MSC/M/016/2011
(Adopted at MSC-17)
PUBLIC

Final Minutes

Minutes of the 16th Meeting of the Member State Committee (MSC-16)
1-3 February 2011

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 16th meeting of the Member State Committee (MSC).
For this 16th meeting, apologies were received from eight MSC members. Two members of MSC who were unable to participate in the meeting had notified the Chair as to their proxies (for the full list of attendees and further details see Part II of the minutes).

Item 2 - Adoption of the Agenda

The Agenda was adopted as proposed by the MSC Secretariat, with two additions under item 13. 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 - Administrative Issues

ECHA Secretariat (SECR) informed the meeting about the preliminary review of the results of the satisfaction survey of 2011. More detailed report will follow as soon as the full analysis is finished.

Item 5 – Adoption of the draft minutes of the MSC-15

SECR explained that written comments on the draft minutes of MSC-15 received from several meeting participants had been taken into account. The minutes - confidential and non-confidential parts - were adopted with some minor further changes in the meeting. The MSC Secretariat will upload the minutes on MSC CIRCA and on the ECHA website.

Upon request of one MSC member, all comments on the minutes of MSC meetings will be made available by SECR in the future.

The action points from the MSC-15 meeting were referred to by SECR. All actions had been carried out or were to be covered at this meeting.

Item 6 – Dossier evaluation

a) Dossier evaluation – general topics

1. Process for dossier evaluation – reminder of the procedural steps

Reviewing the main procedural steps of dossier evaluation, SECR pointed out the following:

- MSCAs' comments on the draft decisions of ECHA has no effect on the process; only MSCAs' proposals for amendment can be taken into account by ECHA for the purposes of the draft decision. Only cases where amendments were proposed by MSCAs will be referred to and discussed by MSC.

- When MSC is seeking agreement on the draft decision, comments of the registrant can only be taken into account if they are addressing the proposed amendments. Registrants' comments on other parts of the draft decision for which no proposals for amendments have been received can not be considered by MSC. The same applies for case owners' interventions at an MSC meeting where the case is discussed in the presence of the case owner: only interventions made on the proposed amendments can be considered by MSC.

- MSC can amend a draft decision in so far as this concerns the proposals for amendment of the MSCAs. Such amendments of MSC must not prejudice registrant's right to be heard, e.g., impose test for endpoints on which registrant could not comment. However, improvements on scientific argumentation for those parts of the draft decision for which no proposed amendments were submitted by MSCAs could still be introduced.

- ECHA's draft decision is based on the version of the registration dossier which was available before ECHA started the MSCA consultation on the draft decision. If the registrant updates its registration dossier after the draft decision was sent to MSCAs, this updated dossier cannot be the basis of the draft decision. If this were the case ECHA would bypass the right of the MSCAs to propose amendments to the draft decision based on the updated dossier. The new information in the updated registration dossier will normally be evaluated only after the deadline for required information in the final decision of ECHA has expired.

If the registrant updates its registration dossier before the draft decision was sent to MSCAs, ECHA can examine the updated dossier and can modify the draft decision or if the dossier complies with all the points addressed in the draft decision, the decision-making process can be stopped.

In the discussion SECR replied to questions that

- MSCAs' comments on draft decisions are not provided to the registrant as these comments would not affect the later steps of the process. It would be confusing to the registrant to receive the comments as they in any case would not have any effect on the content of the draft decision.

- MSC's task is not to discuss the quality observation letters but the draft decisions when seeking agreement on them.

- Theoretically, if ECHA in its draft decision for an endpoint requires a certain test but an MSCA proposes another test for the same endpoint, MSC still can propose and agree upon a third more suitable test for the same endpoint when seeking agreement because the registrant was informed of the proposed amendment for the endpoint.

- MSCAs have no possibility to propose changes on ECHA's responses to MSCAs' comments and proposed amendments as these responses, if requested, can be discussed in the MSC meeting where the concerned draft decision is discussed. News-

group communication in CIRCA is, however, available to the CAs if they wish to comment on the responses.

- In response to a decision a registrant may update the registration dossier with information which he thinks makes a required test unnecessary; however, by not performing the required test, the registrant does take the risk that if the information does not comply with the requirements of ECHA's decision he may be subject to enforcement action.

- For the time being, no informal communication is foreseen between ECHA and the registrant after the final decision is sent out.

2. Evaluation of dossiers for substances that were previously registered under NONS (Notification of New Substances) (closed session)

SECR presented ECHA's approach to the dossier evaluation of registration dossiers for substances which were notified to MSCAs under Directive 67/548/EEC. After reviewing of the legal basis, it was clarified by SECR that ECHA's approach is in line with the policy on which an agreement was found between MSCAs and COM at CARACAL in 2009. This agreement was made on the basis of COM paper CA/58/2009 after careful interpretation of REACH (in particular Article 24). Based on this paper the action plan of ECHA implementing the policy was agreed in CARACAL in autumn 2009. ECHA's action plan was made available to the meeting participants as a Room Document.

3. Review of MSC Working procedures on dossier evaluation

After SECR introduced the proposed changes on the document, MSC adopted the revised version of the Working procedures without further changes. MSC-S will upload the adopted Working procedures on MSC CIRCA and the ECHA website.

4. Thought starter on possibilities for waiving repeat dose studies for low-toxicity substances

An invited expert presented an analysis based on 14 substances with low toxicity profile and a NOAEL of >1000mg/kg/day in an oral 28-day study. Details can be found in the presentation made available to the meeting participants. In these cases, no toxicologically significant changes were observed in the corresponding 90-day study. In his view, based on these data it could be considered that in selected cases where the substance has a low toxicity profile and the NOAEL is >1000mg/kg/day in the 28-day study, the 90-day study could be waived. This approach could significantly reduce the need for animal testing.

The Chair opened the discussion by inviting comments on the scientific arguments included in the thought starter and raised in the presentation.

In the discussion it was suggested that the proposed waiving would be relevant only for situations where the 28-day study is already available beforehand. This would be the case for example where a tonnage upgrade is being done by the registrant from 10-100 tpa to 100-1000 tpa (or the 28-day study is already available beforehand for the substance due to some other reasons). If the substance is originally being registered in the tonnage band 100-1000 tpa, the 90-day study is needed anyway according to the current ECHA Guidance. So in these cases if the 28-day study is not already

available beforehand for the substance due to some other reasons, the suggested waiving would not be possible anyway.

Several members emphasised that such a small number of cases would not allow any statistically valid conclusions.

When assessing the toxicity profile of a substance for the purpose of the suggested waiving, sensitisation, oral acute toxicity and aquatic toxicity were suggested by a member to be taken into account as most important determining factors.

Some other members recommended not taking into account results of 28-day and 90-day studies carried out according to old test guidelines for possible waiving purposes.

Members reminded that in many cases big differences (10-20x) are possible between the results of 28-day and 90-day studies. This could not be seen in the current analysis because a limit-dose of 1000mg/kg/day for NOAEL in 28-day study was used which does not give information about the real toxicity. NOAEL values above this limit were not available for comparison with the results of the 90-day study. Members warned that one of the basic assumptions for the analysis was that NOAEL does not change with increasing study time for substances with a NOAEL above 1000 mg/kg/day. However, this might not be true and NOAEL could even decrease with increasing study time also for these substances. It was also said that to implement waiving as proposed the ECHA Guidance and possibly also REACH Annexes should be changed.

One member expressed sympathy for possible waiving of 90-day study but not on the basis of the 28-day study; one option could be that an extended one-generation study or a two-generation study could be combined with repeated dose toxicity study. Another member reminded that only the oral route of administration was examined in the analysis. Another route might lead to different results.

More members pointed out that the parameters covered by the two different tests are significantly different. The 90-day study offers more data particularly on the reproductive cycle and on histopathology. One member asked if ECHA could carry out a similar analysis on the database of registered substances. SECR replied ECHA needs more time to answer this question.

The Chair concluded that more time as well as further analysis and data are needed to consider this thought starter and to continue the debate. She invited the MSC members to submit their written comments and other scientific contributions to the topic by end of April 2011 and indicated that the discussion will be continued on that basis in the MSC-18 meeting in May 2011.

b. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MSCA reactions *(Session 1, closed except for CCH014/2010)*

and

c. Seeking agreement on draft decisions on compliance checks and testing proposals when amendments were proposed by MS's *(Session 2, closed)*

The Chair introduced the items explaining that in line with the revised Rules of Procedure (RoPs) of MSC registrants were invited to initial discussions of their cases (Session 1). Stakeholder observers can likewise be present if confidentiality rules do not prevent their participation. Regarding the discussion of the cases at this meeting, potential confidentiality issues were identified in all cases because the substances

were so called Notified New Substances under Directive 67/548/EEC or there were other confidentiality reasons.

CCH 014/2010

Session 1 (open)

SECR explained that the registrant could not accept the invitation to participate in this session (session 1) but agreed to the presence of stakeholders. Therefore, an open session was held.

SECR informed that one MSCA proposed an amendment to ECHA's draft decision. The registrant did not provide any comments on the proposed amendment of the MSCA but responded generally. The MSC member representing the Member State that submitted the only amendment agreed in the discussion with the explanation why ECHA did not amend the draft decision, based on the proposed amendment.

SECR responded to a question of a stakeholder observer regarding testing of ingredients of cosmetic products that the EU legislation on cosmetics has no direct link to REACH. It was also replied that ECHA is evaluating the registrations of substances under REACH. Therefore, it is up to the registrant to decide how to comply with ECHA's decision taking into account his other legislative obligations as well.

It was also highlighted by SECR that the weight-of-evidence approach proposed by the registrant was not sufficient to allow ECHA not to ask for a test in its draft decision.

Session 2 (closed)

MSC found unanimous agreement on ECHA's draft decision without amending it, and adopted the formal agreement.

CCH 015/2010

Session 1 (closed)

In line with the RoPs of MSC, the case owner of the registration dossier accepted ECHA's invitation and were present at the initial discussion (session 1). Due to confidentiality reasons, stakeholders were not present.

SECR informed that three MSCAs proposed amendments to ECHA's draft decision. The registrant did not provide comments on the proposed amendments but sent a communication to ECHA stating that it would update the dossier with some information required in the draft decision. The registration dossier had already been updated with further data on Robust Study Summaries (RSSs).

ECHA amended its draft decision based on one amendment of a MSCA requiring RSS also for the rabbit prenatal developmental toxicity study. Another MSC member accepted ECHA's response to the amendment proposed by his MSCA and concluded that amendment to draft decision would not be necessary.

A third MSCA proposed a 28-day inhalation study in rabbit instead of a 90-day study. The MSC member of the same Member State argued in the meeting that 8.6.4 of Annex X to REACH does not explicitly require a 90-day study. A 90-day study in rat is available in the dossier so the requirement of 8.6.2 of Annex IX for a 90-day study is fulfilled. In their view, if the concern is carcinogenicity as it is in this case, a 28-day study would give sufficiently reliable indications for this under 8.6.4 of Annex X. If there are more concerns based on these results, further carcinogenicity studies could be required later.

SECR explained that not only for carcinogenicity but also for other endpoints, e.g. spermatotoxicity, the 90-day study gives better information than the 28-day study. SECR also pointed out that first, rabbits turned out to be greatly more sensitive to the substance than rats in the available prenatal developmental toxicity studies. According to ECHA Guidance, a study has to be done in the most sensitive species.

Secondly, for substances with a tonnage band above 1000 tpa the standard information requirement of REACH is a 90-day study. A 90-day study gives also more reliable indications for possible carcinogenicity and reproductive toxicity and the statistical power of a 90-day study is higher. These are the main reasons why a 90-day study in rabbits is requested by ECHA.

SECR replied to a question that after the final decision was sent to the registrant no detailed discussion is foreseen between ECHA and the registrant on the results of the studies (e.g. on results of range finding studies). ECHA also clarified that car accidents are considered to be reasonable foreseeable exposure conditions for this case due to the high number of car accidents in the EU.

The Chair concluded that the registrant has proposed to extend the deadline for submission of the test results on 90-day study by inhalation in rabbit from 12 months to 18 months or 24 months. MSC did not see a problem to consider amending the deadline for submission of the test results. However, it was suggested that the deadline of 12 months should be kept for submission of the other information.

The Chair suggested that an *ad-hoc* group would continue discussions in the margins of the meeting focusing on the main controversial issue, namely whether the 28-day study would provide the necessary information instead of a 90-day study. The group was invited to report back to the plenary meeting on the outcome of the discussions.

Session 2 (closed)

After the report of the *ad-hoc* group, MSC found unanimous agreement on ECHA's draft decision after amending it at the meeting by introducing two deadlines for submission of the required information instead of one. The deadline for submission of test data was extended from 12 months to 24 months and was left to 12 months for the other information requirements. Otherwise ECHA's draft decision, as already amended on the basis of one proposed amendment, was not modified in the meeting.

Although agreeing to the draft decision as proposed by ECHA one member asked SECR to introduce a confidential statement to the minutes of MSC-16 expressing his concerns on 28-day vs. 90-day study, based on the proposed amendment from his MSCA. The statement contains scientific arguments for the views of the member to use 28-day study instead of 90-day study (see Part V).

MSC also adopted the formal agreement.

CCH 012/2010 (Pigment Additive 1799u)

Session 1 (closed)

The registrant did not react to ECHA's invitation to attend session 1. The session was kept closed, due to confidentiality reasons.

SECR informed that four MSCAs proposed amendments to ECHA's draft decision. The registrant did not provide any comments on the proposed amendments.

Three of the proposed amendments suggested to state a clear preference in the draft decision for long-term toxicity tests in invertebrates and plants. MSC members also expressed their concerns that the current formulation in the draft decision for the preferred tests is not clear enough and can be easily misunderstood or disregarded by the

registrant. SECR replied that these tests have to be considered by the registrant but cannot be required. However, SECR agreed that the wording needs to be further clarified.
Two members noted that information on test results which are available in other registration dossiers of the same substance should be made available also to MSCAs to make their work easier and to avoid extra work when preparing their comments and proposals for amendment. SECR agreed to try to improve the distribution of information to MSCAs in the future.

SECR also clarified that a reminder concerning data sharing obligations and for updating the registration dossier with certain data which are available in another registration dossier will be put in the notification letter and not into the draft decision because the data concerned do not constitute standard information requirements for this dossier. Similar reminders concerning data that falls within the standard information requirements will be put in the decision (see CCH 013/2010).

Session 2 (closed)
MSC found unanimous agreement on ECHA's draft decision after amending it at the meeting by reformulating the wording as discussed in session 1.
MSC also adopted the formal agreement.

CCH 013/2010 (Zinn(II)-Methansulfonat)

Session 1 (closed)

The registrant did not react to ECHA's invitation to attend the session (session 1). The session was kept closed, for confidentiality reasons.

SECR informed that four MSCAs proposed amendments to ECHA's draft decision. The registrant did not provide any comments on the proposed amendments.
ECHA took all proposed amendments into account and amended its draft decision.
SECR explained that the registrant was reminded in the draft decision and also in the notification letter of the obligation to share data before generating new data. Data on perinatal toxicity and effects on fertility can not be required but the registrant is recommended in the notification letter to fill the data gap on these effects, too. With this regard, the registrant is also reminded in the notification letter that a one-generation reproductive toxicity study might be available for sharing the data, too.

Session 2 (closed)
MSC found unanimous agreement at the vote on ECHA's draft decision as it was amended before the meeting taking into account the proposed amendments.
MSC also adopted the formal agreement.

TPE 006/2010 (Distillates (Fisher-Tropsch), C8-26 – branched and linear)

Session 1 (closed)

The registrant did not react to ECHA's invitation to attend the session. The session was kept closed, due to confidentiality reasons.

SECR informed that two comments have been received in the third party consultation on the testing proposal and both are discussed in the draft decision. Furthermore, three MSCAs proposed amendments to ECHA's draft decision. The registrant did not provide any comments on the proposed amendments but asked for additional time to respond to the proposals. ECHA has responded to the registrant that according to the legal procedure no additional time can be granted.

ECHA took the proposed amendments of one MSCA into account and amended its draft decision.

In the discussion of the case, SECR highlighted that the substance is a UVCB substance and the related difficulties in determining the compounds to be tested in the bioaccumulation test. ECHA's intention with the draft decision was to require the registrant to identify the relevant substances including transformation products for bioaccumulation testing on the basis of the results of the biodegradation study in soil. Part of the difficulties was that ECHA could not take a stepwise approach in decision-making i.e. first to ask the registrant to complete the biodegradation study, then analyse the results and ask the registrant again to do the bioaccumulation test with the substances which are the most relevant for bioaccumulation.

One member was not convinced that the level of details required in the biodegradation study is feasible and necessary but otherwise MSC generally supported ECHA's approach in the draft decision. However, it was concluded and generally agreed upon by members that a more precise formulation of the requirements concerning biodegradation and bioaccumulation test needed to be found. It was agreed that a small *ad-hoc* group would work on the revised wording in the margins of the meeting and report back to the Plenary on their proposals.

The possible need for a PBT working group was raised by one member although he acknowledged the limited time for these kind of working group discussions under REACH. The Chair suggested that a PBT working group could prove to be useful outside the remit of MSC.

Session 2 (closed)

After the report of the *ad-hoc* group, MSC found unanimous agreement on ECHA's draft decision after reformulating the wording for the required biodegradation and bioaccumulation testing.

MSC also adopted the formal agreement.

d. Status report on ongoing evaluation work

SECR announced that in February 2011 a new sub-site was opened on ECHA website dedicated to evaluation work where for example a practical guide on evaluation for registrants and third parties was made available. On the public consultation site, ECHA started publishing parts of the final testing proposal decisions showing how third party information was used during the decision making process.

SECR then gave a summary report on the current situation and on future challenges of dossier evaluation work in ECHA. Estimates for the increasing workload of the next MSC meetings were given. SECR also reported on preliminary approach with the next steps of the pilot project to improve communication between ECHA and MSCAs in the evaluation work.

MSC took note of the report.

Item 7 – Substance evaluation

a. Update on the CoRAP criteria and development process *(closed session)*

SECR announced that a 2nd Substance Evaluation workshop will be organised on 23-24 May 2011 for MSCAs, MSC members, COM and ECHA experts, back to back with the MSC-18 meeting. The main focus of the workshop will be the follow-up of substance evaluation including links to identification of risk management options, the

format and content of necessary documentation (reports/assessments, draft decisions), training and support needs and the experience gained from the application of CoRAP criteria and ranking of substances.

Input for the workshop as well as nominations for participants in the preparatory working group are welcome from members by 15 March 2011.

Later in its update SECR informed in a presentation about the status of development of criteria and plans for selection of substances for CoRAP. The details can be found in the presentation made available to the meeting participants. Further discussion on and refinement of the criteria is foreseen in the 2nd Substance Evaluation workshop. It was also clarified by SECR that REACH-IT is available as a searchable database for most of the MSCAs. However, query on properties of substances is not possible. Access to IUCLID for MSCAs is not feasible in the coming months mainly because security and performance aspects are not yet clarified. IT applications CASPER and ProSP that will be used in support of selection of substances by ECHA are still under development. As a short term solution, ECHA will provide MSCAs with Excel files of substances with some information from registration dossiers and these files can then be further searched/filtered by MSCAs. Once this filtering is done by an MSCA, it can request the registration dossiers of the selected substances from ECHA.

SECR replied to questions that it would be possible and from MSCAs' point of view logic first to create a longer candidate CoRAP list and preliminary draft CoRAP list and then later drop some substances from these lists if needed. Adding new substances to these lists would be more difficult later in the process.

It was also explained that ranking for the preliminary draft CoRAP list would be done in batches – low, medium, high – and possibly using comparable information that would make the ranking as transparent as possible. Ranking criteria have not yet been developed; this would be one of the tasks of the 2nd Substance Evaluation Workshop.

SECR also clarified that although officially the approximately 80 substances belonging to the group referred to under Article 135(2) of REACH are part of CoRAP, a significant part of the substance evaluation for these substances has already been done. Although too much more work for these substances would not be expected, they need to be listed in a separate section of CoRAP. The workload will depend very much on how the assessing MSCAs deal with the companies' replies given to MSCAs information requests under Article 16 (1) of Directive 67/548/EEC.

b. Planning of substance evaluation work in MSC - First discussion on MSC Working Procedures on providing the opinion on CoRAP

SECR introduced an early draft working procedure for MSC on providing its opinion on draft CoRAP. The working procedure is aimed to describe the tasks of MSC and the different steps of the process as well as how these could be organised within the Committee when its opinion is requested on the draft CoRAP (Article 44(2) of REACH). Besides the task of drafting an opinion on the draft CoRAP and its annual updates, the working procedure included some suggestions on how proposals from MSs in accordance with Article 45(5) could be addressed by MSC and channelled to the CoRAP. Some members made suggestions to add text in this regard in particular to the part describing the work flow. SECR emphasised that it is still too early to discuss the content of the MSC opinion in detail as the content of CoRAP and supporting documentation is still being developed.

The Chair invited members to provide comments in writing on the first draft, and suggested to discuss the next version in the upcoming MSC-18 meeting in May 2011. SECR will also invite the members in writing to express their interest to act as a Rapporteur for the MSC opinion on draft CoRAP.

Item 8 – Update of the Stakeholder participation in the MSC meetings

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

As agreed during MSC-9 (27-28 October 2009), MSC needed to review participation of the stakeholder organisations in one year's time to take account of any changes in the list of eligible stakeholder organisations that have expressed an interest to follow MSC work, and to review the situation in general.

SECR highlighted in its report that between 1 April 2009 and 31 March 2010, four organisations were added to the list of eligible organisations. One out of these four organisations expressed interest in the MSC work. This organisation represents one specific industry sector (recycling). Since March 2010 few more organisations have registered via ECHA website and their eligibility review will be finished in early 2011. However, none of these that registered until now have indicated interest in the work of MSC.

Since MSC-9, SECR accepted a few requests from sectoral organisations to take part in MSC meetings during a specific agenda point. These organisations will also in future be invited, at the discretion of the MSC Chair and/or MSC if technically possible, on a case-by-case basis depending on the items on the agenda.

MSC took note of the situation and agreed with SECR to continue with the present practice regarding participation of stakeholders in the work of MSC.

Item 9 – MSC tasks related to authorisation

- **Update by ECHA on the work related to SVHC process and prioritisation and inclusion of substances in Annex XIV**

Before ECHA's report, COM informed that the first list of substances included in Annex XIV of REACH, following on from ECHA's 1st recommendation, will be published in the Official Journal of the EU (OJ) mid-February this year. In the best case, substances to be added on Annex XIV from ECHA's 2nd recommendation could possibly be published in the OJ by the end of 2011.

SECR presented the timeline for the first SVHC identification process in 2011. The agreement seeking on the Annex XV proposals would be in MSC-18 meeting in May 2011. Also the substances submitted for identification as SVHC were shortly mentioned for which the accordance check is still to be carried out for inclusion to the SVHC identification process.

SECR gave also a presentation on how the opinion of MSC on ECHA's second recommendation was taken into account. The only issues for which ECHA did not follow the MSC opinion were the proposed transitional arrangements, *i.e.* date of entry into force, the application dates and sun set dates. The MSC opinion recommended that the application dates should be established as close as possible to the entry-into-force of inclusion in Annex XIV and that the interval between inclusion and application date should normally not be more than 12 to a maximum of 18 months.

ECHA recommended to COM for consideration that the standard time interval between entry-into-force and application date given in the Guidance should be respected (normally 18 months) and that potential overlaps with the application dates set out in the 1st amendment of Annex XIV should be considered in order to avoid capacity problems of ECHA with incoming authorisation applications. For the latter reason it was also proposed to COM to consider for the recommended substances at least 2 application dates with 3 months time difference between the lots.

Furthermore, SECR also presented a detailed timeline for the 3rd draft recommendation for Annex XIV and MSC to provide its opinion on it. In 2011 the same approach will be followed as in 2010. The opinion is scheduled to be adopted by MSC in MSC-21 on 7-9 December 2011. All substances on the candidate list by the end of 2010 and not yet included in any recommendation will be considered for the 3rd recommendation. SECR will provide MSC with the detailed timeline of the process for adoption in MSC-17 meeting (13-15 April 2011).

The Chair invited MSC members to consider their intentions to take part in preparation of the MSC opinion on ECHA's 3rd draft recommendation as Rapporteur or member of the possible working group supporting the Rapporteur. SECR will send a written invitation to the members in this regard.

Item 10 – Manual of Decisions (MoD)

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

SECR introduced the three issues proposed by MSC members in MSC-15 meeting. After discussion, MSC agreed that two proposals relating to PPORD exemptions and to route of authorisation should be included in the MoD. MSC came to the conclusion that inclusion in the MoD of the third issue concerning calculation of the relevant volume for prioritisation of substances to be included in Annex XIV is not appropriate for the time being.

SECR will prepare the two text proposals for the next meeting for discussion and possible adoption. MSC members are also invited to submit their further proposals.

Item 11 – Update on provisional work plan for MSC

SECR presented a slightly updated work plan for 2011 and indicated that the schedule for recommendation and development of MSC opinion on draft CoRAP are still provisional. Number of meetings planned for 2011 is unchanged (*i.e.,* six plenary meetings). SECR will make the updated work plan available on CIRCA.

Item 12 – Report from other ECHA bodies and activities

SECR reported about the last meeting of the Management Board (MB) in December 2010. From MSC point of view, the most relevant issues were related to the renewal of members, appointment of new members and alternates and the increasing workload of Committees which was a clear concern for the MB. The discussion on Committees' workload will continue at the next MB meeting in March 2011. The Chair invited the members to brief their MB representatives for the discussion as appropriate.

SECR also shortly introduced the new organigram of ECHA valid from 1 January 2011.

Item 13 – Any other business

- **Information from a member on a planned expert meeting *(closed session)***

MSC was informed of an expert meeting to be held on 12 April, back-to-back with MSC-17 on 13-15 April 2011. In the meeting, experts from Member States and ECHA will discuss potential criteria for endocrine disrupting properties.

- **Report from OECD: Recent activities from SIAM**

The OECD representative gave a short overview on the revised OECD Existing Chemicals Programme and recent learning from category assessments. The presentation has been circulated to the meeting participants. Scope and rationale of category assessment were reviewed and some preliminary conclusions based on the experience gained with use of analogues and quantitative read-across were provided. Information on plans in OECD to update the OECD Guidance for Grouping Chemicals was also given.

- **Suggestions from a member: Improving efficiency of MSC meetings**

The suggesting member shortly presented the meeting document prepared. The four main ideas of the document aimed at stricter agenda management, clustering of agenda items, enhanced interaction between SECR and MSC members and better co-ordination and cooperation between MSC members.
Reflecting to the suggestions, SECR agreed that due to the increasing workload of MSC mostly originating from dossier evaluation, members amongst them and also with SECR have to cooperate better and more intensively in the future. More frequent pre-meeting teleconferences and videoconferences could be very effective to this end.
The importance of cooperation and better coordination between MSCAs was also pointed out as having a direct impact to the workload of MSC.
The Chair concluded that MSC-S will come back to the issue later in the spring with more concrete proposals.

- **Report from the work of an informal meeting on potential PBT/vPvB screening**

One participating alternate member reported that experts from three Member States and from ECHA were present on this meeting on 25 January 2011 in Copenhagen. The aim of the meeting was to review screening methods to find potential PBTs/vPvBs and if possible to combine the resulting lists of potential PBTs/vPvBs of the different screening methods. Such a combined list could be well used for the purposes of the SVHC identification and CoRAP development process. Monthly follow-ups of the meeting are planned and results will be published as soon as conclusions can be drawn.

Item 14 - Adoption of conclusions and action points

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

Signed

Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
ANASTASI, Audrey-Anne (MT) (alternate member)
BIWER, Arno (LU) (alternate member)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
GEUSS, Erik (CZ)
HEISKANEN, Jaana (FI)
HUMAR-JURIC, Tatjana (SI)
KORENROMP, Rene (NL)[1]
KOUTSODIMOU, Aglaia (EL)
LULEVA, Parvoleta Angelova (BG)
MARTIN, Esther (ES)
MARTINS, Ana Lilia (PT) (alternate member)
MIHALCEA-UDREA, Mariana (RO)
PISTOLESE, Pietro (IT)
RÁCZ, Éva (HU) (alternate member)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)

Representatives of the Commission
KOBE, Andrej (DG ENV)
GARCIA JOHN, Enrique (DG ENTR)
Observers
ANNYS, Erwyn – CEFIC
BOHDAN, Dmytrasz – CONCAVE
DIDERICH, Bob – OECD
LEENAERS, Joeri - EUROMETAUX
MUSU, Tony – ETUC
ROBLOT, Ophelie – FECC
TAYLOR, Kathy – ECEAE
VAN VLIET, Lisette – HEAL
ECHA staff
BALOGH, Attila
BELL, David
BRAUNSCHWEILER, Hannu
BROERE, William
CARLON, Claudio
DE COEN, Wim
DE WOLF, Watze
FEDTKE, Norbert
HAUTAMAKI, Anne
KARJALAINEN, Antti
KORJUS, Pia
LEPPER, Peter
MALM, Jukka
NAUR, Liina
PREVEDOUROS, Konstantinos
ROCKE, Timo
SUNDQUIST, Anna-Liisa
VAHTERISTO, Liisa
VAKRA, Liisi
YLÄ-MONONEN, Leena

[1] Not present during agreement seeking on CCH012/2010 and CCH013/2010 (Item 6c)

Proxy's

DOUGHERTY, Gary (UK), also acting as proxy of COSGRAVE, Majella (IE)
LULEVA, Parvoleta (BG), also acting as proxy of KYPRIANIDOU-LEODIDOU, Tasoula (CY)

Experts and advisers to MSC members

ANDERSSON, Lars (expert to FLODSTRÖM, Sten)
ANDRIJEWSKI, Michal (expert to MAJKA, Jerzy)
ARTUS, Hannela (expert to VESKIMÄE, Enda)
ATTIAS, Leonello (expert to PISTOLESE, Pietro)
BALCIUNIENE, Jurgita (expert to DUNAUSKIENE, Lina)
CONWAY, Louise (expert to COSGRAVE, Majella)
DOYLE, Ian (adviser to DOUGHERTY, Gary via phone connection on the 1 February, for the discussion of case TPE 006/2010 under agenda point 6b)
INDANS, Ian (expert to DOUGHERTY, Gary during 1-2 February)

KULHANKOVA, Pavlina (expert to GEUSS, Erik)
RAMOS, Cesaltina (expert to MARTINS, Ana Lilia)
TRAAS, Theo (expert to KORENROMP, Rene)
TALASNIEMI, Petteri (adviser to HEISKANEN, Jaana)

Case owners (attending only to agenda item 6b, case CCH015/2010):
A representative of the registrant
An accompanying expert of the registrant

Apologies:
CAMILLERI, Tristan (MT)
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
KYPRIANIDOU-LEODIDOU, Tasoula (CY)
LUDBORZS, Arnis (LV)
MAJKA, Jerzy (PL)
PALMA, Maria do Carmo Ramalho Figueira (PT)
WELFING, Joelle (LU)

III. Final agenda

Final Agenda

16th meeting of the Member State Committee

1-3 February 2011
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

1 February**: starts at 9:30**
3 February**: ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/016/2011

For adoption

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

Item 4 – Administrative issues

- Results from the satisfaction survey

For information

Item 5 – Draft minutes of the MSC-15

- Adoption of the draft minutes of MSC-15

MSC/M/15/2010

For adoption

Item 6 – Dossier evaluation

Closed session for 6b(except for CCH014/2010)& 6c
Tentative timeline: Item 6b to start at 2 pm on the Day 1

a. Dossier evaluation – general topics

1. Process for dossier evaluation – reminder of the procedural steps *(presentation)*

For information

2. Evaluation of dossiers for substances that were previously registered under NONS (Notification of New Substances) *(presentation)*

For information

3. Review of MSC Working procedures on dossier evaluation

ECHA/MSC-16/2011/019
For discussion and decision

4. Thought starter on possibilities for waiving repeat dose studies for low-toxicity substances

ECHA/MSC-16/2011/002
For information and discussion

b. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MS-CA reactions *(Session 1, closed except for CCH014/2010)*

ECHA/MSC-16/2011/003

For discussion followed by agreement seeking under 6c:

- CCH 014/2010
ECHA/MSC-16/2011/013 & 014
- CCH 015/2010
ECHA/MSC-16/2011/016 & 017
- CCH 012/2010
ECHA/MSC-16/2011/007 & 008
- CCH 013/2010
ECHA/MSC-16/2011/010 & 011
- TPE 006/2010
ECHA/MSC-16/2011/004 & 005

For information and discussion

c. Seeking agreement on draft decisions on compliance checks and testing proposals when amendments were proposed by MS's *(Session 2, closed)*

- CCH 014/2010
ECHA/MSC-16/2011/013 & 015
- CCH 015/2010
ECHA/MSC-16/2011/016 & 018
- CCH 012/2010
ECHA/MSC-16/2011/007 & 009
- CCH 013/2010
ECHA/MSC-16/2011/010 & 012
- TPE 006/2010
ECHA/MSC-16/2011/004 & 006

For agreement

d. Status report on ongoing evaluation work

For information

Item 7 – Substance evaluation

Closed session for item 7a

a. Update on the CoRAP criteria and development process

For information

b. Planning of substance evaluation work in MSC

First discussion on MSC Working Procedures on providing the opinion on CoRAP

ECHA/MSC-16/2011/001

For information and discussion

Item 8 – Update of the Stakeholder participation in the MSC meetings

Closed session

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

ECHA/MSC-16/2011/020

For discussion and decision

Item 9 – MSC tasks related to authorisation

- Update by ECHA on the work related to SVHC process and prioritisation and inclusion of substances in Annex XIV

For information and discussion

Item 10 – Manual of Decisions (MoD)

- Discussion on next new entries for the MoD

ECHA/MSC-16/2011/021

For discussion

Item 11 – Update on provisional work plan for MSC

For information

Item 12 – Report from other ECHA bodies and activities

For information

Item 13 – Any other business

- Information from a member on a planned expert meeting

- Report from OECD: Recent activities from SIAM
- Suggestions from a member: Improving efficiency of MSC meetings
- Report from the work of an informal expert meeting on potential PBT/vPvB screening

ECHA/MSC-16/2011/022

For information

Item 14 – Adoption of conclusions and action points

- Table with action points and decisions from MSC-16

For adoption

IV. Main conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
MSC-16, 1-3 February 2011
(Adopted at the MSC-16 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
5. Adoption of the minutes of MSC-15	
The confidential and non-confidential version of the minutes was adopted with some minor changes made during the meeting.	MSC-S to upload the adopted versions on MSC CIRCA and to publish the non-confidential version of the minutes on the ECHA website. MSC-S to make available meeting participants' comments on the minutes of MSC meetings on MSC CIRCA in the future.
6. Dossier evaluation **6a) Dossier evaluation – general topics**	
(2) Evaluation of dossiers for substances that were previously registered under NONS (Notification of New Substances) ***(presentation, closed session)***	
MSC took note of ECHA's presentation and arguments reflected in the discussion.	
(3) Review of MSC Working procedures on dossier evaluation	
MSC adopted the revised version of the Working procedures.	MSC-S to upload the adopted Working procedures on MSC CIRCA and the ECHA website.
(4) Thought starter on possibilities for waiving repeat dose studies for low-toxicity substances	
MSC discussed the arguments presented and acknowledged the need for further scientific discussion on the issue.	MSC members to submit their written comments and scientific contributions to the topic as well as similar type of analysis based on other databases if they have any by 30 April 2011. MSC to continue the discussion at MSC-18 on 25-27 May 2011 based on the contributions of MSC members.
6. Dossier evaluation **6b) Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MS-CA reactions** ***(Session 1, closed session except for CCH 014/2010)*** **6c) Seeking agreement on draft decisions on compliance checks and testing proposals when amendments were proposed by MS's** ***(Session 2, closed)***	
CCH 014/2010 **Discussion (6b, Session 1)** MSC discussed the case based on ECHA's	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
draft decision, the proposed amendments of MSCAs and the registrant's comments on the proposed amendments. No changes on the draft decision as originally submitted to the registrant were suggested by MSC members for further discussion in Session 2 (agreement seeking). **Agreement seeking (6c, Session 2)** MSC reached unanimous agreement on ECHA's draft decision (no amendments in the meeting). MSC adopted the formal agreement. **<u>CCH 015/2010</u>** **Discussion (6b, Session 1)** MSC discussed the case based on ECHA's draft decision, the proposed amendments of MSCAs, registrant's comments on the proposed amendments and registrant's contributions in the discussion. Two changes to the draft decision as amended re suggested by MSC members to be discussed in Session 2 (agreement seeking): • extension of the deadline for the test required to 24 months; for other information required the deadline should be kept at 12 months and • whether 28-d study could be requested instead of 90-d study. **Agreement seeking (6c, Session 2)** MSC reached unanimous agreement on ECHA's draft decision including the two deadlines above for information requirements but did not introduce other amendments on the draft decision. MSC adopted the formal agreement. **<u>CCH 012/2010</u>** **Discussion (6b, Session 1)** MSC discussed the case based on ECHA's	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
draft decision, the proposed amendments of MSCAs and the registrant's comments on the proposed amendments. One change to the draft decision was suggested by MSC members to be discussed in Session 2 (agreement seeking): • when referring to the long term toxicity testing to invertebrates and plants, wording should be reconsidered **Agreement seeking (6c, Session 2)** MSC reached unanimous agreement on ECHA's draft decision including the revised wording when referring to the two tests above but did not introduce other amendments on the draft decision. MSC adopted the formal agreement. **<u>CCH 013/2010</u>** **Discussion (6b, Session 1)** MSC discussed the case based on ECHA's draft decision, the proposed amendments of MSCAs and the registrant's comments on the proposed amendments. No changes to the draft decision were suggested by any MSC members for further discussion in Session 2 (agreement seeking). **Agreement seeking (6c, Session 2)** MSC reached unanimous agreement on ECHA's draft decision (no amendments in the meeting). MSC adopted the formal agreement. **<u>TPE 006/2010</u>** **Discussion (6b, Session 1)** MSC discussed the case based on ECHA's draft decision, the proposed amendments of MSCAs and the registrant's comments on the proposed amendments. MSC members agreed with ECHA that the bioaccumulation test as proposed by the regis-	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
trant was not acceptable but concerns were expressed regarding ECHA's proposal for biodegradation test and bioaccumulation test. Reformulation of the test requirements should be further discussed in Session 2 (agreement seeking). **Agreement seeking (6c, Session 2)** MSC reached unanimous agreement on ECHA's draft decision including the revised test requirements for the biodegradation test and bioaccumulation test but did not introduce other amendments on the draft decision. MSC adopted the formal agreement.	MSC-S to upload in MSC CIRCA the final ECHA decisions and agreements on cases CCH 012/2010, CCH013/2010 CCH014/2010 CCH015/2010 and TPE 006/2010. Declarations to be submitted to MSC-S by a MSC member to cases CCH012/2010, CCH013/2010 and CCH015/2010.
7. Substance evaluation **7a) Update on the CoRAP criteria and development process**	
MSC took note of the report of ECHA.	MSCAs, MSC members, ECHA and COM experts to be invited to the workshop on Substance Evaluation on 23-24 May 2011. MSCAs to be informed about the CoRAP criteria and development process.
7. Substance evaluation **7b) Planning of substance evaluation work in MSC - First discussion on MSC Working Procedures on providing the opinion on CoRAP**	
MSC took note of the draft Working Procedures.	MSC members to consider their resources and their intentions to take part in preparation of the MSC opinion on the CoRAP as Rapportuer or member of the possible working group supporting the Rapporteur. MSC to submit their written comments on the draft Working Procedures (WP) by 28 February 2011. Based on the comments, MSC-S to prepare and present an updated version of the WP for MSC-18 (25-27 May 2011).
8. Update of the Stakeholder participation in the MSC meetings - Discussion and update	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
of the MSC decision about the invited organisations	
MSC took note of the report and supported the proposal to continue the current practice for involvement of stakeholders in the work of the Committee.	
9. MSC tasks related to authorization - Update by ECHA on the work related to SVHC process and prioritisation and inclusion of substances in Annex XIV	
MSC took note of ECHA's report on the time plan of the process of ECHA's 3rd recommendation.	MSC-S to submit the detailed time plan of the process for adoption in MSC-17 meeting (13-15 April 2011). MSC members to consider their intentions to take part in preparation of the MSC opinion on ECHA's 3rd draft recommendation as Rapporteur or member of the possible working group supporting the Rapporteur.
10. Manual of Decisions (MoD) - Discussion on next new entries for the MoD	
MSC agreed to take up two of the three proposed topics in the MoD of MSC.	MSC-S to provide MSC with text proposals of the two topics agreed for the MoD at the next MSC meeting (MSC-17, 13-15 April 2011).
13. Any other business • **Information from a member on a planned expert meeting**	
MSC took note of the planned expert meeting.	SECR to provide technical assistance and a dedicated CIRCA folder for the planned expert meeting on 12 April 2011.
14. Adoption of conclusions and action points	
The conclusions and action points were adopted.	MSC-S to upload the conclusions and action points on MSC CIRCA together with the presentations delivered at the meeting, by 4 February 2011.