**MSC/M/012/2010 Final**
**Adopted by written procedure,**
**1 September 2010**

# Final Minutes

## Minutes of the 12th Meeting of the Member State Committee (MSC-12)
## 9-10 June 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 12th meeting of the Member State Committee (MSC).
For this 12th meeting, apologies were received from seven MSC members. Four 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. 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 – Adoption of draft minutes of the MSC-11

ECHA Secretariat (SECR) explained that written comments on the draft minutes of MSC-11 received from one meeting participant had been taken into account. The minutes –confidential and non-confidential parts - were adopted without any further changes. The MSC Secretariat will upload the minutes on CIRCA and on the ECHA website.

The action points from the MSC-11 meeting were referred to by SECR. Long term actions related to the satisfaction survey are still in progress. Otherwise all actions had been carried out or were to be covered at this meeting.

## Item 5 - Administrative Issues

SECR informed the meeting that the renewal process of the membership of MSC members who started their 3-year term in February 2008 will be launched by ECHA early September 2010. To this end, permanent representations of the relevant Member States will be invited by ECHA to renew the term of their current MSC member or to appoint a new MSC member, as a gap in terms of office of MSC members is not desirable after February 2011.

The renewal process will be started simultaneously also for the other ECHA Committees and Forum. SECR invited the MSC members to forward this message to their permanent representations and ministries in charge for these matters.

## Item 6 – Participation of stakeholder representatives and case-owners during specific dossier evaluation related debates in MSC – MSC members' view (closed session)

## Item 7 – Evaluation tasks

### a) Seeking agreement on draft decisions on a testing proposal and two compliance checks when amendments were proposed by MS's (closed session, public minutes)

Regarding case TPE 001/2010, the registrant did not provide any comments on the proposed amendment of an MSCA. The MSCA proposing the only amendment made it clear in the meeting that their intention was not to propose an amendment but to submit a comment. MSC found unanimous agreement on ECHA's draft decision without amending it.

Regarding case CCH 001/2010, MSC took into account the comments of the registrant on the proposed amendments of MSCAs. In MSC's view, the comments did not provide any new information that would affect the content of the draft decision. Based on the discussion in MSC-11, MSC decided to amend ECHA's draft decision and found unanimous agreement on it. ECHA's draft decision was agreed to be supplemented by requiring the registrant also to provide full study summaries on all available *in vitro* mutagenicity tests, and not limiting the requirement only to the mutagenicity test *in vivo*. The justification for the requirement was that according to the REACH Regulation all available information has to be provided so that information also on the *in vitro* mutagenicity tests needs to be included in the registration dossier although this test is not part of the information requirements for the registered tonnage level of the substance. MSC considered also the information on the *in vitro* tests being relevant for the comprehensive assessment of mutagenicity of the substance.

Regarding case CCH 003/2010, MSC took into account the comments of the registrant on the proposed amendments of MSCAs. In MSC's view, the comments did not provide any new information that would affect the content of the draft decision. Based on the discussion in MSC-11 on the same case, MSC decided to amend ECHA's draft decision and found unanimous agreement on it. Compared to ECHA's draft decision, the agreed draft decision does not contain data requirements for endpoints as those cannot be specified without having confirmed information on substance identity. The amended draft decision requires the registrant to provide further information on the identity of the substance, and to update the dossier with analytical methods and spectral data. In light of the amendment also the deadline to update the registration dossier was changed from 12 month to 6 month.

SECR also informed MSC that the form for MSCAs to propose amendments will be made clearer for future draft decisions, to make the distinction between comments and proposal for amendments easier.

### b) Organisation of evaluation work: technical discussions in the MSC – report from the written commenting round

On the MSC-11 meeting, SECR introduced a document proposing to establish a working group for MSC to deal with high number of dossier evaluation draft decisions which are likely to reach MSC in the near future. As the proposal did not gain support on the MSC-11 meeting, SECR invited the MSC members to submit their

comments and views on the issue in writing. SECR informed MSC of the results of the written commenting round.

In the discussion of the topic, as a response to a comment SECR explained that it has plans on improving the communication between ECHA and MSCAs. It is considered to be of key importance to explain transparently and fully the rationale behind ECHA's draft decisions and reduce the number amendments to them proposed by MSCAs. This also would reduce the workload of MSC. SECR will probably be able to further reflect these plans in MSC-13 on 15-16 September 2010.

Regarding the communication with the registrants, ECHA is currently introducing more informal ways to make this communication and the cooperation with the registrants more effective.

It was also clarified by SECR, that draft decisions will always be submitted to MSCAs in batches according to the meeting dates. The meeting dates with the corresponding dates when MSCAs will receive the batches of draft decisions will be announced to MSCAs in advance to help MSCAs to plan their work regarding dossier evaluation.

Reflecting to further comments, the Chair pointed out that to make the work of MSC in the process of dossier evaluation the most efficient, SECR will establish CIRCA Newsgroup on dossier evaluation and the agenda of the MSC meeting will be streamlined, keeping the number of agenda points only for information as low as possible.

MSC members expressed the wish that SECR would present a short summary of arguments to kick off the discussion on a testing proposal or compliance check, if logistically possible.

To organise these first discussions and the decision making in separate MSC meetings will not always be possible as that would require still more frequent meetings. However, longer MSC meetings having separate sessions for initial discussion and for decision making can well be organised. SECR reminded about the challenges and time needed in the near future for discussions when more complex cases of registration dossiers of high volume substances will need to be discussed and solutions found.

Otherwise SECR did not find difficulties in supporting the proposals made in the members' contributions regarding organisation of work of MSC.

**c) Update on the ongoing dossier evaluation work and plans for substance evaluation**

SECR gave a summary report on the situation of the dossier evaluation work in ECHA.

SECR introduced the meeting document on ECHA's plans for substance evaluation. Based on the conclusions of the evaluation workshop in September 2009, substances should be selected by the suspected risk and the likelihood that the outcome i.e. a draft decision drafted by the evaluating Member State will confirm or refute the suspicion. Exact selection criteria will be discussed in a workshop, in cooperation with the Member States. The workshop on prioritisation criteria for Compliance check and Substance evaluation will be organised on 18-19 October 2010, back to back with the MSC-14 meeting. The refinement of and the agreement on the prioritisation criteria should be reached by the end of 2010. Input for the workshop as to MSs' views on

the scope of substance evaluation and on development of the prioritisation criteria, as well as nominations for participants in the preparatory working group, are welcome by 31 August 2010.

There was broad support for the workshop by the MSC members, but it was also remarked that several reasons for concern (and thus, criteria) may need to be combined in order to be effective and flexible.

## Item 8 –Identification of SVHC

### a) Reporting back on written procedure on identification of SVHC's in written procedure

SECR shortly informed the MSC meeting of the outcome of the written procedure. Five substances were identified as SVHC with unanimous agreement of the MSC members. Some editorial changes in the five support documents and agreements of MSC were also unanimously agreed upon in the meeting (see Annex IV for details).

### b) Seeking agreement on Annex XV proposals for identification of SVHC

The Chair clarified that the basis for the agreement is the inherent properties i.e. the hazards of the substances and if they meet the criteria in Article 57 of REACH. Information on uses, alternatives and exposure are taken into account later on in the authorisation process when the substances are being prioritised from the candidate list for inclusion into the Annex XIV (authorisation list).

The Chair also reminded MSC of the conclusions of the discussions held in the MSC-11 meeting on the relationship between the CLP Regulation and REACH Regulation. According to Article 59 (2) and (3), an Annex XV dossier may be limited to a reference to an entry with harmonised classification in Annex I of Directive 67/548/EEC (or in Annex VI of CLP Regulation (EC) 1272/2008. No further justification to identify a substance as SVHC is needed. If any new information became available since the substance was classified on Community level, challenging the existing harmonised classification, a new proposal to revise this classification has to be made by a MSCA in accordance with the CLP Regulation. This new proposal has to be submitted to the Risk Assessment Committee (RAC) of ECHA. RAC will examine this proposal and give its opinion on it to the Commission. Based on the opinion of RAC, the Commission may amend the harmonised classification in Annex VI of the CLP Regulation. According to this, MSC has no power to amend existing harmonised classification of substances included in the Community legislation.

Following this introduction, the representatives of the proposing MSCAs presented the proposals for the following three substances to be agreed upon by MSC in this meeting as a substance of very high concern (SVHC):

- **Boric acid**
- **Disodium tetraborate anhydrous**
- **Tetraboron disodium heptaoxide, hydrate**

MSC agreed unanimously on the proposals to identify the above three substances as a SVHC. The three support documents and the three agreements of MSC were also unanimously agreed upon with some editorial changes (see Annex IV for details).

## Item 9 – Discussion on ECHA's 2nd draft recommendation for inclusion of priority substances in Annex XIV

### a) Results of the application of the priority setting approach for inclusion of substances in Annex XIV

Introducing the topic, the Chair explained that based on written commenting before and discussion at MSC-11, ECHA had refined the general priority setting approach. This refined approach was applied on the substances of the candidate list. The results of this work were provided to MSC. No comments were received by ECHA on this document.

ECHA presented the changes in the general priority setting approach. As agreed by MSC at MSC-11, ECHA applied a scoring algorithm and also the verbal argumentative approach to the substances of the candidate list simultaneously. Regulatory effectiveness of a potential authorisation requirement was also taken into account. As suggested in the discussion at MSC-11, weighting of PBT/vPvB substances vs. CMR substances was slightly increased. Scoring of wide dispersive use was also slightly changed: the score for insignificant release can now be '1' instead of '0' if the number of sites where the substance is used is higher than 100.

For the establishment of background reports and prioritisation of the substances on the candidate list, ECHA collected and used data from the Annex XV dossiers, from comments received during consultation in the context of the SVHC identification process, and from investigations on volumes, uses and releases carried out by ECHA or by its consultants. Background reports for "old" substances in the candidate list (i.e. substances which were on the candidate list already at the time of the previous prioritisation) were updated if new information on use, volume and release was available.

The result of the priority setting was presented for each substance on the candidate list (and not included in ECHA's first recommendation). One MSC member proposed that non-prioritised substances should be categorised based on the reasoning why these substances were not prioritised. ECHA responded that the reasoning for not–prioritisation of each non-prioritised substance is included in the document describing the results of the priority setting by ECHA.

Concerning anthracene oils and their derivatives as well as coal tar pitch high temperature the MSC supported ECHA's conclusion not to include the substances in the draft recommendation but expressed its concern at the same time that measures should be taken to reduce the PAH emissions.

In case of acrylamide, a MSC member proposed it to be prioritised for public consultation for the reason that no formal measure restricting the use of acrylamide is in place at the moment and there is neither any formal information available from the Commission that would confirm the plan to restrict uses. ECHA is not proposing acrylamide to be prioritised and addressed in the public consultation because grouting, which is the only currently known use of acrylamide falling under the scope of authorisation, is currently being proposed for restriction by the Commission. It was agreed that SECR will make its conclusion whether to address acrylamide in the draft

recommendation for public consultation after hearing the status of the Commission plans on restricting the use of acrylamide in grouting applications at the CARACAL meeting on 15-16 June 2010.

It was clarified by SECR, that grouping of substances for prioritisation e.g. for chromates could possibly be done in the next recommendation round but not in this current one because several chromates would be introduced in the candidate list soon after they had been identified as SVHC. MSC emphasised again the need to come up with proposals addressing a group of substances so that a sound approach could be taken as regards prioritisation and addressing for authorisation chemically similar substances for similar uses. It was mentioned by ECHA that grouping should preferentially be discussed at the CARACAL meetings.

In the context of cobalt dichloride and other cobalt compounds it was concluded that when more cobalt compounds will be placed on the candidate list, they will be looked at in the light of possible grouping for the recommendation.

Regarding diarsenic trioxide and diarsenic pentaoxide, MSC suggested to place them in the draft recommendation for the public consultation in order to get more information on use and exposure. It is only after the public consultation that SECR will decide whether to prioritise or not these two compounds for the recommendation.

According to a statement of a meeting participant concerning arsenic trioxide, there is currently no known use of arsenic trioxide in battery lead in Europe. This information could be taken into account in the discussion on prioritisation of arsenic trioxide.

MSC supported ECHA's proposal not to prioritise refractory ceramic fibres (RCFs) until inclusion in the candidate list of the rest of the man-made mineral fibres (Index number 650-017-00-8) classified as carcinogenic in Annex VI of the CLP Regulation that currently fall outside the definition of RCFs on the candidate list. A member announced that her MSCA is considering to prepare an Annex XV SVHC dossier for these substances soon after the registration deadline of 1 December 2010 when more information becomes available on the fibres on the market.

Regarding prioritisation of substances on the candidate list with no known use in the EU, ECHA's plan is to monitor the registration dossiers of these substances. As soon as ECHA becomes aware of uses of these substances, then it is time to consider again prioritisation of these substances.

After discussion on each of the substances on the candidate list, MSC expressed general support for ECHA's proposal on which substances should and should not be prioritised (see further details in Annex IV).

**b) Draft Annex XIV entries and their justifications for prioritised substances**

SECR introduced the topic presenting the general approach for the draft recommendation, the draft Annex XIV entries and the justification documents for these entries.

MSC generally supported the Annex XIV entries for the draft recommendation including the application dates and sunset dates proposed by ECHA. However, MSC suggested ECHA not to include the exemption for the use of artist paints for lead sulfochromate yellow and lead chromate sulphate molybdate red in the public consultation because there were doubts that generic exemptions of carcinogens in artist's

paints can be justified from a risk perspective. According to information received from one of the meeting participants, these substances are no longer used in artist's paints.

SECR agreed to decide whether a PPORD exemption for lead sulfochromate yellow and lead chromate sulphate molybdate red is appropriate in the draft recommendation for public consultation, after contacting a company having submitted to ECHA a request for a possible PPORD exemption for the above two substances. It was felt that the company should provide more information to allow concluding in which category of possible exemptions (i.e. scientific research and development, product and process oriented research and development or exemption on the basis of Article 58(2)) their use could fall.

**c) Next steps of the work for the 2nd draft recommendation for Annex XIV**

SECR highlighted the next main steps of the process in a short presentation. No questions were raised by the meeting participants.

## Item 10 – Opinion on the draft recommendation of priority substances to be included in Annex XIV: Tasks and appointment of Rapporteur and possible working group

**a) Tasks of the Rapporteur in drafting the opinion of MSC**

SECR introduced the meeting document describing the mandate and tasks of the Rapporteur. The document was based very much on the same kind of document from the last recommendation process taking into account the changes of the relevant working procedures of MSC. No questions were raised by the meeting participants. MSC agreed to the Terms of Reference for the Rapporteur as presented.

**b) Appointment of Rapporteur**

MSC unanimously appointed one of its members as the Rapporteur based on his expression of interest for this role.

**c) Establishment of a working group to support the Rapporteur**

MSC established a working group to support the Rapporteur consisting of seven of its members and agreed also on the mandate of the working group.

## Item 11 – Update on provisional work plan for MSC

- Provisional meeting dates of MSC for 2011

The Chair briefly introduced the document listing the provisional meeting dates for 2011. No questions were raised.

## Item 12 – Any other business

- *Suggestions from members*

There were no suggestions from MSC members.

- *Possible updates to Manual of Decisions (MoD)*

There was one proposal from MSC members regarding grouping issues. The Chair explained that ideas for MoD entries on the recommendation process will be collected

after finishing the current recommendation process. SECR proposed a new entry for the MoD relating to the SVHC identification process and relationship between REACH and CLP Regulations. Another proposed entry regarding the dossier evaluation process was related to the decision of MSC taken at the current meeting stating that all available information has to be submitted in the registration dossier even if it is not specifically requested for the tonnage band in question.

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

- *Update toMSC on its potential task on identification of biocidal active substances with PBT, vPvB and POP properties*

SECR explained that since the last MSC-11 meeting, ECHA sent a letter to the Commission asking for clarification whether the Commission would like to use the standard SVHC route or the Article 77(3)(c) route to receive the opinion of MSC on PBT/vPvB properties of certain biocidal active substances. ECHA's wish would be to follow the SVHC route. So far ECHA did not receive any response to its letter and the legal clarification of the issue in the Commission is still ongoing.

Responding to a question ECHA explained that there is nothing in the legal text of the REACH Regulation preventing biocides or pesticides from being subject to identification as PBT or vPvB substances if the appropriate Annex XV SVHC dossiers will be received by ECHA. It was noted by one member that biocides are outside the scope of authorisation.

- *QSAR Workshop*

ECHA is organising a workshop on how to deal with scientific uncertainty, when non-test methods such as QSAR, read-across and chemical categories are used for regulatory decision making in the context of REACH. The workshop called "Dealing with Uncertainty from the use of Non-Test Methods under REACH" will be held in Helsinki at ECHA on 23$^{rd}$ – 24$^{th}$ September 2010 (1.5 days). MSCAs are invited to identify their experts with regulatory experience of applying non-test methods. The workshop is also open to Industry, NGOs, and also possibly to other international regulatory bodies.

## Item 13 - Adoption of conclusions and action points

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

## II. List of attendees

| **Members/Alternate members** |
|---|
| ANGELOPOULOU, Ioanna (EL) |
| COSGRAVE, Majella (IE) |
| DOUGHERTY, Gary (UK) |
| DRUGEON, Sylvie (FR) |
| DUNAUSKIENE, Lina (LT) |
| FINDENEGG, Helene (DE) |
| FAJFAR, Simona (SI) |
| FLODSTRÖM, Sten (SE) |
| GEUSS, Erik (CZ) |
| KYPRIANIDOU-LEODIDOU, Tasoula (CY) |
| LUDBORZS, Arnis (LV) |
| LULEVA, Parvoleta Angelova (BG) |
| MARTIN, Esther (ES) |
| MARTINS, Ana Lilia (PT) (alternate member) |
| MIHALCEA-UDREA, Mariana (RO) |
| PISTOLESE, Pietro (IT) |
| REIERSON, Linda (NO) |
| RUSNAK, Peter (SK) |
| STESSEL, Helmut (AT) |
| TRAAS, Theo (NL) (alternate member) |
| TYLE, Henrik (DK) |
| VANDERSTEEN, Kelly (BE) |
| VESKIMÄE, Enda (EE) |
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| **Representatives of the Commission** |
|---|
| BINTEIN, Sylvain (DG ENV) |
| ROZWADOWSKI, Jacek (DG ENTR) |
| **Observers** |
| ANNYS, Erwyn - CEFIC |
| DOOME, Roger - EBA, adviser of Mr. LEENAERS, Joeri |
| LEENAERS, Joeri - EUROMETAUX |
| MUSU, Tony - ETUC |
| VAN VLIET, Lisette - HEAL |
| WARNON, Jacques - CEPE/DUCC |
| **ECHA staff** |
| AJAO, Charmaine |
| BALOGH, Attila |
| BRAUNSCHWEILER, Hannu |
| BROERE, William |
| CARLON, Claudio |
| DE BRUIJN, Jack |
| DE COEN, Wim |
| KARHU, Elina |
| KNIGHT, Derek |
| KORJUS, Pia |
| LEPPER, Peter |
| LEFEVRE, Remi |
| MALM, Jukka |
| NAUR, Liina |
| NETZEVA Tatiana |
| SUNDQUIST, Anna-Liisa |
| THUVANDER, Ann |
| VAHTERISTO, Liisa |
| YLÄ-MONONEN, Leena |

**Replacements**
AHTIAINEN, Jukka (FI) replacing HEISKANEN, Jaana
ANDRIJEWSKI, Michal (PL) replacing MAJKA, Jerzy
BIWER, Arno (LU) replacing WELFRING, Joëlle

**Proxy's**
COSGRAVE, Majella (IE), also acting as proxy of DEIM, Szilvia (HU)
LULEVA, Parvoleta (BG), also acting as proxy of MAJKA, Jerzy (PL)
TYLE, Hendrik (DK) also acting as proxy of HEISKANEN, Jaana (FI)
DRUGEON, Sylvie (FR) also acting as proxy of WELFRING, Joëlle (LU)

**Experts and advisers to MSC members**
ANDERSEN, Sjur (expert to REIERSON, Linda)
ANDERSSON, Lars (expert to FLODSTRÖM, Sten)
ATTIAS, Leonello (expert to PISTOLESE, Pietro)
BALCIUNIENE, Jurgita (expert to DUNAUSKIENE, Lina)
HERBST, Uta (expert to FINDENEGG, Helene)
KOZMIKOVA, Jana (expert to GEUSS, Erik)
LAGRIFFOUL, Arnaud (adviser to DRUGEON, Sylvie)

MICHEL, Cecil (adviser to DRUGEON, Sylvie)
PECZKOWSKA, Beata (expert to MAJKA, Jerzy)
RÁCZ, Éva (expert to DEIM, Szilvia)
SCIMONELLI, Luigia (adviser to PISTOLESE, Pietro)
SORENSEN, Peter Hammer (expert to TYLE, Henrik)

**Apologies:**
CAMILLERI, Tristan (MT)
DEIM, Szilvia (HU)
HEISKANEN, Jana (FI)
KORENROMP, Rene (NL)
MAJKA, Jerzy (PL)
PALMA, Maria do Carmo Ramalho Figueira (PT)
WELFING, Joelle (LU)

## III Final agenda

9 June 2010
Final agenda

# Final Agenda
# 12th meeting of the Member State Committee

9-10 June 2010
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

9 June**: starts at 9:30**
10 June**: ends at 17:30**

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

MSC/A/012/2010
***For adoption***

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

**Item 4 –Adoption of draft minutes of the MSC-11**

MSC/M/11/2010
***For adoption***

**Item 5 – Administrative Issues**

- Renewal of memberships for Committees and Forum

***For information***

**Item 6 – Participation of stakeholder representatives and case-owners during specific evaluation dossier related debates in MSC - MSC members' view**
***Closed session***

ECHA/MSC-12/2010/004
***For discussion***

**Item 7 –Evaluation tasks**

***Closed session for 7a***

**a. Seeking agreement on draft decisions on a testing proposal and two compliance checks when amendments were proposed by MS's**

ECHA/MSC-12/2010/001

- TPE 001/2010

ECHA/MSC-12/2010/017-019

- CCH 001/2010

ECHA/MSC-12/2010/020-022

- CCH 003/2010

ECHA/MSC-12/2010/023-025

***For discussion & agreement***

ECHA/MSC-12/2010/002

***For information***

**b. Organisation of evaluation work: technical discussions in MSC – report from the written commenting round**

ECHA/MSC-12/2010/005

***For information & discussion***

**c. Update on the ongoing dossier evaluation work and plans for substance evaluation**

ECHA/MSC-12/2010/030

***For information***

**Item 8 –Identification of SVHC**

**a. Reporting back on written procedure on identification of SVHC's in written procedure**

Room document on the outcome of the written procedure

***For information***

**b. Seeking agreement on Annex XV proposals for identification of SVHC**

Discussion and seeking agreement on the identification of SVHCs based on the proposals and the comments received

- Boric acid

ECHA/MSC-12/2010/008-010

- Disodium tetraborate anhydrous

ECHA/MSC-12/2010/011-013

- Tetraboron disodium heptaoxide hydrate

ECHA/MSC-12/2010/014-016

***For discussion & agreement***

**Item 9 – Discussion on ECHA's 2nd draft recommendation for inclusion of priority substances in Annex XIV**

a. Results of the application of the priority setting approach for inclusion of substances for Annex XIV*

ECHA/MSC-12/2010/026

b. Draft Annex XIV entries and their justifications for prioritised substances*

ECHA/MSC-12/2010/027-029

c. Next steps of the work for the 2nd draft recommendation for Annex XIV

***For discussion***

****Please note that background documents for substances relevant for AP-08 a&b are available on Circa in folders for Recommendation process/2010.***

**Item 10 – Opinion on the draft recommendation of priority substances to be included in Annex XIV: Tasks and appointment of Rapporteur and possible working group**

c) Tasks of the Rapporteur in drafting the opinion of MSC

ECHA/MSC-12/2010/006

d) Appointment of Rapporteur

e) Establishment of a working group to support the Rapporteur

ECHA/MSC-12/2010/007

***For discussion & decision***

**Item 11 – Update on provisional work plan for MSC**

- Provisional meeting dates of MSC for 2011

ECHA/MSC-12/2010/003

***For information***

**Item 12 – Any other business**

- Suggestions from members
- Possible updates to MoD
- Update to MSC on its potential task on identification of biocidal active substances with PBT, vPvB and POP properties

***For information***

**Item 13 – Adoption of conclusions and action points**

- Table with action points and decisions from MSC-12

***For adoption***

## IV Main conclusions and action points

**MAIN CONCLUSIONS & ACTION POINTS**
**MSC-12, 9-10 June 2010**
(Adopted at the MSC-12 meeting)

| CONCLUSIONS / DECISIONS / MINORITY OPINIONS | ACTIONS REQUESTED |
|---|---|
| **4. Adoption of the minutes** | |
| Both confidential and non-confidential minutes were adopted without further changes during the meeting. | MSC-S to upload adopted versions on CIRCA and to publish the non-confidential version of the minutes on the ECHA website. |
| **7. Evaluation tasks** | |
| **7a) seeking agreement on draft decisions on a testing proposal and two compliance checks when amendments were proposed by MS's *(closed session)*** | |
| TPE 001/2010 -<br>MSC agreed with the draft decision.<br>MSC agreed with the draft agreement.<br><br>CCH 001/2010 –<br>MSC agreed with the amended draft decision.<br>MSC agreed with the draft agreement.<br><br>CCH 003/2010 –<br>MSC agreed with the amended draft decision after changing the deadline for the registrant to reply to ECHA to 6 months instead of 12 months.<br>MSC agreed with the draft agreement. | TPE 001/2010 –<br>MSC-S will perform the final editing of the draft decision and agreement and will check the description of the process details of the agreement with the legal unit.<br><br>CCH 001/2010 –<br>MSC-S will perform the final editing of the draft decision and agreement and will check the description of the process details of the agreement with the legal unit.<br><br>CCH 003/2010 –<br>MSC-S will perform the final editing of the draft decision and agreement and will check the process details of the agreement with the legal unit. |
| **7b) Organisation of evaluation work** | |
| A CIRCA newsgroup to discuss the evaluation cases will be established. | ECHA will inform the MSC in the MSC-13 meeting in more concrete terms on how ECHA Secretariat will try to improve the communication between ECHA Secretariat and the MSCAs when addressing the draft decisions for proposal for amendments of the MSCAs. This is currently work in progress.<br><br>MSC-S to provide a CIRCA newsgroup to discuss evaluation cases. |

| CONCLUSIONS / DECISIONS / MINORITY OPINIONS | ACTIONS REQUESTED |
|---|---|
| The MSC-S will streamline the agenda to provide sufficient time for discussions.<br><br>Discussion on dossier evaluation can be split in two parts:<br>1. discussion of draft decision, proposed amendments, registrants' comments and responses<br>2. agreement seeking<br>Discussion of the evaluation cases will take place in the plenary meetings which may then result in extension of the meeting. | |
| **7c) Update on the ongoing dossier evaluation work and plans for substance evaluation** | |
| | ECHA will organise a workshop on prioritisation criteria for substance evaluation on 18-19 October 2010 (back to back with MSC-14 [20 - 22 October 2010]). |
| **8. Identification of SVHCs** | |
| **8a) Reporting back on written procedure on identification of SVHC's** | |
| Trichloroethylene, sodium chromate, potassium chromate, ammonium dichromate and potassium dichromate were identified as SVHCs in written procedure.<br><br>It was agreed that the support document (SD) for the five substances will be edited as follows:<br>1. the sentence expressing the conclusion will be revised as follows:<br>*[substance name] is identified as a substance meeting the criteria of Article 57[a]/[b]/[c] of Regulation (EC) 1907/2006 (REACH) owing to its classification as [carcinogen]/ [mutagen]/[toxic for reproduction]category 2.*<br>2. a footnote explaining that the category is based on the old classification, packaging and labelling of dangerous substances directive (67/548/EEC) will be added.<br><br>MSC agreed to harmonise the sentence of the agreements on the identification of the substance with what was agreed for the SD (see above). | |

| CONCLUSIONS / DECISIONS / MINORITY OPINIONS | ACTIONS REQUESTED |
|---|---|
| | |
| **8b) Seeking agreement on Annex XV proposals for identification of SVHC**<br>**Discussion and seeking agreement on the identification of SVHCs based on the proposals and the comments received** | |
| *Boric acid*<br>*Disodium tetraborate anhydrous*<br>*Tetraboron disodium heptaoxide hydrate*<br><br>MSC agreed on the text of the SD as presented in Doc 9, 12 and 15 respectively including as well the same editorial change as for the SD for those five substances agreed via written procedure.<br><br>MSC agreed on the text of the draft agreement as presented in Doc 8, 11 and 14 respectively as amended in the meeting. The sentence of the agreements on the identification of the substance will be harmonised with what was agreed for the SD (see above).<br><br>*Disodium tetraborate anhydrous*<br><br>On the text of the SD MSC agreed also to revise the CAS numbers of the substances on the cover page. | MSC-S will finalise all the documents and place them on ECHA website. Subsequently the candidate list will also be updated. This will all be done very soon. |
| **9. Discussion on ECHA's 2nd draft recommendation for inclusion of priority substances in Annex XIV** | |
| **9a) Results of the application of the priority setting approach for inclusion of substances for Annex XIV** | |
| **CTPHT, Anthracene and Anthracene oils**<br><br>The MSC supports ECHA's proposal not to prioritise CTPHT and Anthracene oils. There are concerns on what should be done regarding PAH emissions in general under other EU regulatory approaches. These can be expressed in the Committee opinion. It was also agreed to clarify the sentence referring to the movement of PAHs from one part of the supply chain to another.<br><br>**2,4-dinitrotoluene**<br><br>The MSC supports ECHA's proposal to prioritise the substance. There is a bit of unclarity | |

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| about the volumes and the scoring allocated to it. This total could thus vary from 15 – 19. The report that is awaited from the contractor would clarify the volumes used in the EU. However even with a score of 15 points it was agreed to be recommended just the same.<br><br>**Diisobutyl phthalate**<br><br>The MSC supports ECHA's proposal to prioritise diisobutyl phthalate.<br><br>**Lead sulfochromate yellow (C.I pigment Yellow 34)**<br>**Lead chromate molybdate sulphate red**<br><br>The MSC supports ECHA's proposal to prioritise the two lead sulfochromates.<br><br>**Lead chromate**<br><br>The MSC supports ECHA's proposal to prioritise lead chromate. The pending information from the contractor is not expected to change such prioritisation.<br><br>**Diarsenic trioxide**<br>**Diarsenic pentaoxide**<br><br>The MSC suggested to place diarsenic trioxide and diarsenic pentaoxide in the draft recommendation for the public consultation in order to get more information on the use and exposure. It is only after the public consultation that the ECHA Secretariat will decide whether to prioritise the diarsenics or not in the draft recommendation.<br><br>**Tris (2-chloroethyl) phosphate**<br><br>The MSC supports ECHA's proposal to prioritise tris (2-chloroethyl) phosphate.<br><br>**Acrylamide**<br><br>The MSC agreed for the ECHA Secretariat to decide whether to propose the substance for public consultation after discussion of the re- | |

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| striction proposal during the CARACAL meeting taking place on 15-17 June.<br><br>**(Zirconia) Al-silicate refractory ceramic fibres**<br><br>The MSC supports ECHA's proposal not to prioritise RCFs until inclusion in the candidate list of the rest of the man-made mineral fibres (Index number 650-017-00-8) classified as carcinogenic in Annex VI of CLP Regulation that currently fall outside the definition found on the candidate list .<br><br>**Sodium dichromate**<br>**Cobalt dichloride**<br>**Bis (tributyl tin) oxide**<br>**Triethyl arsenate**<br>**Lead hydrogen arsenate**<br><br>The MSC agreed with ECHA's proposal not to prioritise these substances.<br><br>It was noted that the grouping approach is a good way forward and it needs to be further discussed with the MSCAs. | |
| **9b) Draft Annex XIV entries and their justifications for prioritised substances** | |
| The MSC supports the application dates and sunset dates proposed by ECHA.<br><br>The MSC suggested not to include the exemption for the use of artist paints for lead sulfochromate yellow and lead chromate sulphate molybdate red in the public consultation.<br>The ECHA Secretariat will decide whether the PPORD exemption for lead sulfochromate yellow and lead chromate sulphate molybdate red is needed for public consultation, after contacting the company concerned. | ECHA will contact the company concerned to clarify the basis for the exemption they are requesting. |
| **10. Opinion on the draft recommendation of priority substances to be included in Annex XIV: Tasks and appointment of Rapporteur and possible working group** | |
| **10a) Tasks of the Rapporteur in drafting the opinion of the MSC** | |
| The MSC agreed to the Terms of Reference for the Rapporteur as presented by MSC-S. | |

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| **10b) Appointment of Rapporteur** | |
| The MSC appointed one of its members as the Rapporteur. | |
| **10c) Establishment of a working group to support the Rapporteur** | |
| The MSC established the working group to support the Rapporteur consisting of seven of its members.<br><br>The MSC agreed on the composition and mandate of the working group. | The MSC-S will place on CIRCA the mandate of the working group with its final composition. |
| **12. Any other business** | |
| **Possible updates to MoD:** | |
| MSC-S proposed to include the following updates to the MoD with regard to the dossier evaluation process:<br>1. Explain the relationship between REACH and the CLP Regulation<br><br>2. If information is available, study summaries have to be included in the dossier | MSC-S to include these two proposals for next meeting and the MSC members are welcome to send their proposals as well to the MSC-S. |
| **Scientific Workshop on application of non-test methods** | |
| | MSC-S will send the information about this workshop in writing to the MSC-members for the members to nominate QSAR experts for this workshop.<br><br>MSC-S will inform the stakeholder observers if industry and NGOs are invited as well to the workshop. |
| **13. Adoption of conclusions and action points** | |
| The conclusions and action points were adopted. | MSC-S will upload the non-confidential version of the conclusions and action points on CIRCA together with the presentations delivered at the meeting, by 11 June 2010. |