviations only from the guidance (not from the legal requirements).

Communication letters are not enforceable and not subject to an appeal as they are not decisions.

Finally, the dossier may be closed without any action if the dossier is found to be in compliance for the parts examined.

With regard to MSC involvement, draft decisions will come to the MSC only if the MSCAs propose amendments to them. The MSC should reach unanimous agreement on the draft decisions within 60 days of the referral.

In the discussion, interest from the MSC was shown in the possibility to know the details of what was examined during the compliance checks of dossiers which were in compliance. It was considered particularly important because REACH does not have any provisions on ensuring communication between ECHA and MSCAs in this regard. This issue is relevant for substances for which no formal draft decision is sent to the MSCAs (cases 2 and 3 above) or for which the evaluation was ceased following the comments from registrant on the draft decision.

SECR informed in reply that MSCAs will be informed on dossiers selected by ECHA for compliance check as soon as it launches the evaluation according to Article 43(3). MSCAs will then have the chance to submit their remarks and concerns regarding the specific dossiers. Further experience will show whether cases 2 and 3 will frequently occur. It could be considered to predominantly select dossier for evaluation which are most probably incompliant. Such a selection could be accomplished by screening the submitted registrations using specific IT supported search criteria. The application of these measures could increase the percentage of compliance checks which result in a formal decision. In this context the MSC was informed that the ECHA Secretariat plans to host a workshop on dossier evaluation to discuss on the focus of the compliance check. Exact dates of this workshop were not yet determined. Issues regarding communication between ECHA and MSCAs can be further discussed there as well.

Responding to a question on promoting non-animal testing methods, SECR referred to Article 117(3) which obliges ECHA to prepare and submit a report on the issue to the Commission every three years.

Concerning the involvement of stakeholders in the MSC discussions on draft decisions on a compliance check, SECR clarified that confidential information can be discussed only in closed sessions, but otherwise stakeholders can participate in these discussions as well.

SECR also replied to a question relating to the calculation of the PEC/PNEC ratio and DNEL. It was explained that if PEC/PNEC ratios or DNELs were derived by the registrant but such derivation were not carried out according to the guidance, this fact would not constitute a reason for incompliance of the dossier. As a consequence, ECHA could not force the registrant to change the PEC/PNEC ration or the DNEL through a formal decision under the compliance check.

c) ECHA activities and work plan on compliance checks and testing proposals

SECR informed the meeting in a presentation that seven compliance checks had been started by March 2009, three of which were concluded without a draft decision and four of which are still being processed. Maximum three draft decisions as a result of this work are currently estimated to reach the MSC but not before autumn 2009. Altogether this year, around 100 compliance checks will be started, but indeed only few of these will affect the work of the MSC in 2009.

At the time of the meeting, there was only one testing proposal which had passed the technical completeness check. The deadline for a draft decision in this case is 8 August 2009. This means that there is estimated to be altogether maximum four draft decisions to be discussed in the MSC this autumn and that there is no need to arrange a separate MSC meeting for this discussion.

ECHA is also involved in other informal evaluation activities where no MSC involvement is foreseen at all. 13 test dossiers had been submitted by CEFIC six of which were being evaluated. The main purpose of this exercise is to provide general feedback to industry on the quality of the test dossiers and to test a number of ECHA processes. The general findings of this activity will be disseminated at the next ECHA Stakeholder Day in May 2009.

ECHA also contributes to the OECD HPVC Programme, in the framework of which ECHA reviews and makes comments on dossiers prepared by the OECD member countries and industry, and also participates in discussions at OECD assessment meetings (SIAMs). The multiple benefits of this work are that e.g. results may be used under REACH, registration dossiers can be a basis for preparing OECD dossiers and vice versa and the workload of ECHA and MSCAs can be potentially reduced if dossiers assessed and agreed by OECD meetings will be subject to evaluation under REACH.

In the discussion ECHA clarified that testing proposals will only be published on the ECHA website for the public to provide related scientifically valid information if testing proposals contain vertebrate animal testing.

One MSC member was concerned about the many registration dossiers for intermediates which do not require testing proposals and wondered if the conditions for intermediates are met in all of these cases. SECR replied that it is rather considered an issue for the enforcement authorities and not for ECHA as ECHA cannot examine whether the conditions for transported isolated intermediates set out in Article 18(4) are met in practice. Furthermore, on-site isolated intermediates are specifically exempted from compliance check and substance evaluation (Article 49).

As a last item under the Agenda point, SECR gave a presentation on the plans of checking of GLP claims in ECHA, explaining the planned way forward on checking of GLP status of the studies presented in registration dossiers, and how this integrates into the compliance check work. It was highlighted that the aim of the GLP checking is to promote the reliability of data and to give a clear message to the registrants that GLP issues will be monitored regularly. During the completeness check, it will be checked if all key studies finalized after or in 2009 are done according to GLP. If a

study is claimed to be done according to GLP, a report year or date and the name of the testing laboratory shall also be included into the registration dossier. In the process of a compliance check, a GLP claim verification procedure may be carried out, for which a working procedure is already under finalisation. During evaluation of testing proposals, a GLP claim verification procedure is carried out only if some studies in the registration dossier raise some concerns.

One stakeholder observer raised the issue that some academic institutes without GLP facilities produce very important studies, but these studies then cannot be taken into account in the future. SECR clarified that these studies can be regarded as supporting studies, but the ecotoxicity and toxicity studies required to fulfil the information requirements in REACH must be conducted according to GLP.

The Chair concluded the item pointing out the three possible outcomes of a compliance check and highlighting that a draft decision will come to the MSC only if a MSCA submits a proposal for amendment. In 2009, one testing proposal draft decision and maximum three compliance check draft decision can be expected in the MSC. SECR will develop working procedures for handling of draft decisions on compliance checks and testing proposals in the MSC and will present them either in the May meeting or the first meeting in the autumn (end of October - beginning of November).

Item 11 - Feedback from ECHA

SECR gave a short presentation on Forum activities and plans.

Item 12 – AOB

- *Information on planned cooperation with other community bodies working on REACH related fields*

SECR informed that regarding the tasks included in Articles 95 and 110 of REACH, ECHA has developed a road map for starting co-operation with other Community bodies. These tasks include prevention, early identification and handling of potential conflicts of opinions with other Community bodies (Article 95) and establishment of rules of procedures (RoP) for co-operation with EFSA and the Advisory Committee on Safety and Health at Work (Article 110). The aim of this co-operation is ensuring mutual support and avoiding duplication of work.

Establishment of these two RoPs is on the official work program of ECHA for 2009 and the RoPs would have to be adopted by the Management Board by the end of 2009. Concerning EFSA, the first steps had already been taken in terms of taking up contacts with the aim of agreement on the Memorandum of Understanding and on the possible elements of the RoPs.

In the framework of ECHA's co-operation with the Advisory Committee, the Chair of the MSC had recently given a presentation in the meeting of the Working Group on Chemicals at the Workplace. This Working Group is the operative body of the Committee in REACH related issues. Future visits and presentations to ECHA Committees' meetings will follow either from the Advisory Committee or from DG Employment which has the lead on the Advisory Committee.

In the course of 2009, elements of these RoPs for co-operation will be presented to the MSC although Article 110 requires consultation only with RAC and SEAC. Basic elements of these RoPs include ways of exchange of information, participation in each other's work and prevention and handling of conflict between opinions. Any input from the MSC will be welcome.

The Chair explained that the Working Group on Chemicals at the Workplace is currently working on a Guide as to how to deal with this interface which then will be provided to the Member States (exact timeline is not yet known). Regarding the work of ECHA, the Working Group showed particular interest in authorisation and evaluation work and they will come back to ECHA with their proposals for the rules of procedure in the near future.

- *Feedback from REACH Competent Authorities meeting*

The main issues such as conclusions and recommendations of the ECHA workshop and the timeline for 2009-2010 for submission of Annex XV dossiers for identification of SVHCs had already been covered earlier in the meeting.

- *Status report on the review of Annex XIII*

A representative of the Commission explained that the outcome of the review of Annex XIII conducted in 2008 was that Annex XIII needed to be amended, and the new draft text had been presented to the December CA meeting. The three main elements of the amendment were: (1) given the often limited amount of data available on the PBT/vPvB properties, in particular for low volume substances, screening data should be used to identify whether a substance has the potential to be PBT or vPvB; (2) the weight-of evidence approach should be used to take into account all available information relevant to the PBT properties in the identification process of PBTs/vPvBs and (3) the PBT properties of constituents and degradation and transformation products should be taken into account during the identification of PBTs/vPvBs.

Many comments on the draft text had been received from MSCAs and from the European Parliament as well, stating mainly that the draft text did not sufficiently allow the use of the weight-of-evidence approach for all available information relevant to PBT properties by comparing the information to the criteria. The exact timeline was not known but the adoption of the revised Annex XIII is expected by the end of 2009 and will hopefully provide sufficient legal clarity for both the registration and authorisation processes in the future.

- *New PBT documentation from ESIS and the relation to the work of the MSC*

Responding to a question of an MSC member, SECR clarified that new PBT summary fact sheets available in ESIS (European chemical Substance Information System) represent the conclusions and summary of the work which started in the PBT working group of TCNES in JRC years ago. These fact sheets were compiled on the basis of the then relevant Technical Guidance Document and can be used as a source of information for MSCAs when starting to prepare an Annex XV dossier for SVHC identification. Using these documents, MSCAs can save a lot of resources and time.

Stakeholder observers expressed their view on the need of a PBT working group in the framework of ECHA. The Chair explained that ECHA recognized the need for a PBT working group as well but the final decision on the issue is not yet taken.

Item 13 - 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
ANGELOPOULOU Ioanna (EL)
BÖHLER, 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)
LUDBORZS Arnis (LV)
LULEVA, Parvoleta (BG)
MAJKA Jerzy (PL)
MIHALCEA-UDREA Mariana (RO)
MOREAU Emmanuel (FR)
PALMA, Maria do Carmo Ramalho Figueira (PT)
PISTOLESE Pietro (IT)
RAUTALAHTI Katariina (FI)
REIERSON Linda (NO)
RUSNAK Peter (SK)
STESSEL Helmut (AT)
VESKIMÄE Enda (EE)
WELFRING Joëlle (LU)

Representatives of the Commission
VAN DER JAGT Katinka (DG ENTR)
VAN DER ZANDT Peter (DG ENV)
Observers
ANNYS Erwyn - CEFIC
LEENAERS Joeri - EUROMETAUX
OWEN David - ECETOC
REINEKE Ninja - WWF
TAYLOR Katy - ECEAE
ECHA staff
AJAO Charmaine
BALOGH Attila
BRAUNSCHWEILER, Hannu
BROERE William
DE COEN, Wim
DE BRUIJN Jack
GRADZKA Agnieszka
HERDINA Andreas
KNIGHT Derek
KORJUS, Pia
KOSKINEN Marjo
LEBSANFT, Jörg
LEPPER Peter
LEFEVRE Remi
MALM Jukka
MARKKULA Liisa
NAUR Liina
POPESCU, Raluca
SIHVONEN, Kirsi
SUNDQUIST Anna-Liisa
VAHTERISTO Liisa
YLÄ-MONONEN Leena

Replacements
SANCHEZ, Pablo replacing MARTIN, Esther (ES).

Proxy's
ANGELOPOULOU, Ioanna (EL) also acting as proxy of KYPRIANIDOU-LEODIDOU, Tasoula (CY),
FLODSTRÖM, Sten (SE) also acting as proxy of TYLE, Henrik (DK),
MOREAU, Emmanuel (FR) also acting as proxy of MARTIN, Esther (ES)

Experts and advisers to MSC members
ARTUS, Hannela (expert to VESKIMÄE Enda).
BIWER, Arno (expert to WELFRING, Joëlle).
HEISKANEN, Jaana (adviser to RAUTALAHTI, Katariina)
KOZMIKOVA, Jana (expert to GEUSS, Erik)
KREUZER, Paul (adviser to RAUTALAHTI, Katariina)
LAGRIFFOUL, Arnaud (adviser to MOREAU, Emmanuel)
LEONELLO, Attias (expert to PISTOLESE, Pietro)

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:
FAIRHURST, Steve (UK)
KYPRIANIDOU-LEODIDOU, Tasoula (CY)
MARTIN, Esther (ES)
TYLE Henrik (DK)

III Final agenda

1 April, 2009
ECHA/MSC-7/2009/A/07

Final Agenda

Seventh meeting of the Member State Committee

1 - 2 April 2009
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

1 April**: starts at 9:00**
2 April**: ends at 14:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/07/2009
For adoption

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

Item 4 – Final minutes of the MSC-6

Reporting back on the written procedure concerning adoption of draft minutes of MSC-6

MSC/M/06/2008/
For information

Item 5 – Administrative Issues

For information

Item 6 – Rules of Procedure (RoP) of the MSC

Reporting back on the outcome of the Management Board discussion on the Rules of Procedure of the ECHA Committees

For information

Item 7 –Implications for the MSC of the outcome of the ECHA workshop on the Candidate List and Authorisation as Risk Management Instruments

a) Clarification of the interrelationship between authorisation and restriction

ECHA/MSC-7/2009/003

b) Recommendation and conclusions of the ECHA workshop

ECHA/MSC-7/2009/001& 002

For information and discussion

Item 8 –Draft recommendation for inclusion of priority substances in Annex XIV

Status report on the consultation on

- Priority setting for inclusion of substances for Annex XIV
- Draft Recommendation and Draft Annex XIV entries for prioritised substances

For information and discussion

Item 9 – Preparations for the opinion on the draft recommendation of priority substances to be included in Annex XIV

a) Scope of the opinion – Implications of the MSC opinion on prioritisation of substances for the first and following draft recommendations

ECHA/MSC-7/2009/004, 005 and 010

b) Status report on development of the MSC opinion on draft recommendation for Annex XIV - Reporting back by the Rapporteur

ECHA/MSC-7/2009/011

For information and discussion

Item 10 – Process and work plan for evaluation work

a) Information about transitional dossiers

b) Role of the MSC for compliance check

c) ECHA activities and work plan in 2009 concerning compliance checks, testing proposals and substance evaluation

ECHA/MSC-7/2009/006-009

For information and discussion

Item 11 – Feedback from ECHA

For information

Item 12 – AOB

- Information on planned cooperation with other community bodies working on REACH related fields
- Feedback from REACH Competent Authorities meeting
- New PBT documentation from ESIS and its relation to the work of the MSC

ECHA/MSC-7/2009/012

For information and discussion

Item 13 – Adoption of conclusions and action points

IV Main conclusions and action points

MSC-7 MAIN CONCLUSIONS & ACTION POINTS

1-2 April 2009

(Adopted at the MSC-7 meeting)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
3. Declarations of conflicts of interest to items on the Agenda	No conflict of interest was declared	
4. Final minutes	/	/
5.Administrative issues	Revised re-imbursement rules were adopted by the MB	Meeting participants to provide immediate feedback on the Kaleva Travel to the meeting Secretariat and preferably in free text form by e-mail to the MSC-secretariat (msc@echa.europa.eu). Those participating for the first time shall hand over declarations on confidentiality to the secretaries before the end of the meeting. Annual declarations on conflicts of interest to be collected during the meeting or else returned by mail to the secretariat by 17th April.
6. Rules of procedure (RoP) of the MSC	Revised RoPs were put forward to the MB and were approved in the MB February meeting.	The secretariat will initiate a survey well before MSC-9 to all members and other meeting participants to invite for suggestions for modifications on the current RoP which would then be used by the SECR to present a proposal for a revised version.
7. Implications for the MSC of the outcome of the ECHA workshop on the Candidate List and Authorisation as Risk Management Instruments		
a) Clarification of interrelationship between authorisation	The explanation was much appreciated as it provided clarification to many questions raised by the MSC members earlier.	/

and restriction **b) Recommendation and conclusions of ECHA workshop**	1. The MSC took note of the agreement of the CARACAL meeting on the conclusions and recommendations of the workshop. 2.For the MSC, the implementation of the conclusions and recommendations of the workshop would result in the following benefits: a. a more systematic approach of the dossiers and the reasons explaining why a substance is being proposed for the authorisation route. This refers to the workshop conclusion that the competent authorities should exchange reasons at an early stage. b. facilitates identification of substances for the candidate list in the future. c. simplifies the planning of the work of the MSC. d. more information in Annex XV dossiers will be available for prioritisation which will be necessary when the MSC is developing its opinion on whether a substance should be prioritised for Annex XIV. 3.Grouping is an important point to pay attention to in the future.	
Timetable for processing of Annex XV dossiers	1. MSC will follow the timetable that was endorsed at the CARACAL meeting 2. No September meeting will be held when following the new timetable schedule. ECHA will follow the same time schedule as agreed during the CARACAL meeting for the submission of the Annex XV dossiers for the coal/tar substances.	SECR to make available in May meeting a more detailed time schedule for the rest of the meetings in 2009.
8. Draft recommendation for inclusion of priority substances in Annex XIV	1. Very few comments were received up to this stage. Comments from the CAs are appreciated ASAP. ECHA is interested in getting more specific information in particularly on the uses requested to be exempted from authorisation. 2. It is not enough for MS CAs or stakeholder organisations to provide comments	1. MSC members to ask their CAs to submit their comments ASAP via the public consultation webform on the ECHA website. 2. Stakeholder organisations to send their comments on the indi-

	only to the MSC but comments should be provided via the public consultation web-form on the ECHA website.	vidual substances ASAP via the webform.
9. Preparations for the opinion on the draft recommendation of priority substances to be included in Annex XIV		
a) Scope of the opinion – Implications of the MSC opinion on prioritisation of substances for the first and following draft recommendations	1. MSC acknowledges the fact that no more substances can be prioritised for this current recommendation. If the MSC considers that more substances should have been prioritised, then this will be for the next recommendation. 2. The MSC agreed that option 'e' is the best way forward for future draft recommendations on the inclusion of substances in Annex XIV. Option 'e' is that the MSC's view on the prioritisation will be requested prior the public consultation and documented and that the MSC's opinion will be requested on the (amended) draft recommendation after the public consultation.	1. SECR to review the *Working Procedures on providing the opinion on the recommendation for the Annex XIV* using option 'e' as a starting point and present them for discussion and adoption in the May meeting.
b) Status report on development of the MSC opinion on draft recommendation for Annex XIV - Reporting back by the Rapporteur	1. The link between REACH and other Community legislation (e.g food contact material) still needs to be further clarified. 2. The ECHA approach for prioritisation is broadly acceptable as a solid one for the current round of prioritisation. Other approaches are feasible as well and could lead to different outcomes. 3. Parallel approaches could be useful to pinpoint difficult issues/ different options. 4. Support was expressed by some members for the 7 substances that were prioritised in the draft recommendation for inclusion in Annex XIV, most of the members did not express any position yet. 5. Five substances (Anthracene, TBTO, Sodium dichromate, diarsenic trioxide, diarsenic pentaoxide) that were not prioritised by ECHA for inclusion in Annex XIV were discussed. The following conclusions were made: a. General comment on analytical use to be looked at further from a legal perspective. b. MSC is in favour with the prioritisation of the grouping approach. There are different views on the timing of prioritisation of sodium dichromate.	1. Members of the MSC to sub their comments on the draft rec mendation directly to the Rappor and to the SECR for information. 2. ECHA to respond to the elements raised by WG in the RCOM's in consultations with the legal adviser and the Commission (if necessary). 3. SECR will provide the responses, including the explanations on legal issues, to the Rapporteur and the WG. 4. Rapporteur to consider the comments received during the meeting. 5. ECHA to keep on providing the Rapporteur and the Working Group with draft responses to comments (including the generic issues and/or policy questions) as soon as they have been developed and at the latest by 08.05.09. 6. SECR will provide the comments after the end of the public consultation period. 7. Rapporteur will continue working with the WG via tele-

	c. To examine if sodium dichromate can be regarded as an intermediate. The French CA propose to consider to prioritise substances that are carcinogen cat.1. For diarsenic trioxide they suggest that wide dispersive use may be possible and exposure of workers to both diarsenic oxides cannot be excluded. More data would be needed to confirm this.	conferences to reflect on the comments received and they will meet face to face on 24 April.
10. Process and work plan for evaluation work		
a) Information about transitional dossiers **b) Role of the MSC in the compliance check of registration dossiers** **c) ECHA activities and work plan on compliance check and testing proposals**	Process has been clarified. It relates mainly to the work of the MS CAs and is very unlikely that the MSC has a role to play with regard to transitional dossiers. 1. The process for compliance check was clarified. It was explained that the outcome of the compliance check can be either: a. no actions are needed and the dossier is in compliance for the parts examined b. or, communication letter is sent to the registrant and for information to MS CAs c. or, draft decision due to the non-compliance is sent to the registrant and for possible proposals for amendment to MS CAs. 2. Draft decision will come to the MSC only if the MS CAs will propose amendments on the draft decisions sent by ECHA. This implies that only limited number of compliance check will arrive to the MSC. 3. The number of compliance checks will increase this year – 100 dossiers. However, only 1-3 draft decisions are envisaged for the MSC for 2009, mostly because most of the compliance checks will start later this year. 4. One draft decision for testing proposals may end up at the MSC. 5. Overall only 4 draft decisions are envisaged for the MSC for 2009, thus these can be done in conjunction with meetings dealing with SVHCs. 6. ECHA is considering organising a workshop on evaluation with the MS CAs.	SECR to develop working procedures for the dossier compliance check and the testing proposals either by May meeting or November meeting.
11. Feedback from		

ECHA		
12. AOB • Information on planned cooperation with other community bodies working on REACH related fields	ECHA needs to cooperate with other community bodies and scientific committees working on REACH related fields according to Articles 95 and 110 of REACH.	SECR to prepare draft rules of procedure to include the co-operation with other Community bodies, and distribute them for comments to the MSC.
• Feedback from REACH Competent Authorities meeting	The Commission is working on the revision of Annex XIII to be able to provide clear criteria for identification of PBT's/vPvB's allowing the use of all available information in a weight-of-evidence approach. No time-line is yet available when the revised Annex XIII would be available, but hopefully before the end of the year.	
• New PBT documentation from ESIS and the relation to the work of the MSC	The data base established by the former ECB makes available data and conclusions on evaluation of potential PBT's that were created as result of the former PBT-working group. This database can be used as a source of information when preparing Annex XV proposals or when identifying SVHCs.	SECR to inform MSC on the outcome of the internal discussions regarding the establishment of a PBT working group in ECHA.
13. Adoption of conclusions and action points		All presentations and room documents to be uploaded on Circa (SECR /by 07/04/09). Conclusions and action points (= this doc) to be uploaded to Circa (SECR /by 07/04/09).