MSC/M/03/2010 Final

Adopted on 20 October 2010
during MSC-14 meeting

Final Minutes

Minutes of the 13th Meeting of the Member State Committee (MSC-13)
14 – 16 September 2010

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 13th meeting of the Member State Committee (MSC).

For details on the participants, proxies and alternates please see Part II of the minutes.

Item 2 - Adoption of the Agenda

The Agenda was adopted as proposed by the Secretariat (SECR), with the start of discussion on case TPE003/2010 in item 5 of the agenda. The Chair proposed to include one information item under AOB regarding the recent court cases launched against ECHA. The final Agenda is presented in Part III to these minutes.

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

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

Item 4 – Minutes of MSC-12

- Reporting back on the written procedure concerning adoption of draft minutes of MSC-12

The Chair informed the Committee that the MSC-12 minutes were adopted on 1 September 2010 by written adoption. Written commenting round preceded the written adoption process. After adoption the non-confidential version of the minutes were uploaded on ECHA website.

Item 5 - Evaluation tasks (*closed session*)

The Chair introduced this item by explaining that the evaluation discussions would now take place in two parts, session 1 for the initial discussion and session 2 for agreement seeking. She reminded MSC that it is not always possible to have the two sessions in separate meetings. Then the Chair continued by referring to the note from the Chair. She explained that this note was only intended for information to help the members of the Committee to understand the reasoning of ECHA on the dossier evaluation cases presented for the meeting, with the aim of assisting the members in preparing for the meeting.

Case for information (case withdrawn):

TPE 003/2010 (Polysulfo {5-hydroxy-1-naphthalen-2-yl-[4-[4-(2-sulfatoethyl-sulfonyl)-phenyl]diazenyl]-1H-pyrazole-3-carboxylic acid}, alkali metal salt)

SECR gave a brief overview of the case. The registrant has informed ECHA that he will cease manufacture. The registrant marked the dossier as inactive in REACH-IT. For this reason a note informing MSC on withdrawal of the case has been sent. This is a case that falls specifically under Article 50 (3) of REACH and so ECHA marked the dossier as revoked in REACH-IT and informed the registrant accordingly.

Cases for discussion followed by agreement seeking under 5b:

As a follow-up of the teleconference held on 31 August 2010 SECR explained the different terminologies used for the documents (other than the decision) ECHA is using to communicate with the registrant. These were:

- Quality observation letter (QOBL) formerly called Communication Letter which raises issues not feasible or not appropriate to be included in a draft decision.

- Cover letter which is also called Decision Notification Letter which is needed to notify the registrant of the ECHA's actions, their legal basis, and the results. To increase administrative efficiency the cover letter has been combined in some cases with the issues in the quality observation letter.

The members were concerned that such different types of communication could create confusion not only to MSCAs but also to the registrant. To this, SECR replied that there has been a lot of feedback from MSCAs regarding the communication of ECHA with them on dossier evaluation issues. SECR was taking note of the improvements proposed by MSCAs and would carefully examine the options of what kind of documentation would be needed and how to improve the clarity and consistency of the documents. SECR is working on how to clarify the documentation in CIRCA by putting all the relevant documents in one dossier specific folder on CIRCA. A wider exercise for the SECR than just the explanation of the terminology is ongoing to improve the communication with MSCAs. SECR highlighted as well that sometimes even other informal forms of communication with the registrant are necessary. As an example it was mentioned the dossiers of on site isolated intermediates to which ECHA is not supposed to open a compliance check. This type of communication is separate from the QOBL, cover letter and draft decision.

It was also explained that all QOBL now have target dates i.e. a date by when ECHA invites the registrant to update the dossier. These target dates have been systematically placed in the QOBL only since spring 2010, so ECHA has limited experience yet on how the registrants will react on the QOBLs. This is however, a target date and not a date requiring formally the registrant to update the dossier. If the registrant does not respect the target date, this information would then be made available to MSCAs by ECHA for their actions. Also ECHA can decide on follow-up action including draft decision. The members raised their concern regarding how to ensure an efficient follow-up of these issues covered in QOBL, cover letter or communication letter. They asked ECHA to think about tools to ensure traceability of these issues and their follow-up actions.

TPE 002/2010 (Ethoxypropyl-hydroxy-hexanamide)

5.a. Introduction to (and preliminary discussion on) draft decisions on testing proposals and compliance checks after MS-CA reactions *(Session 1)*

Three proposals for amendment on TPE 002/2010 were received from three MSCAs. Comments were also received which were discussed during this meeting. The deadline for the registrant to submit his comments closed but the registrant did not comment on the amendments proposed by MSCAs.

The main concerns raised by the members were as follows:

1. Pre-natal study has a higher resolution than the screening study because screening study uses less animals and the investigations are less detailed. However the screening study provides first information on possible adverse effects on fertility and perinatal toxicity not provided by the prenatal study design.
2. Sub-chronic toxicity study (90 day) in rats - some members felt that it is not appropriate for ECHA to request such a study since:
    a. it was not proposed by the registrant
    b. the outcome of the workshop in spring 2010 was that ECHA should focus on endpoints proposed by the registrant in the examination of testing proposals and not perform automatically a compliance check during a testing proposal examination, so as not to discourage industry from submitting testing proposals and not to prioritise substances of less concern for compliance check. Thus the request for a 90 day study should be part of a compliance check evaluation and not part of a testing proposal examination.
    c. One member felt it is inappropriate to ask for the 90 day study since the result for the 90-day study may be extrapolated from the 28-day study as the 28 day study indicated low toxicity, the substance has low acute toxicity, there was no indication on skin sensitisation and negative findings *in vitro* mutagenicity studies and thus the substance has low toxicity profile. This conclusion was thought to be supported by an analysis carried out on information contained in the NONs database of one MS. Unfortunately, no peer reviewed report of such an analysis was made available for the basis of such a conclusion. MSCA has suggested using such arguments on the basis of the general waiving statement included in the introductory part of each of the Annexes .
3. Even though the draft decision (DD) was already communicated to the registrant before MSC meeting, yet the members felt that the DD can still be amended during MSC meetings, but it was not clear to them to what extent this was possible.
4. The reference to the fact sheet found in the DD as a recommendation to the registrant should change to a reference to the guidance document, since it provides scientific argumentation for the information needed.

To these interventions ECHA:

1. explained that the outcome of the workshop was immediately taken into account for any new DDs issued after the workshop. However, there were transitional DDs that were already being processed and sent to registrant's comments before the April 2010 workshop. These were not revisited, and so they were not changed by ECHA. The case TPE002/2010 is one of such transitional DDs. Thus, SECR proposed that for this reason, the 90 day study will still be requested in the DD as there is a data gap for this information in the dossier.
2. reminded the members that the registrant saw the proposal by ECHA to perform a 90-day study in rats and yet he did not comment. Companies can waive certain tests by using column 2 in Annexes VII to X or Annex XI. The general statement found in the end of the introductory paragraph of each Annex can in principle not be used by the MSCA. The consequence of accepting a waiver proposed by one MSCA using this basis would be far reaching. Moreover, the burden of proof is on the registrant to show why a test is not necessary and this has not happened in this case.
3. explained that the REACH legal text does not prevent ECHA from requesting the 90 day study during a testing proposal examination. REACH already strikes a balance between protection of health and the environment and animal welfare aspects. It is mainly for the registrant to consider when it would be possible to adapt the information requirements based on the legal text. To avoid a test in Annex IX based on results of other tests found in Annex VII and VIII, there is need for strong scientific argumentation.
4. presented the results of a literature review with regard to comparisons of the results in 28 day studies (subacute) and in 90 day (subchronic) studies by one of the experts. The expert said that in a 28 day study additional tissues are studied compared to a 90 day study. A 90 day study has twice as much animals as the 28 day study thus statistically is a stronger test. The mean difference between the potency of a chemical in sub-acute and subchronic study varies from 1.6-4.4 fold in the work cited, i.e. 1.6-4.4 times lower NOAELs are identified by the 90 day study. However, it is important to be clear that this is an average, and all the studies concur in showing that the standard deviation of their estimate is appreciable. For example, Groeneveld *et al* show that 10% of compounds are >7-fold more potent in a 90-day study, whereas Kalberlah and Schneider find that 10% of compounds are >9-fold more potent in a 90-day, as opposed to a 28-day, study. It was agreed that this analysis would be made available to MSC after the meeting.
5. agreed to cite the guidance document instead of referring to the fact sheet.

The Commission (COM) contributed to the discussion by explaining that if no unanimous agreement is reached in MSC, the outcome would need to be formulated in a way so that it can pass through the COM structure. The history of the Annex is that the two generation study during the REACH decision making process moved between being an Annex VIII or IX or X requirement and then Annex IX under certain requirements. In doing so the legislator was interested also in costs and impacts and not only on the scientific reasoning. Similarly the history of when the 90-day study should be conducted and when the 28-day study was based on

recommendations from several of the Commissions Scientific Committees, reflecting the preference for basing risk management on the 90-day study. The MSC will therefore need to implement these annexes as they were adopted. COM also stated that regarding compliance check of the Annexes VI-X the decision for the MSC to make is if they agree or not with the SECR that a derogation statement is not conform with Annex XI. If a MSCA therefore rejects a DD due to for example animal welfare reasons then this should be made clear to the COM so that COM would know the political reasoning behind the disagreement at MSC when preparing the Commission proposal forthe Regulatory Committee. For the discussion in MSC, however, the MSCA needs to put forward scientific arguments. The political arguments or scientific arguments not pertaining to the validity of the derogation statement according to Annex XI can not be used.

MSC needs to be sure that procedures are followed. If procedural mistakes are made there is a risk that an appeal would be brought before the Board of Appeal and that this appeal would result in the annulment of the decision. In this case it is legally possible to request the 90 day study. If MSC decides to remove it because they believe it should have been taken under compliance check, then that is a wrong argument, as it is legally possible to request for such test under the testing proposal process. On the other hand, a MSC decision to remove the 90 day study because e.g. a read across provided relevant information, would be a valid argument.

The MSC however proposed keeping the 90 day study as the outcome of the study in relation to its information on histopathology of the reproductive organs would be useful for deciding which type of further reproductive toxicity study to conduct if relevant.

Further discussion was held in a break out group after day one of the meeting seeking options for a unanimous agreement. As peer reviewed evidence to back up the proposed amendment was not yet available, the arguments raised could not be supported. However, it was recognised that there is a reason to explore this issue further.

MSC concluded that the best way forward would be for the one MSC member to prepare a thought starter for MSC discussion, based on the proposed amendment presented in the discussion of the current meeting, in particular on the scientific data in extrapolating results from a 28 day study to a 90 day study under the specified conditions.

Depending on the conclusions of the discussion at the meeting where the thought starter is to be discussed, ECHA could consider organising a workshop or expert discussion to allow further elaboration on the topics proposed by MSC members. This discussion would be organised and hosted by ECHA and would be aimed at finding ways of using the data on registered substances (including those transferred into REACH from the former NONS regime) to devise weight-of-evidence (or other) strategies aimed at avoiding the use of animal testing where possible. Any outcomes could be incorporated into the guidance or even a possible proposal for a revision of Annexes VII - XI.

On the proviso that these actions were to take place, this member agreed to drop the proposed amendments in this case as well as in the testing proposal case TPE004/2010.

5 b. Seeking agreement on draft decisions on testing proposals and a compliance check when amendments were proposed by MS's *(Session 2)*

MSC found unanimous agreement on ECHA's DD as amended in the current meeting. The basis for the agreement were the conclusions of the discussion, the action points mentioned above, the formulation for the cover letter to the registrant on fertility and perinatal toxicity based on the text in the guidance document (the reference to the fact sheet was deleted in the DD) and draft agreement document.

TPE 004/2010 (4-(Triethoxysilyl)methyl) morpholine)

5a. Introduction to (and preliminary discussion on) draft decisions on testing proposals and compliance checks after MS-CA reactions *(Session 1)*

Two proposals for amendment from two MSCAs and several comments were received which were discussed during this meeting. The deadline for the registrant to submit his comments closed and the registrant informed ECHA that they consider their TP as still appropriate.

Since this testing proposal case (TPE004/2010) was very similar to the previous testing proposal case (TPE002/2010), the members' comments during the discussion were more focused on the harmonisation of the two DD with regards to where to place the recommendations made by ECHA:, in the DD or in the cover letter. It was also made clear by the members that they would prefer the DD to be as detailed and clear as possible.

ECHA explained that the differences in the two DD arise because of the differences in the dossiers. For example, in the first case (TPE002/2010), the registrant proposed the screening study and thus this is mentioned in the DD, whilst in the second case (TPE004/2010) the registrant does not propose the screening study, so ECHA mentioned it in the cover letter.

5 b. Seeking agreement on draft decisions on testing proposals and a compliance check when amendments were proposed by MS's *(Session 2)*

No change in ECHA's DD was needed. MSC agreed that the same sentence as in the case of TPE002/2010 should also be included in the cover letter for the registrant on fertility and perinatal toxicity based on the text in the guidance document (the reference to the fact sheet was deleted in the DD) in this case. MSC found unanimous agreement on ECHA's DD (no amendments) and draft agreement document.

CCH 004/2010 (Methacrylamide)

5a. Introduction to (and preliminary discussion on) draft decisions on testing proposals and compliance checks after MS-CA reactions *(Session 1)*

The Chair introduced this compliance check case by reminding the members of the outcome of the teleconference held on 31 August that was reflected in the summary document. She highlighted that any comments on the summary can be sent in writing to MSC functional mailbox. During the teleconference two papers were made available, one from ECHA and another one from a Committee member. Following the teleconference this member provided a more detailed paper with a draft text that was presented as a room document. The COM also made some observations which were also presented in a room document.

The Chair reminded the Committee that the task of MSC is to resolve divergences of opinions on ECHA's DDs. The discussion that took place in CARACAL on a similar topic on a more general level should not be continued in MSC meeting. The Chair proposed to continue such general discussion in CARACAL which is an advisory body to COM and ECHA in policy issues. MSC is to resolve divergent issues on specific cases based on sound scientific and technical (including legal) arguments. Thus the aim is to seek agreement to this specific case and perhaps the conclusions could contribute to the said general discussion.

The floor was then given to SECR to introduce the case briefly since most of MSC heard about this dossier already during the teleconference. The Committee member then presented the more detailed proposals for amendment made. They clarified that they do not object to the proposals made by ECHA regarding the granulometry and flammability tests. They explained that even though they proposed four amendments yet, in the draft text they proposed in the room document they only highlight two:

1. Derivation of DNEL for developmental reproductive toxicity
2. Assessment factors for DNEL derivation.

They believe that their other proposals for amendments on risk characterisation and risk management measures would be included in the general request for updating the dossier and the Chemical Safety Report (CSR).

SECR on the other hand elaborated in a presentation the thinking of ECHA on this case by explaining that when the registrant appeals to a decision it has a suspensive effect on the decision as a whole, i.e if the decision requests for three tests and the registrant does not agree with one test, still the whole decision is suspended. Pursuant to Article 92 of the REACH Regulation only natural or legal persons can appeal against a decision that is addressed to that person or against a decision, which although addressed to another person, is of direct and individual concern to the former. MSCA will normally not meet these criteria for bringing an appeal against dossier evaluation decisions. MSCA as a privileged applicant can only challenge a decision when the decision is referred to the Commission which adopts a decision

under the Comitology process. SECR explained that Article 41(1) of REACH allows ECHA to verify if the information requirements of Annex I REACH and thus also for the Chemical Safety Report (CSR) have been met. Article 41(3) permits ECHA to take decisions requiring the registrant to submit information to make the registration compliant. If information required by the legal text is missing or not relevant in CSR ECHA can request it. However ECHA can carry out targeted compliance checks (Ref. Article 41(1)) and is not obliged to verify the CSR for each dossier.

The main points raised during the discussion were:

1. MSC welcomed the clarification that ECHA has the mandate to issue DDs regarding the content of CSR.
2. The consequences of such a decision should be thought of in advance to be able to avoid a ping pong game with the registrant if the justification required is insufficient. The responsibility needs to remain with the registrant.
3. Examination of CSRs will mean a lot of work for ECHA. If a targeted assessment is made by ECHA it is important that it can be traced by the MSCAs and follow-ups can be done.
4. Finding out the consequence of amending the DD when the registrant has already seen the recommendations in the QOBL. Anything that ECHA writes in QOBL should not hinder MSCAs to come with suggestions for amendments. The QOBL could be a good short cut for MSCAs to come with issues for amendment to the DD. A disclaimer should be introduced also in the QOBL to show that ECHA can always come back to a dossier compliance check of the same dossier.
5. Solving the issue of unclarity for the registrant by writing a disclaimer in the DD that a compliance check evaluation can be started at any time on the same dossier.
6. From the enforcement point of view DD are easier to tackle and looking from resources needed from the MS perspective a DD is a better option than a QOBL.
7. To date it is not known which of the two forms of communications (QOBL and DD) is the most effective. Past experience showed that the registrants are willing to update their dossiers if they know what they need to do.
8. That the legal line presented by ECHA is 100% in line with the COM's legal interpretation, namely that requests for missing information in Annex I can in principle be made through a compliance check, however it remains a challenge to do so whilst giving legal certainty, being enforceable and ensuring that member states and ECHA are not taking the responsibility away from the registrant.

SECR explained that:

1. When the proposals for amendment are clearly written then they would also be clear to the registrant. The DD during the agreement seeking phase of MSC can be amended on this basis. However, in this particular case, the proposal for amendments made, is questionable whether the registrant understood what would be changed in the DD on the basis of the proposed amendments. If MSC agreed to amend the DD on this basis it could be challenged by the

registrant before the Board of Appeal. It would not be acceptable to ECHA to be challenged for an issue related to a possible breach of fundamental rights of the registrant. MSCAs are expected to draft very clear proposals for amendment for the registrant to understand what is requested from him. .

2. To avoid any confusion for the registrant and to respect fully the rights of MSCAs ECHA agrees that normally where an element required by the legal text is missing such issues should be raised in a DD and not in a QOBL. ECHA however, will still follow-up the target dates in QOBL.
3. When a justification given by the registrant as response to a decision on a CSR issue is not considered adequate by ECHA, and ECHA considers that the substance constitutes a risk, this substance can be flagged for substance evaluation or for restrictions.

The main conclusions of this discussion were:

1. ECHA to evaluate this registration dossier as follow up under Article 42 of REACH in compliance check when the registrant has submitted the information required in the DD.
2. ECHA to address at the same time the consequences in case the registrant has not updated the dossier in accordance with QOBL and possibly open a compliance check which should as relevant be concluded by a DD.
3. ECHA to evaluate the updated dossier after the deadline for the update (six months).

5 b. Seeking agreement on draft decisions on testing proposals and a compliance check when amendments were proposed by MS's *(Session 2)*

Taking into account the conclusions of the discussion and the agreed actions MSC found unanimous agreement on ECHA's DD (not amended) and draft agreement document.

For discussion following commenting by MSCAs (no agreement seeking):

The Chair introduced this part of the agenda by reminding MSC that the comments made by MSCAs can be discussed at MSC meetings only when MSCAs specify the need in writing next to the comment. It was noted that a member of MSC can also always ask a comment to be discussed at MSC meeting. However, since it was not clear whether MSCAs wanted their comments to be discussed or not, then SECR decided for this time only, to discuss the comments received during MSC-13 meeting.

- CCH 005/2010

SECR introduced the case and the four comments received. No proposals for amendment were received on this case thus it was not referred to MSC and the decision was not open for discussion. The final decision was sent to the registrant before MSC-13 meeting.

A discussion followed on whether this substance is a nano-object. Even if so, it is very difficult to investigate the matter further due to the discussions going on in different fora and the lack of definition of a nano-object. It was proposed that ECHA could take this case as a case study and flag it for the future. In fact ECHA intends to wait for the newer IUCLID 5 version that would give the registrant the possibility to address such issues in sections 2.1 and 4.1 of IUCLID. Possibility to apply read-across, as raised in one of the comments, will be addressed only when the substance identity is clarified based on the decision.

- CCH 006/2010

- CCH 007/2010

SECR introduced these two cases together. These two substances were submitted by the same importer with a third similar substance. Comments were only received for these two substances and not for the third one. Thus the third one was not even presented to MSC-13 meeting. The comments raised an issue related to a tonnage upgrade of a former NONS. It was concluded that there are many complications related to evaluation of non-finished NONS or tonnage upgrades of former NONS, and such discussion would deserve a special event.

For discussion followed by agreement seeking in October:

- CCH 009/2010

The Chair introduced this compliance check case as being for agreement seeking in the October meeting. She explained that this is just the initial discussion of this case.

SECR then followed by summarising the case. Only one proposal for amendment was received. ECHA considered it as valid and so the DD was amended and uploaded to CIRCA for MSC. Since the commenting period for the registrant was still open during the duration of the meeting, MSC needs to wait until it expires to conclude on this case.

MSC agreed that if no comments are received from the registrant or if the comments don't challenge the present amended DD, the amended DD will be sent to MSC for seeking unanimous agreement via written procedure. The written procedure would start on 23 September and close on 5 October. If someone does not support the amended DD then the DD can still be discussed in the October meeting.

Item 5 - Evaluation tasks (*open session*)

Briefing to the Stakeholder Observers

SECR explained that the Committee had a good discussion on the three DDs - two testing proposal DDs and one compliance check DD. More details can be found in the minutes above for the closed session.

Following the briefing, one stakeholder observer asked why the names of the substances that were subject to public consultation were not listed in the agenda. They also asked if the information given to them in the briefing was going to be made available in a press release.

SECR explained that a news alert would be published after the meeting and that with the new changes agreed for the RoPs and the WPs in this Committee, the dossier evaluation discussions would become more transparent.

c. Status report on other ongoing evaluation work (*open session*)

SECR presented two issues:

1. the new interaction policy with the registrants in dossier evaluation.
2. the status of dossier evaluation work until the end of August 2010.

<u>The new interaction policy with the registrants in dossier evaluation</u>

SECR explained that in addition to the formal possibility to comment ECHA is now offering the possibility for the registrant to get also informally in touch with ECHA during the 30 day of commenting. There is a paragraph in the cover letter which states that if the registrant wants to get an insight of the scientific reasoning behind the DD they can contact ECHA through a functional mailbox. This could end up in a phone discussion where technical details or and general arguments which are possible to improve e.g. a justification for adaptation of the standard information requirements could be explained to the registrant. It is always emphasized that the communications made by ECHA during this telephone conference do not constitute advice to the registrant in any respect nor could they be regarded under any circumstances as a formal opinion or position of ECHA concerning specific scientific issues. If the registrant following the interaction with ECHA brings forward valid arguments and promises to update the dossier, ECHA could accept to wait for such an update a short period of time (e.g. three months) after the 30 days of commenting has expired. Update of the dossier within this period of time could make the DD unnecessary for some or all of the issues raised in a compliance check. It was emphasised that the new interaction policy would now be tested and experience gained. If it turns out that the new practice was misused by the companies ECHA would not continue with the interaction with the companies. This is an initiative that will be reviewed in the end of the year. A written record of all the communication with the registrant would be kept by ECHA.

The Chair explained that this process would affect also MSCAs and MSC process in the sense that MSCAs might be notified with the DD a bit later for their comments or proposals for amendment and subsequently it would be referred slightly later to MSC if a proposal for amendment is made by a MSCA.

The SECR believes that such a policy provides better transparency of ECHA's decision making to the registrants and could reduce the number of compliance check

decisions that need to be addressed at MSC and it might reduce the uncertainty about the design of a specific test in a testing proposal examination.

The status of dossier evaluation work until the end of August 2010.

SECR introduced this item by announcing that now there are in ECHA three evaluation units. Also, monthly statistics as shown in the slides are made available to MSCAs via CIRCA.

The members raised some points for clarification and one member asked whether it could be possible to send the DDs to MSCAs in groups following a specific schedule so that MSCAs would be able to plan their work. SECR replied that they would discuss this internally and would provide further feedback later. Following the presentation of the statistics, some members asked SECR for a timeframe of when are the expected dates for DDs to be notified to MSCAs and subsequently referred to MSC. SECR promised to provide the time schedules for the dossier evaluation DDs that have been estimated based on the fixed dates of MSC meetings. These estimated time schedules would give an indication to MSCAs when they can expect a MSCA consultation to be started on draft dossier evaluation decisions.

One stakeholder observer asked whether the number of testing proposals is expected to rise and whether it is possible for the public consultation to be staggered. The SECR replied that the number of testing proposals is indeed expected to rise and that unfortunately the public consultation cannot be staggered since ECHA is aiming to have a batch-wise publication each month so as to be able to meet the legal timeframes.

Item 6 - Stakeholder and case-owner participation in the MSC meetings during specific dossier evaluation related debates

Open session

a) Revision of MSC Rules of Procedure

b) Update of MSC Working Procedures on Dossier Evaluation

c) Code of conduct for case owners

Briefing to the Stakeholder Observers

The Chair introduced this item by informing the stakeholder observers that following the discussion by the Committee during the MSC-12 meeting on possible participation of stakeholder observers and case-owners in dossier evaluation discussions, the conclusions of that discussion were sent to the Management Board (MB) as a Room Document. The MB appreciated the document and it was used as a basis for their discussion. The MB came up with a proposal that the RoPs would need to be updated to set the rules for the participation of stakeholder observers and case

owners during the dossier evaluation discussions. As the text of the RoPs need to be kept quite general, SECR concluded that MSC working procedures on dossier evaluation need to be updated to include the details of practical arrangements for participation of stakeholder observers and case-owners. A separate code of conduct for case owners was also prepared to accompany this change.

SECR highlighted that the discussions on dossier evaluation would be divided into two sessions – an initial phase and a decision making phase. Case owners and stakeholder observers could participate in the initial discussion. The second session is where MSC would seek agreement on the cases and that session would remain closed. Due to potential confidential business information rules sometimes the stakeholder representatives may not be able to participate during the initial discussion phase. As the case-owners have to be treated equally the initial discussion phase has to take place in the presence of case-owners always after the registrant has already commented on the proposed amendments. Normally one case-owner representative would be invited. Exceptionally a case-owner can be accompanied by an expert if it provides added value.

The stakeholder observers were informed that the RoPs have been endorsed by MSC and the next step would be to send them to MB for approval at the MB meeting starting on 30 Sept. When they have been adopted SECR can start to invite case owners and stakeholder observers for the meeting gradually. However, the cases that would be on the table need to be properly analysed due to the confidential information that might be at hand so as to be sure when to invite the stakeholder observers. The issues that may prevent stakeholder observers' presence are listed in the Working Procedures (WP) that would be published on ECHA website:

a) cases where the full chemical (IUPAC) name of the substance is claimed confidential under Article 119(2) of REACH;

b) cases where data on the precise use of the substance is indispensably linked to the question whether an animal test is necessary or in a compliance check case where data is proposed to be waived based on limited exposure, unless the data is known to already be disseminated;

c) cases where there is another reason to consider the information to be confidential and sensitive to the business of the registrant; or

d) cases in which the Committee decides to hold a discussion in closed session for other reasons.

The Chair explained that this is the first attempt to start opening the sessions for stakeholder observers and case-owners to be more transparent. The MB agreed that based on the experience gained on the new practice MSC should review the situation in one year's time.

Following this briefing some questions for clarification were raised by the stakeholder observers. These were:

1. whether stakeholder observers would not be allowed to participate when the first session would be closed whilst case owners would be allowed to participate. Chair confirmed that that was the correct understanding.
2. whether the RoPs specifically include that for a IUPAC name to be claimed confidential the claim would have been already accepted by ECHA as justified. Chair explained that it is not included in the RoPs and that the judging of claims is a totally different procedure from the evaluation process. If the colleagues responsible for the judging of claims did not have time to consider the claim then MSC would take a precautionary approach and consider the name as confidential, thus having a closed session in that case. With time it is expected that the confidentiality claims would have been assessed and decisions made by the time when the draft dossier evaluation decisions are addressed at MSC.
3. stakeholder observers asked for the reasons for not being allowed to be present during the decision making phase and whether there would still be a briefing of the closed session. The Chair replied that it was the members of MSC that decided that the decision making phase should be kept closed. However, a briefing of the closed session would still be given to the stakeholder observers. The Chair highlighted that during the initial phase of the discussion, the case owners and the stakeholder observers would not be provided with any documentation. Thus they were encouraged to seek for the information on the public dissemination website.

Item 7 – Identification of SVHC

a) Brief listing of substances for which Annex XV proposals for identification of SVHCs have been submitted

SECR presented the list of substances that were being proposed for the identification of SVHC and that at the time of the meeting were for public consultation. Further information was given to the Committee on the proposed way forward and the timeframes of this process.

No comments were raised by the members following the presentation.

Item 8 – Preparations for the opinion on the draft recommendation of priority substances to be included in Annex XIV

- **Possible exchange of views on the draft recommendation and comments received**

Following the discussion on the draft recommendation of priority substances to be included in Annex XIV held in MSC-12 meeting, the Chair explained that additional information was received for lead chromate from the consultants. This was introduced to the background documents before placing them for public consultation that started on 1 July 2010. For the pigment red and the pigment yellow, where an exemption from authorisation was suggested by a company, SECR contacted the company for

more information. The company did not come back to ECHA until recently and therefore the substances have been included in the draft recommendation for Annex XIV without any exemption. The company asked for a teleconference in September 2010. SECR proposed to the company to send in the information on which basis they request the exemption as comments in the public consultation. SECR asked them as well to provide further information on the use and risk management measures in place.

- **Status report on development of MSC opinion on draft recommendation for Annex XIV – Initial reporting by the Rapporteur**

The Rapporteur reminded the Committee that the public consultation started on 1 July and that it would last for three months until the end of September. Until the day of the meeting there were only a few comments on the eight substances. There was one rather extensive comment by industry on arsenic compounds (diarsenic trioxide, diarsenic pentaoxide). The final opinion must be prepared and the first draft opinion should be ready by 8 October 2010. Then it would be discussed at the October meeting. The final opinion would be adopted in December 2010. Since the eight substances could be divided into groups it was proposed that such groups would be divided between the members of the working group. The first meeting of the working group to decide on the way forward took place after the plenary meeting.

The Committee asked SECR to provide the information to MSC on the lead chromate. Another member asked SECR how would conflicting information like presented in recently published report on one hand and in the submission by industry on the other hand be handled by ECHA. One stakeholder representative then explained that with regards to the arsenic compounds when the information was up for consultation the arsenic industry was in the process of getting organised in a consortium and therefore was not able to comment within the given timeframe.. However, it was clarified that the key use of the arsenic compounds that are for public consultation is the Murano glass. It was also mentioned by a member of the Committee that the industry circulated a letter stating that the use for arsenic trioxide is an intermediate use thus it does not qualify for the authorisation process.

The Chair thanked everybody for the contributions made and promised to send to the Committee the information requested for lead chromate. She also explained that the time schedule would be very tight for drafting the opinion because it was expected that comments would only arrive in the last moment. SECR would then organise a place for the working group to meet. This issue would again be presented in the October meeting with further discussions on the comments received during the public consultation together with the work the working group would have been able to do by that time.

Item 9 – Manual of Decision (MoD)

- **Discussion on new specific entries for the MoD**

Two items were proposed to be introduced in the MoD by SECR:

1. process of identification of SVHC – regarding changing of classification in Annex XV dossiers based on new available information for SVHC identification
2. request for all relevant and available information via DDs in the dossier evaluation process.

A member proposed to also include in the MoD the Committee's view of the withdrawal of substances from the candidate list even if there is no legal provision on how this could be done. This conclusion was to balance the conclusion expressed by item 1. The procedure of how to withdraw a substance from the candidate list was discussed in MSC-11 meeting. The COM explained that in general just because REACH does not refer to what to do, it does not mean it is not possible to do it, especially if it is in the spirit of REACH.

The Chair and the rest of the Committee agreed with this proposal and SECR proposed the new text based on the agreed minutes of MSC-11.

The MSC agreed on all the three inclusions in the MoD. They also agreed on the publication of the non-confidential version of the MoD on ECHA website. Stakeholder representatives were also in favour of publishing the MoD since it covers a lot of interesting points for industry as well.

Item 10 – Report from other ECHA bodies and activities

Draft guidance consultation: SECR explained that a draft guidance consultation on the Guidance on the communication of information on the risks and safe use of chemicals was started slightly before the MSC-13 with a closing date of the middle of October. This guidance update consultation is an ongoing process and one or two more guidance updates are expected to be consulted with MSC.

Renewal of membership: SECR explained that all the three Committees and Forum have been functioning for three years, and the term for the members is three years. Thus it is time to renew the terms of these bodies. ECHA sent out to the MS an invitation for appointments or nomination for the membership, copying MSCAs and the members. The nominations would need to come via the permanent representation by 15 November 2010. For the members of MSC that joined from the beginning, their term of office ends February 2011, but for other committees their term of office is much sooner so the renewal was launched together for all ECHA bodies. Out of the 29 members of MSC, 21 of the memberships would expire by end of February 2011.

Item 11 – Any other business

SECR informed the Committee on the new court cases launched against ECHA. These are the following:

T-268/10 PPG and SNF / ECHA (second acrylamide case). In Case T-1/10 the same applicants only challenged the MSC agreement to identify acrylamide as a substance of very high concern. ECHA argued in the first acrylamide case that the MSC agreement is in itself not a challengeable act. Therefore, the applicants to safeguard

their right bought this new case challenging ECHA's actual decision including acrylamide in the Candidate List.

T-343/10 Etimine and Etiproducts / ECHA (boric acid and disodium Tetraborates). The parties are challenging the decision of ECHA to include boric acid and disodium tetraborates in the Candidate List.

The Chair reminded the Committee that the next meeting would take place back to back with the workshop on prioritisation criteria for dossier and substance evaluation, thus due to this, a one day meeting was considered enough especially since the agreement seeking for the DD could also be done via written procedure. The Chair explained that the main points for discussion at the meeting are to agree on which of the items proposed to be identified as SVHC could be agreed upon via written procedure and the discussion on the opinion on the draft recommendation of priority substances to be included in Annex XIV.

Item 14 – 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)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)
FAJFAR Simona
FINDENEGG Helene (DE)
FLODSTRÖM, Sten (SE)
GEUSS Erik
HEISKANEN, Jaana (FI)
KORENROMP, René (NL)
KYPRIANIDOU-LEONITIDOU Tasoula
LUDBORZS Arnis
LULEVA, Parvoleta (BG)
MAJKA Jerzy (PL)
MARTIN, Esther (ES)
MIHALCEA-UDREA, Mariana (RO)
PISTOLESE Pietro
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
Alternate
BIWER Arno (LU)
MARTINS Ana Lilia (PT)
Representatives of the Commission
HANSEN Bjorn (DG ENV)
ROZWADOWSKI Jacek (DG ENTR)

Observers
ANNYS, Erwyn - CEFIC
LEENAERS, Joeri - EUROMETAUX
MUSU, Tony – ETUC
TAYLOR, Katy - ECEAE
WARNON Jacques – CEPE/DUCC
ECHA staff
AJAO, Charmaine
BALOGH, Attila
BRAUNSCHWEILER, Hannu
BROERE, William
CARLON, Claudio
DE COEN, Wim
FEDTKE, Norbert
GRADZKA, Agnieszka
HAUTAMÄKI, Anne
KARJALAINEN, Antti
KOSKINEN, Marjo
KOULOUMPOS, Vasileios
LOUEKARI, Kimmo
LUTOMSKA, Agnieszka
MALM, Jukka
MÜLLER, Birgit
NAUR, Liina
PREVEDOUROS, Kostas
RIALA, Riitta
RÖCKE, Timo
RUOSS, Jurgen
SUNDQUIST, Anna-Liisa
TISSIER, Chrystele
VAHTERISTO, Liisa
VERSONNEN, Bram
YLÄ-MONONEN, Leena

Proxy's
DOUGHERTY, Gary (UK) also acting as proxy of COSGRAVE, Majella (IE);

Experts and advisers to MSC members
ANDERSSON Lars (expert to FLODSTRÖM, Sten)
ARTUS, Hannela (expert to VESKIMÄE, Enda)
ATTIAS, Leonello (expert to PISTOLESE, Pietro)
HEINRICH-HIRSCH, Barbara (expert to FINDENEGG, Helene)
KOZMIKOVA, Jana (expert to GEUSS, Erik)
MICHEL, Cécile (expert to DRUGEON, Sylvie)
PEDERSEN Finn (expert to TYLE, Henrik)
RÁCZ, Éva (expert to DEIM, Szilvia)
TRAAS, Theo (expert to KORENROMP, René)

LAGRIFFOUL Arnaud (adviser to DRUGEON, Sylvie)
SCIMONELLI Luigia (adviser to PISTOLESE, Pietro)
TALASNIEMI Petteri (adviser to HEISKANEN, Jaana)

Apologies:

CAMILLERI Tristan (MT)
COSGRAVE, Majella (IE)
KYPRIANIDOU-LEONITIDOU Tasoula (CY) for Day 1
PALMA Maria do Carmo Ramalho Figueira (PT)
WELFRING, Joëlle (LU)

III Final agenda

1 September, 2010
ECHA/MSC-13/2010/A/13 Draft agenda

Draft Agenda
13th meeting of the Member State Committee

14-16 September 2010
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

14 September**: starts at 9:30**
16 September**: ends at 16:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/013/2010
For adoption

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

Item 4 –Minutes of the MSC-12

- Reporting back on the written procedure concerning adoption of draft minutes of MSC-12

MSC/M/12/2010
For information

Item 5 –Evaluation tasks

Closed session for 5a and b

Tentative timeline: Item 5a on Day 1 and item 5b on Day 2-3 of the meeting

a. Introduction to (and preliminary discussion on) draft decisions on testing proposals and compliance checks after MS-CA reactions *(Session 1)*

For discussion followed by agreement seeking under 5b:

- TPE 002/2010

ECHA/MSC-13/2010/003-004

- TPE 004/2010

ECHA/MSC-13/2010/009-010

- CCH 004/2010

ECHA/MSC-13/2010/012-013

For information (case withdrawn):

- TPE 003/2010

ECHA/MSC-13/2010/005[1]

For discussion following commenting by MSCAs (no agreement seeking):

- CCH 005/2010

ECHA/MSC-13/2010/018-019

- CCH 006/2010

ECHA/MSC-13/2010/020-021

- CCH 007/2010

ECHA/MSC-13/2010/022-023

For discussion followed by agreement seeking in October:

- CCH 009/2010

ECHA/MSC-13/2010/024-025

For information & discussion

b. Seeking agreement on draft decisions on testing proposals and a compliance check when amendments were proposed by MS's *(Session 2)*

- TPE 002/2010

ECHA/MSC-13/2010/002-004

- TPE 004/2010

ECHA/MSC-13/2010/008-010

- CCH 004/2010

ECHA/MSC-13/2010/011-013

For discussion & agreement

c. Status report on other ongoing evaluation work

For information

[1] There are not going to be Documents 006 and 007 for this meeting.

Item 6 –Stakeholder and case-owner participation in the MSC meetings during specific dossier evaluation related debates

Closed session, morning of Day 2

a) Revision of MSC Rules of Procedure

ECHA/MSC-13/2010/014

For discussion and endorsement

b) Update of the MSC Working Procedures on Dossier Evaluation

ECHA/MSC-13/2010/015

For discussion and adoption

c) Code of conduct for case owners

ECHA/MSC-13/2010/016

For discussion

Item 7 –Identification of SVHC

- Brief listing of substances for which Annex XV proposals for identification of SVHCs have been submitted

For information

Item 8 – Preparations for the opinion on the draft recommendation of priority substances to be included in Annex XIV

- Possible exchange of views on the draft recommendation and comments received
- Status report on development of the MSC opinion on draft recommendation for Annex XIV – Initial reporting by the Rapporteur

For discussion

Item 9 – Manual of Decisions (MoD)

- Discussion on new specific entries for the MoD

ECHA/MSC-13/2010/017

For discussion& decision

Item 10 – Report from other ECHA bodies and activities

For information

Item 11 – Any other business

- Suggestions from members

For information

Item 12 – Adoption of conclusions and action points

- Table with action points and decisions from MSC-13

For adoption

IV Main conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
MSC-13, 14-16 September 2010
(Adopted at the MSC-13 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
5 - Evaluation tasks (closed session)	
5a) Introduction to (and preliminary discussion on) draft decisions on testing proposals and compliance checks after MS-CA reactions *(Session 1)* and 5b) Seeking agreement on draft decisions a compliance check when amendments were proposed by the MS's *(Session 2)*	
Discussion TPE 002/2010 (5a) MSC agreed upon the following: - The arguments for the amendment raised by one CA to drop the request for the 90-day study from the draft decision are not backed up with peer reviewed scientific data .	One MSC member to prepare a thought starter for the MSC discussion, based on the proposed amendment in the discussion in the current meeting, in particular on the scientific data in extrapolating results from a 28 day study to a 90 day study under the specified conditions. Depending on the conclusions of the discussion at the meeting where the thought starter is to be discussed, ECHA to consider organising a workshop or expert discussion to allow further elaboration on the topics proposed by MSC members.
- For draft decisions that were already being processed before the TPE workshop in spring, the decision making can proceed without following the conclusions of the said workshop not to always prioritise for TPE dossiers for compliance check. ECHA will follow the workshop conclusions for any such dossier where the evaluation process has been started after the workshop. The recommendation to the registrant how to cover reproductive toxicity regarding fertility and perinatal toxicity was agreed to be moved from the body of the draft decision to the cover letter with more detailed advice to the registrant. The reference to the fact sheet in the draft decision should be replaced with the reference to the Guidance in the cover letter. **Draft decision TPE 002/2010 (5 b)** MSC found unanimous agreement on ECHA's	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
draft decision as amended in the current meeting. The basis for the agreement were the conclusions of the discussion, the action points above, the formulation for the cover letter to the registrant on fertility and perinatal toxicity and draft agreement document. **Information TPE 003/2010 (5a)** As the registrant ceased the manufacture of the substance and deactivated the corresponding registration via REACH-IT resulting in the revocation of the registration by ECHA in accordance with Article 50(3) of REACH, the draft decision on this case has been withdrawn by ECHA. **Discussion TPE 004/2010 (5a)** No change in ECHA's draft decision needed. MSC agreed that the same sentence as in the case of TPE002/2010 should also be included in the cover letter for the registrant in this case. **Draft decision TPE 004/2010 (5b)**	
MSC found unanimous agreement on ECHA's draft decision (no amendments) and draft agreement document.	Based on the discussions on cases TPE 002/2010 and TPE 004/2010, ECHA to examine any horizontal issues related to the question what to include in draft decisions and what in cover letters or other documents to ensure consistency of ECHA's administrative practice in the future, and to report back to MSC on this work.
Discussion CCH 004/2010 (5a) MSC agreed upon the following: - No change in ECHA's draft decision needed. – Justification for the choice of critical study for DNEL derivation, and in particular in this case, deviation from conclusions of the OECD SIDs report as well as justification for the assessment factors used in DNEL derivation (first two points of one MSCA proposal for amendments in this specific case) could in principle be included in ECHA's draft decision instead of a QOBL (quality observation letter) as there is a legal basis in Annex I of REACH to require the registrant to provide full justification for the information	- ECHA to evaluate this registration dossier as follow up under Article 42 of REACH in compliance check when the registrant has submitted the information required in the draft decision. - ECHA to address at the same time the consequences in case the registrant has not updated the dossier in accordance with QOBL and possibly open a compliance check. - ECHA to evaluate the updated dossier after the deadline for the update (six months).

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
used in the dossier. - Pursuant to Article 41(1)(c) ECHA may verify the CSR. ECHA can address shortcomings of a CSR in its draft decisions when the CSR is missing information required by Annex I. Following its evaluation of the CSR, ECHA should be prepared to address CSR defects in draft decisions when legally possible. Issues that can be addressed in a draft decision should normally not be included in a QOBL. - When addressing CSR shortcomings in a draft decision the consequences of such a requirement should be considered in advance and concluded how to react on the submitted information if not fully appropriate and scientifically relevant. In such cases there may be grounds to consider that the substance constitutes a risk. One option to react then would be to flag the dossier as a candidate for other actions, like for substance evaluation or restrictions. - The content of the draft decisions has to be specific and detailed so that the registrant would know what is required. - ECHA should always inform the MSCAs clearly which parts of the registration dossier it has evaluated and how the compliance check is targeted. **Draft decision CCH004/2010 (5 b)** - MSC found unanimous agreement on ECHA's draft decision (not amended) and draft agreement document.	MSC-S to upload in CIRCA the final ECHA decisions on cases TPE 002/2010, TPE 004/2010 and CCH 004/2010 for information.
CCH 005/2010 (5a) **CCH 006/2010 (5a)** **CCH 007/2010 (5a)** MSC took note of ECHA's presentation on the MSCAs' comments.	ECHA to address for discussion only such comments which were requested to be discussed by MSCAs or a MSC member.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
CCH 009/2010	MSC-S to launch a written procedure for agreement seeking on the draft decision on 23 September 2010 with a deadline of 5 October 2010 on the condition that registrant's comments received by 20 September 2010 do not challenge ECHA's amended draft decision on the case.
5c) Status report on other ongoing evaluation work	
	ECHA to provide MSC with the dates of MSCA consultation periods on draft dossier evaluation decisions relating to the MSC meetings in 2011.
6 - Stakeholder and case-owner participation in the MSC meetings during specific dossier evaluation related debates (closed session)	
6a) Revision of MSC Rules of Procedure (RoP)	
MSC endorsed the RoP as presented and modified in the current meeting.	ECHA to present the RoP to the next Management Board (MB) meeting (30 September – 1 October 2010) for approval. After approval, MSC-S to start applying the new provisions as appropriate.
6b) Update of the MSC Working Procedures on Dossier Evaluation	
MSC adopted the Working Procedures as presented and modified in the current meeting.	MSC-S to launch the review of the Working Procedures when more experience is gained. MSC-S to provide the Working Procedures for information to the MB together with the endorsed RoPs.
6c) Code of Conduct for case owners	
MSC had no comments on the draft Code of Conduct as presented in the current meeting.	MSC-S to present the Code to the Executive Director of ECHA for adoption. After adoption, MSC-S to start applying the new provisions as appropriate.
8 - Preparations for the opinion on the draft recommendation of priority substances to be included in Annex XIV	
MSC took note of the Rapporteur's report on the status of the work on the opinion of MSC.	ECHA to provide MSC members with the reports from the consultant of lead chromate and the information related to the meeting held with a lead manufacturer of Lead Chromate Pigments, during collection of information for priority setting.
9 - Manual of Decisions (MoD)	
The MSC agreed on the two inclusions suggested by MSC-S and one inclusion proposed during the meeting. MSC agreed that the non-confidential version of MoD will be published on the ECHA website.	MSC members to propose more inclusions to t SECR following the MSC-13 discussion. MSC-S to publish the non-confidential version of MoD on the ECHA website.
12 - Adoption of conclusions and action points	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
The conclusions and action points were adopted.	MSC-S will upload the non-confidential version of the conclusions and action points on MSC CIRCA together with the presentations delivered at the meeting, by 17 September 2010.