MSC/M/08/2009 Final
Adopted by written procedure
on 12/09/09

Final Minutes

Minutes of the 8th Meeting of the Member State Committee (MSC-8)
18-20 May 2009

I. Summary Record of the Proceedings

Item 1 - Welcome and Apologies

The Chair of the Committee, Ms Anna-Liisa Sundquist, opened the meeting and welcomed the participants to the 7th meeting of the Member State Committee (MSC). She informed the participants that the meeting would be recorded solely for the purposes of taking the minutes and that the recording will be destroyed after the adoption of the minutes.

Two new members replacing previous members were welcomed and introduced to the rest of the committee. These are Ms Jaana Heiskanen appointed by Finland and Mr Maarten Roggeman appointed by Belgium.

For this 8th meeting, apologies were received from six MSC members. The list of attendees is given in Part II of the minutes. Three members of the MSC who were unable to participate in the meeting had notified the Chair as to their proxies (for details see Part II of the minutes).

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

The ECHA staff introduced themselves to the members.

Item 2 - Adoption of the Agenda

The Chair went through the Agenda as presented explaining how to proceed during the meeting and proposing some amendments. The Agenda was adopted as amended (see part III).

The Chair explained that now the provisional Agenda is also being placed on the ECHA website as soon as it is sent out to the members with the invitation. This is then replaced with the final draft Agenda when available.

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

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

Item 4 – Final minutes of the MSC-6

4a Adoption of draft minutes

Written comments on the draft minutes of MSC-7 received from two MSC members were taken into consideration. Another member proposed a change to the minutes during the meeting. This was taken into account and the minutes were adopted as amended.

The Chair reminded the MSC that the final minutes will be published on the ECHA website soon after the meeting.

4b Action points

The Secretariat reported that all the action points from the last meeting were on track or completed.

Item 5 - Administrative Issues

The MSC Secretariat informed the MSC about the following administrative issues:

Kaleva travel:

The Chair announced that the feedback received from the members on the use and functionality of the travel system was overall very positive. This feedback together with other feedback from other meetings of ECHA was compiled for further analysis. The travel agency was already provided further guidance for further improvement.

Clarification of the meaning of 'public services' in the rules for remuneration of co-opted members and invited experts:

With regard to the clarification of the meaning of 'public services' in the rules for remuneration of co-opted members and invited experts adopted by the Management Board 18 December 2008 (MB/77/2008 final**)**, ECHA explained that this was not meant to include experts from universities or public research institutions, who would normally be eligible for remuneration. However, REACH Competent Authorities (CAs) and the enforcement authorities will not be entitled for remuneration by ECHA. This interpretation has not been formalised yet in the MB decision, this will happen at the latest when the decision is reviewed.

Declarations of confidentiality

The Chair reminded those that joined the MSC for the first time about the need to complete the declarations of confidentiality before the end of the meeting. The Chair also stressed the importance to keep all the discussions held at these meetings confidential and not to be shared with the outside. To this comment, some members requested some clarification. It was then further clarified that all the information published on the ECHA website can be considered as non-confidential thus can be distributed and shared by the members. The Chair explained that transparency is one of the most important goals for ECHA.

Annual declarations on conflict of interest

The Chair reminded the members that some declarations still need to be submitted.

The declaration of commitment

The Chair explained that in line with the Rules of Procedure (ROPs) the declaration of commitment (Annex I of ROPs) has to be signed annually, and handed in during the meeting.

Item 6 – MSCAs' and MSC's access to confidential data - Data security issues

ECHA Secretariat delivered a presentation on data security issues. This had been presented to the MB but was left on the table to be able to consult the competent authorities

properly on the issue. Data security becomes a very important issue once REACH-IT is fully functional.

The Chair explained that this issue will also be discussed during the CARACAL meeting so as to gather as much feedback as possible from the relevant stakeholders before the Management Board can take its decision. It was explained that the members of the MSC that are members of the REACH CAs will be given access to REACH –IT through the REACH CAs.

More secure tools to provide confidential information to MSC members will be developed by ECHA. A solution of how to provide access to confidential information for the members of the MSC needs to be developed. Similar conditions of data security for the members of the MSC will then be applied as for MSCA's for the use of REACH-IT. There will be implications on the MSC members' access to confidential data so that MSC rules for the use of CIRCA have to be changed. From the MSC-8 meeting onwards, ECHA will delete from CIRCA all documents containing confidential information after every MSC meeting. As long as CIRCA will be used, all experts and advisers using the MSC CIRCA Interest group will have to provide their declaration of confidentiality to the MSC-S.

A member questioned the correctness of the background analysis given in the presentation. The REACH regulation does neither stipulate that MSCAs shall have full access to registration data nor does it stipulate the contrary. Generally this does not need to be detailed in a law, because for an Authority the access to data and information generated by a law is defined by the tasks that an authority has under this law. In REACH the MSCAs have (besides enforcement) the tasks to propose substances for authorisation, restriction and evaluation procedures and to provide a sound scientific argumentation to start with. It is evident that they cannot fulfil these tasks without having access to all registration data which they must search and examine in order to be able to propose the correct substances which need further attention.

The member questioned also the degree of detail requested from Member States on data security issues e.g. with respect to buildings and work organisation, which might be in conflict with national provisions, which provide the same level of security.

Item 7 – (Updated) draft recommendation for inclusion of priority substances in Annex XIV

The Chair introduced this Agenda item by going through the documents related to it. The full set of documents consisted of the priority setting approach, the general approach for defining the Annex XIV entries, the draft recommendation, and also the response to comments (RCOMs) for each substance and the justifications for Annex XIV recommendation for each substance.

a) Reporting on the consultation outcome on

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

The ECHA Secretariat delivered a presentation on the outcome of the public consultation highlighting:

1. main trends and lessons learnt for the future
2. types of comments received focused on -
    a. priority setting (mainly from national authorities and NGOs)
    b. comments on the exemptions suggested by ECHA (mainly from national authorities and NGOs)
    c. requests for exemptions (mainly from industry)

It was also explained that a non-confidential version of the RCOMs would be published on the website when the recommendation is finalised and sent to the Commission on 1 June. A general overview of the comments received, highlighting the comments that were repeated for several substances, was also delivered.

A general discussion on the contents of the presentation followed. The main issues raised were about synergistic effects; interaction of different Community legislation with REACH; and a clarification on the modifications made to the background documentation.

The second day started with a closed session where issues related to the confidential comments were discussed. It was explained that when a company requests to keep the information submitted during the public consultation as confidential, then such comments cannot be discussed during the MSC meeting in the presence of the observers. Also, ECHA cannot provide responses to those comments in the public version of the RCOMs.

The closed session lasted for around thirty minutes. The observers were then invited back in the meeting to continue the discussion on the non-confidential version of the comments.

b) Responses of ECHA to the comments received

ECHA Secretariat gave an overview of the comments received for each substance. Below is a summary of the discussion points per substance.

Substances proposed by ECHA to be prioritised during the public consultation:

5-tert-butyl-2,4,6-trinitro-m-xylene (Musk Xylene) – No particular comments were received in the public consultation, thus no specific issues were raised by the members.

4,4'-Diaminodiphenylmethane (MDA) – ECHA explained that the use of MDA as hardener in epoxy resin is not a use as intermediate. The justification in the RCOMs for MDA is- *'The use of MDA in the manufacture of high performance polymers and processing to 4-4'methylenebis(cyclohexamine) is considered to be an intermediate use because in these cases MDA is the starting material which is transformed during synthesis (manufacture of polymers and 4-4'methylenebis(cyclohexamine)) into other substances, which are then further used. These further uses include also the use of 4-4' methylenebis(cyclohexamine) as a hardener in epoxy resins, which is not considered to be an intermediate use.*
The direct use of MDA as hardener in epoxy resins and adhesives results in a chemical reaction between the MDA and the resin or adhesive. This use is not considered as a use

of an intermediate in a manufacturing process of another substance but as an end use of the substance. The use of MDA as hardener in epoxy resins and adhesives does not result in another substance which is manufactured/imported or placed on the market as such or in a preparation (although an article including the hardened resin may be placed on the market).' Overall the members agreed with this justification.

A longer discussion then followed on whether the use of MDA should be exempted in artists' paints as suggested in the draft recommendation.

First, some members of the MSC expressed doubts as to whether the exemption from restrictions of the use in artists' paints could be regarded as necessary since according to available information it is not used in artists' paints.

Secondly, it was not clear for the members whether a general exemption found in entry 29- 31 of Annex I to Directive 76/769/EEC i.e. an exemption that covers a category of substances (all CMRs) rather than a specific substance e.g MDA could meet the requirements for exemption from authorisation under Article 58(2) of the REACH Regulation. Furthermore, the reason why artists' paints were included in the exemption was unclear for the members. Even though the aim of the Committee is to come up with a scientifically based decision, this legal uncertainty created a lot of discussion.

During the discussion ECHA explained recital (80) of the REACH Regulation requires that a proper interaction should be ensured between the provisions of authorisation and restriction. Therefore, in determining whether an exemption from authorisation should be granted, ECHA considered that it should take into account specific exemptions of a use from restrictions under Directive 76/769. The restriction and its related exemptions must be examined as a whole in order to determine whether an exemption under Article 58(2) of the REACH Regulation should be granted. It was also mentioned that it is unclear whether for the decision on the exemptions from restrictions socio-economic impact was taken into account.

It was agreed that further clarification is needed by the Commission on how the restriction process and the authorisation process should relate to each other. The ECHA Secretariat stated that the strong debate would be reflected in the recommendation that ECHA would send to the Commission by 1 June 2009.

<u>Alkanes, C10-13, chloro</u> (Short Chain Chlorinated Paraffins - SCCPs) – The exemptions proposed by ECHA for this substance were the main discussion point for SCCPs, where some members voiced their disagreement with the proposed SCCPs exemptions. Thus again the discussion focused on the relationship between restriction and authorisation. The exemptions discussed for SCCPs were for its use in metalworking or fat liquoring of leather. The restriction in Directive 76/769 permits the use of SCCPs in these applications in preparations in concentrations at or lower than 1 %. However, unlike the exemption from restrictions for use of substances in artists' paints which addressed a category of substances, the restriction (and conditions for exemption) of the use of SCCPs specifically identified the substance that is subject to the restriction. Some members were on this basis in agreement with the position of ECHA represented in the RCOMs, i.e. to have the use of SCCPs permitted in Directive 76/769 to be also exempt from authorisation, and others were not.

Hexabromocyclododecane (HBCDD) – The introduction of the comments received by ECHA was followed by a short discussion. One of the participants of the meeting stated that the majority of the comments on this substance were not introduced by the manufacturers but by a specific downstream industry – the polystyrene industry which had stated in their comments that there are no alternatives for their uses. The absence or presence of alternatives is not a reason for not including this substance in Annex XIV. This will be discussed and taken into account at a later stage during processing of authorisation applications and the respective assessment of socio-economic effects.

Phthalates: The discussion on the exemption of the use of MDA in artists' paints referred to above is applicable also for the three phthalates mentioned below.

Bis(2-ethylhexyl) phthalate (DEHP) – ECHA explained that the comments focused on requests for exemptions and on longer periods for the transitional arrangements. The rest of the comments gave additional information on the complexity of the supply chain.

The discussion of the MSC focused on the potential occurrence of cumulative effects of phthalates due to simultaneous exposure to these substances. Some members stated that the RCOM provided by ECHA was too limited in scope and did not answer the questions raised. ECHA explained that even though they recognise a potential for the occurrence of cumulative effects upon combined exposure to different phthalates, the assessment of risk posed by combined exposure to a set of substances is very difficult from the aspect of how authorisation applications have to be assessed under REACH. In REACH the authorisation process, and thus the evaluation of applications for authorisation, is based on a substance specific and use specific approach. Only if an application for authorisation would address a group of substances and a range of uses potential cumulative effects of these substances could be considered in the assessment of the application. A member still expressed some reservations to this comment. Also another participant of the meeting showed interest in some follow-up discussions on this issue since they would have some contribution to be made to the discussion in order to assist the different actors that are going to be affected by this decision.

Benzyl butyl phthalate (BBP) – Following the introduction by ECHA on the comments received, a member stated that fish tests received recently show that there are some risks to the environment thus they were wondering whether the adequate control route also deals with the adequate control route for the environment.

ECHA explained that this substance was identified as SVHC and proposed for prioritisation for Annex XIV based on its reprotoxic intrinsic properties and that is the property that will be considered for authorisation. However, when a potential registrant is preparing its Chemical Safety Assessment (CSA) for its registration dossier, then risks to the environment should also be included.

Dibutyl phthalate (DBP) – ECHA explained that the comments received made ECHA aware of the uses of DBP in military, explosives, polypropylene and maleic anhydride. No major discussion followed.

A participant of the meeting informed the committee that the companies that will be affected by the inclusion of the three phthalates in the authorisation list will prepare their

joint application dossier. It was again observed that the comments received from the public consultation on the three phthalates are mostly from downstream users.

Substances proposed by ECHA not to be prioritised during the public consultation:

Anthracene – ECHA explained that some commenters wanted anthracene to be prioritised by ECHA based on synergistic or additive effects with other PAH substances. Also it was stated that workers' exposure has not been considered. To this comment a participant of the meeting presented to the Committee a different priority setting approach that resulted in another list of substances ranked according to a combination of chosen factors/ intrinsic properties. Some members of the committee welcomed the contribution and felt that this list could be of assistance in identifying substances of very high concern. On the other hand, another participant of the meeting stated that the additional list presented by the meeting participant might create confusion amongst companies. It was however, made clear by the observer presenting this prioritisation approach that the intention is to contribute to the discussion on the criteria used for priority setting and not to replace Annex XIV by their priority list.

A request was made by a member to discuss possible further development of ECHA's general priority setting approach considering the different proposals and contributions made so far in order to have a more advanced approach available when the preparation of the next recommendation will be started. The Chair then concluded this discussion by proposing to discuss further development of the prioritisation approach in the October meeting.

Bis(tributyltin) oxide (TBTO) – Some comments received during the public consultation requested prioritisation of TBTO because of its PBT properties. Other comments asked to consider cumulative effects of other organotin compounds. The Committee, however, did not have any issues to discuss on this substance.

Cobalt dichloride – For this substance similar comments on prioritisation, grouping and use as an analytical standard were received as for the majority of the other substances. However, there was a comment which stated that electrochemical use (electroplating) is an intermediate use, to which ECHA did not agree. ECHA explained in the RCOM as well as during the meeting that an intermediate is used to produce another substance, unlike in the case of electroplating, which is the end-use of a substance. On this issue one participant of the meeting asked for more dialogue since he wants to better comprehend ECHA's understanding of an intermediate.

Diarsenic trioxide – Some comments from MSCAs and NGOs asked for prioritising this substance because of its potential wide dispersive use. This needs to be further investigated. However, ECHA did not propose it for prioritisation since it can easily be replaced by another form of the substance with similar hazard profile (grouping approach).

Since during MSC-7 it was agreed that further information is needed for these substances on the exposure during the production of Murano glass, a member explained that they sent questionnaires and received detailed information from a research institute in Venice. This information was sent last week to ECHA. This is late for this round but will be useful for the future prioritisation.

Another member expressed disagreement with the fact that a substance is not prioritised because of the grouping approach.

Arsenic pentaoxide - No major discussion took place on this substance.

Lead Hydrogen Arsenate - No major discussion took place on this substance.

Triethyl arsenate - No major discussion took place on this substance.

Sodium dichromate - No major discussion took place on this substance.

The Chair concluded the discussion on the comments received on the fifteen substances currently on the candidate list and stated that the discussion would serve as basis for discussing the draft opinion.

c) Implications of the consultation outcome to the published draft recommendation and justification documents

It was concluded that there was no need to go through the justification documents for each substance since ECHA explained that these were developed by merging the two substance specific justification documents that had been subject to the public consultation. A meeting participant however stated that in the consultant's technical report for HBCDD on manufacture, import, export, uses, releases and alternatives, the human health assessment did not take into account the results of the risk assessment on antimony trioxide. Thus the information provided in the consultant's report is not the most recent information. This was as well made known to ECHA through a formal letter. However, even though ECHA agrees with this observation, ECHA does not intend to subject this report to revision but will, where relevant, take into account the toxicity data provided in the risk assessment report.

Item 8 - Opinion of the MSC on the draft recommendation of priority substances to be included in Annex XIV

a) Report on development of the MSC opinion on draft recommendation for Annex XIV - Reporting by the Rapporteur

The Rapporteur presented the draft opinion of the MSC focusing on the process of preparation of the opinion and on what was written in the draft Support Document.

b) Draft opinion

Following the presentation by the Rapporteur, the Chair opened the floor for discussion. Some first modifications were proposed on the text of the draft support document and agreed as a result of the discussion. Certain specific issues that were left open in discussions under agenda item 7 required further discussion for finding the final wording for the text of the support document and the opinion. These specific issues are listed below:

HBCDD

Following a presentation from the Rapporteur on the opinion of the MSC, six members expressed their concerns. They believe that regarding HBCDD, actions taken under Title VIII of the REACH Regulation would constitute a more appropriate way to control the risk posed by HBCDD from textiles. Their position is annexed to these minutes in the form of a declaration (see Annex V). In addition, one other member, who was not present at the meeting, had sent a written position paper expressing concerns similar to those indicated in the declaration. The opinion of this member is however not represented in the declaration since he was not present at the meeting and had not given a proxy to any other member. The message sent by the member was read out and the position paper of this member was distributed to the participants as a Room Document.

The concerns on HBCDD raised by the six members and reflected in the attached declaration are however related to other issues than those which can be considered for the prioritisation step of the procedure to include substances in Annex XIV on the basis of Article 58(3).

The Rapporteur summarised the issue by stating that since HBCDD is building up in our society and eventually is being emitted, the recycling rate should be close to 100%, so as to avoid significant emission from this stock in our society. When looking at the prioritisation criteria of Article 58(3) and the prioritisation approach presented in the background document it is obvious that these are met. With regards to the request for an exemption for the use of HBCDD in extruded polystyrene (EPS), there appears not to be specific legislation to allow for such an exemption. Even though there may be benefits from the use of the substance, the socio-economic benefits of the continued use are not addressed at this stage but at a later stage.

The Chair and the Rapporteur explained that subjecting a substance to the Authorisation requirement does not impose a ban on the substance. It merely results in the obligation to apply for an authorisation to use a substance. Uses for which an authorisation is granted can continue.

ECHA then explained that for Article 58 (2) of REACH to be applied, existing Community legislation has to address the specific uses for which an exemption from Authorisation is being requested. This legislation has to specifically set minimum requirements ensuring proper control of risks for these uses.

The Chair concluded that the MSC has to look at sound scientific arguments and not political arguments and consider the arguments that are relevant for this specific step in the authorisation process. It was also pointed out that HBCDD fulfils the three prioritisation criteria- PBT, high volumes and wide dispersive use, since no sound evidence was presented against these criteria. On the latter it was agreed that because according to the information available, the releases to the environment at the waste phase are estimated to be significant compared to those releases at other stages of the life-cycle of the substance, it makes HBCDD not only wide spread but also wide dispersive. There is no ground to go for an exemption since there is no specific legislation in place.

It was therefore agreed that this discussion will be documented in the minutes and that together with the MSC opinion, to which the six members agreed not to oppose, ECHA will provide the European Commission with the declaration of the six members as well as a copy of an extract of the minutes of the present MSC meeting addressing this specific topic.

Exemption for artists' paints

The Rapporteur explained that the draft MSC opinion presented for discussion states that the use of MDA and the three phthalates should not be exempted for use in artists' paints. It was concluded that the majority of the members agreed to this conclusion, however the support document to the MSC opinion would as well need to be re-phrased to highlight the concern of the MSC about the relationship between the restriction process (Title VIII and Annex XVII of the REACH Regulation) and the Authorisation process.

SCCPs

For SCCPs, following the discussions that took place at the meeting, the MSC was not able to provide its opinion on the proposal by ECHA to exempt from the authorisation requirement the placing on the market of SCCPs in mixtures in a concentration at or lower than 1% by weight for use in metalworking and in fat liquoring of leather. An opinion on this issue would need further legal analysis. Anyway, some members of the MSC made clear that it does not believe that uses of substances that are explicitly permitted under specific conditions set out in Annex XVII should automatically be exempted from the authorisation requirement.

Further, the preparation of an Annex XV dossier for MCCPs by the Commission/ECHA or a Member State was considered an important next step in the control of SCCP emissions and ECHA was therefore asked to invite the relevant parties to take action.

The support document to the MSC opinion was re-phrased in order to reflect the opinion of the members of the MSC expressed during the discussion. The support document with the agreed modifications was adopted by consensus.

c) Adoption of the MSC opinion

The MSC supported ECHA's proposal on the seven substances and items specified for each substance to be included in Annex XIV as proposed by ECHA but the Committee was not in agreement with ECHA on exemptions proposed for MDA, DEHP, DBP and BBP in artists' paints. For SCCPs, the MSC could not provide its opinion on the proposed exemption for the reasons given above. The draft opinion was adopted by consensus. The extract of the minutes with the declaration on HBCDD of seven members will be submitted to the Commission together with the MSC opinion.

d) Documentation of the MSC opinion and publication of documents

The Chair explained that the two documents i.e., the MSC opinion and the Support Document will be sent to the Commission together with the final recommendation and the supporting documentation by ECHA. They will also be published on the website of ECHA on the MSC page as soon as possible after the meeting when the secretariat has had the time to carry out the editorial checking.

A question was raised on the format of the recommendation, i.e., if it will keep the form presented at the meeting or if it will be changed. The Chair explained that the format of the recommendation will be amended in line with the advices received from the legal experts. In accordance with the REACH Regulation, ECHA will take into account the opinion of the MSC.

The Secretariat promised to make available to the MSC members all documents related to ECHA's recommendation that will be sent to the Commission, including a copy of the cover letter to the recommendation signed by the Executive Director of ECHA.

It was also agreed that the declaration as part of the minutes can be published by the secretariat on ECHA's website with indications of the countries of the members supporting it.

2) Revision of the Working Procedures for the MSC in providing the opinion on the recommendation of priority substances

ECHA Secretariat introduced the revisions made to the working procedures. Preliminary comments were invited by the Chair during the meeting. Further comments will be invited in writing within two to three weeks from the meeting. These comments will then be compiled and an agreement will be sought via written procedure either in the beginning or the end of the summer.

Item 9 - Draft working procedure of the MSC for processing draft decisions from the evaluation work

- **Draft working procedures for the MSC for compliance check and testing proposal draft decisions**

This item was post-poned due to time constraints due to the long discussions that accompanied agenda items 7 and 8.

The Chair introduced this agenda item in this meeting and informed that the secretariat will ask for written comments on the documents. It was explained that the draft working procedure modified on the basis of written comments will be addressed in the October meeting and then possibly adopted.

Item 10 - Planning of the work for 2009

a) Update of the work plan based on Registry of Intentions and any information from the ongoing compliance checks and testing proposals

The Chair introduced this agenda item by stating that no new intentions for SVHC have been notified to the registry of intentions since February 2009. There are 12 substances for which the intended submission date is 3rd August 2009. An extract of the registry of intentions was provided as a room document. The Chair then asked if any other intentions of SVHC Annex XV are known to the members. A member stated that they have the intention of submitting two additional dossiers by 3rd August.

Then ECHA delivered a presentation on the progress of the evaluation work. This explained that from the beginning of May the evaluation unit is divided into two units that are doing the same evaluation work, but work on different dossiers. The three finalised dossiers that were compliance checked were considered complete so no decision from the MSC was needed. No testing proposal evaluation can be started before the dossier has passed the technical completeness check. The deadline for the first testing proposal deci-

sion is 8 August and it may be discussed in the October meeting if the draft decision will be commented by MSCA's. The deadline for other testing proposals received until now is June 2016 but evaluation work on them will commence immediately.

The Chair concluded that the MSC will get a maximum of three compliance check draft decisions and three testing proposals in 2009.

b) Revised meeting calendar for 2009

The Chair explained that the dates shown in the revised meeting calendar have been chosen based on the schedule of the submission of dossiers of SVHC and tried to fit in the evaluation decisions. The 27-29 October meeting will be mainly for the draft decisions of the evaluation dossiers, but also to try and identify any such Annex XV dossiers on which agreement could be sought via written procedure for SVHC.

The working procedures for evaluation dossiers will be discussed in October if these cannot be adopted in written procedure during the summer.

The review of the Rules of Procedure of the Committee will also be carried out in the October meeting. An inquiry will be sent to the members of the Committee to highlight items to be discussed for the review.

The main point of discussion for the 2-4 December meeting is the identification of SVHC to be included in the candidate list and the seeking of agreement on the proposals.

Item 11 - CLP Regulation

- **Presentation on the CLP Regulation - framework and classification of relevance to the MSC**

This item was post-poned to the next meeting due to lack of time.

Item 12 – Feedback from ECHA

Feedback from MB

ECHA informed the Committee on new additions to the list of stakeholders considered eligible by Management Board. Four new organisations were added to the list. This was done on the basis of results of the open call of expression of interest for organisations to register. The new list will be uploaded to ECHA's website.

Based on the amended list and the agreement made already in the MSC-2 meeting, MSC will review the situation of the representation of stakeholder organisations on the MSC meetings in MSC-9 (27-29 October 2009).

Evaluation workshop

The Chair informed the Committee that the evaluation workshop is planned for 22-23 September for MS representatives only. Pre-announcement invitation would be sent out as early as possible and ECHA would re-imburse two representatives per Member State. The Chair promised to send the pre-announcement invitation also to the MSC but then participation should be decided by the Member State Competent Authority.

Item 13 – AOB

ECHA Secretariat presented the draft press release to the Committee for comments from the members. The ECHA Secretariat promised to consider their comments when finalising the text.

Item 14 – Adoption of conclusions and action points

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

II List of attendees

Members
BÖHLER, Elmar (DE)
COSGRAVE Majella (IE)
DEIM Szilvia (HU)
DUNAUSKIENE Lina (LT)
FAJFAR, Simona (SI)
FLODSTRÖM Sten (SE)
GEUSS Erik (CZ)
HEISKANEN Jaana (FI)
KORENROMP René (NL)
KYPRIANIDOU-LEONTIDOU Tasoula (CY)
LUDBORZS Arnis (LV)
LULEVA, Parvoleta (BG)
MAJKA Jerzy (PL)
MARTIN Esther (ES)
MIHALCEA-UDREA Mariana (RO)
MOREAU Emmanuel (FR)
PISTOLESE Pietro (IT)
REIERSON Linda (NO)
ROGGEMAN Maarten (BE)
STESSEL Helmut (AT)
TYLE Henrik (DK)
VESKIMÄE Enda (EE)
WELFRING Joëlle (LU)

Representatives of the Commission
VAN DER JAGT Katinka (DG ENTR)
VAN DER ZANDT Peter (DG ENV)
Observers
ANNYS Ervyn - CEFIC
DMYTRASZ Bohdan – CONCAWE
HAIAMA Nadia – GREENPEACE
IMPERATORI Cecilia - UEAPME
LEENAERS Joeri - EUROMETAUX
MUSU Tony - ETUC
REINEKE Ninja - WWF
ECHA staff
AJAO Charmaine
BALOGH Attila
BROERE William
DE BRUIJN Jack
KARHU Elina
KNIGHT Derek
KORJUS Pia
LEPPER Peter
LEFÈVRE Rémi
MALM Jukka
NAUR Liina
POPESCU Raluca
RUOSS Jurgen
SANDBERG Eva
SUNDQUIST Anna-Liisa
URIONABARRENETXEA Ainara
VAHTERISTO Liisa
YLÄ-MONONEN Leena

Replacements
NORTHAGE Christine replacing FAIRHURST Steve (UK).
CEU NUNES do Maria replacing CARMO PALMA do Maria (PT).

Proxy's
KYPRIANIDOU-LEODIDOU, Tasoula (CY), also acting as proxy of ANGELOPOULOU, Ioanna (EL)
MARTIN Esther (ES), also acting as proxy of CARMO PALMA do Maria (PT)
COSGRAVE Majella (IE), also acting as proxy of FAIRHURST Steve (UK)

Experts and advisers to MSC members

ARTUS, Hannela (expert to VESKIMÄE Enda)
BALCIUNIENE, Jurgita (expert to DUNAUSKIENE Lina)
BIWER, Arno (expert to WELFRING, Joëlle)
HUUSKONEN Hannele (adviser to HEISKANEN Jaana)
KOZMIKOVA, Jana (expert to GEUSS, Erik)
LAGRIFFOUL, Arnaud (adviser to MOREAU, Emmanuel)
LEONELLO, Attias (expert to PISTOLESE, Pietro)
LUNDBERGH, Ivar (expert to FLODSTRÖM, Sten).
PECZKOWSKA, Beata (expert to MAJKA, Jerzy)
RÁCZ, Éva (expert to DEIM, Szilvia)
SCIMONELLI, Luigia (adviser to PISTOLESE, Pietro)
TRAAS, Theo (adviser to KORENROMP, René)

Apologies:

Ioanna ANGELOPOULO (EL)
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III Final agenda

18 May, 2009
ECHA/MSC-8/2009/A/08

Adopted Agenda

Eighth meeting of the Member State Committee

18 - 20 May 2009
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

18 May**: starts at 15:00**
20 May**: ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/08/2009
For adoption

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

Item 4 – Adoption of draft minutes of the MSC-7

MSC/M/07/2009/
For adoption

Item 5 – Administrative Issues

For information

Item 6 – MSCAs' and MSC's access to confidential data - Data security issues

Reporting on the development and current status of ECHA's data security policy

For information

Item 7 – (Updated) draft recommendation for inclusion of priority substances in Annex XIV

a) Reporting on the consultation outcome on

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

b) Responses of ECHA to the comments received

c) Implications of the consultation outcome to the published draft recommendation and justification documents

ECHA/MSC-8/2009/019-051

For information and discussion

Item 8 – Opinion of the MSC on the draft recommendation of priority substances to be included in Annex XIV

1) a) Report on development of the MSC opinion on draft recommendation for Annex XIV - Reporting by the Rapporteur

b) Draft opinion

c) Adoption of the MSC opinion

d) Documentation of the MSC opinion and publication of documents

ECHA/MSC-8/2009/015 and 052

2) Revision of the Working Procedures for the MSC in providing the opinion on the recommendation of priority substances

ECHA/MSC-8/2009/016

For discussion and adoption

Item 9 – Draft working procedure of the MSC for processing draft decisions from the evaluation work

- Draft working procedures for the MSC for compliance check and testing proposal draft decisions

ECHA/MSC-8/2009/017 and 018

For information and discussion

Item 10 – Planning of the work for 2009

a) Update of the work plan based on Registry of Intentions and any information from the ongoing compliance checks and testing proposals

b) Revised meeting calendar for 2009

ECHA/MSC-8/2009/014

For information

Item 11 – CLP Regulation

- Presentation on the CLP Regulation - framework and classification of relevance to the MSC

For information

Item 12 – Feedback from ECHA

For information

Item 13 – AOB

For information

Item 14 – Adoption of conclusions and action points

- Table with action points and decisions from MSC-8

For adoption

IV Main conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
MSC-8, 18-20th May 2009
(Adopted at the MSC-8 meeting)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting
3. Declarations of conflicts of interest to items on the Agenda	No conflict of interest was declared.	
4. Adoption of draft minutes of the MSC-7	Draft minutes of MSC-7 were adopted with the proposed modifications received during the written commenting period and the meeting.	MSC-S to place the minutes of MSC-7 on CIRCA and the ECHA website after the meeting.
5. Administrative issues Feedback of meeting participants on the use and functionality of the travel booking system Declaration of confidentiality Annual declarations on conflicts of interest and annual declaration of commitment.	Feedback was appreciated by MSC-S.	MSC-S to continuously improve the quality of the booking system in cooperation with the service provider. Meeting participants attending to an MSC meeting for the first time are requested to give their declaration of confidentiality to MSC-S during the meeting. MSC members not having yet submitted their declarations requested to provide them to the MSC-S during the meeting.
6. **MSCA's and MSC's access to confidential data - Data security issues**	Recent discussions on data security policy in ECHA and MB have implications on the MSC members' access to confidential data so that MSC rules for the use of CIRCA have to be changed. More secure tools to provide confidential information to MSC members will be developed by ECHA.	From the MSC-8 meeting onwards, ECHA will delete from CIRCA all documents containing confidential information after every MSC meeting. As long as CIRCA will be used, all experts and advisers using the MSC CIRCA Interest group will have to provide their declaration of confidentiality to the MSC-S.

7. **(Updated) draft recommendation for inclusion of priority substances in Annex XIV** **a)** Reporting on the consultation outcome on -Priority setting for inclusion of substances for Annex XIV -Draft Recommendation and Draft Annex XIV entries for prioritised substances **b)** Responses of ECHA to the comments received	ECHA's rationale for responses to comments was generally supported**.** <u>MDA, DEHP, BBP, DBP</u> ECHA shares the concerns of MSC regarding the exemption from authorisation of the consumer use of these substances in artistic paints. It is a legislative issue, if exemptions from currently existing restrictions should automatically be carried over into the authorisation process. <u>SCCP</u> Some members raised their concerns about the proposed exemptions from authorisation. RCOMs of substances not mentioned above were generally supported by the members. General prioritisation approaches were discussed for the future recommendations.	ECHA will address this issue in the recommendation which will be sent to the COM. Suggestions for changes to ECHA's prioritisation approach will be put on the agenda of the MSC-9 meeting (27-29 October 2009).
8. Opinion of the MSC on the draft recommendation of priority substances to be included in Annex XIV **8.1** a) Report on develop-	The rapporteur with assistance of the working group met the tight deadlines set	

ment of the MSC opinion on draft recommendation for Annex XIV - Reporting by the Rapporteur b) Draft opinion c) Adoption of the MSC opinion	for the preparation of the draft opinion. <u>HBCDD</u> Prioritisation has to be based on the fulfilment of Article 58 (3) criteria supported by scientific arguments. The substance fulfils all Art. 58(3) criteria. There is no existing specific Community legislation in force allowing for exemption on the basis of Art. 58(2). Economic considerations, e.g. impact on SMEs, can not be taken into account in the process of prioritisation. These issues shall be considered in the process of granting the authorisation. <u>MDA, DEHP, BBP, DBP</u> Exemption from authorisation for use in artists' paints was not supported by MSC and deletion of this exemption from the draft recommendation was proposed. <u>SCCP</u> MSC was not able to define its opinion on SCCPs with regard to the proposal by ECHA to exempt from the authorisation requirement the placing on the market of SCCPs in mixtures in a concentration at or lower than 1% by weight for use in metalworking and in flat liquoring of leather. An opinion on this issue for SCCP would need further legal analysis.	Declaration prepared by some MSC members reflecting their concerns as regards prioritisation of HBCDD will be attached to the minutes of the meeting by MSC-S and submitted to the COM by ECHA.

d) Documentation of the MSC opinion and publication of documents **8.2** Revision of the Working Procedures for the MSC in providing the opinion on the recommendation of priority substances	MSC agreed on and adopted the opinion of the MSC (with the support document) on the draft recommendation of substances for inclusion in Annex XIV, with the changes proposed by meeting participants during the meeting. MSC greatly appreciated the work of the rapporteur and the working group. The document was briefly discussed and preliminary comments were collected.	The opinion of MSC with the support document and the extract of the minutes of this meeting with the declaration of MSC members on HBCDD, and the recommendation and its supporting documents will be submitted by ECHA to COM by 1 June 2009. MSC-S will make the final recommendation with the accompanying documentation available to the MSC. A written commenting round and afterwards a written procedure for adoption of the Working Procedures will be launched by MSC-S after the MSC-8 meeting.
9. Draft working procedure of the MSC for processing draft decisions from the evaluation work Draft working procedures for the MSC for compliance check and testing proposal draft decisions	Agenda item was postponed to MSC-9	A written commenting round will be launched by MSC-S after the MSC-8 meeting.
10. Planning of the work for 2009 **a)** Update of the work plan based on Registry of Intentions and any information from the	Since February 2009, no new notifications have been received by ECHA. The current Registry of Intention	

ongoing compliance checks and testing proposals	(RoI) contains 12 substances with a latest submission date of 3 August 2009. As for Annex XV dossier for SVHC identification, the identification process will be started according to the adopted working procedures and Rules of Procedures of MSC on all dossiers received by 3rd August 2009. More than ten dossiers are expected to be submitted. Regarding draft decisions from the dossier evaluation process, maximum three draft decisions both on testing proposal and compliance check will be referred to the MSC this year.	
b) Revised meeting calendar for 2009	The tentative meeting dates of MSC for 2009 are the following: MSC-9: 27-29 October MSC-10: 2-4 December In MSC-9 in October, the main focus of discussion will be the draft decisions. Also working procedures of MSC for draft decisions will be discussed. RoP of MSC needs to be reviewed. Annex XV dossiers for identification of SVHCs received by 3rd August will undergo a first discussion. The decision which substances can be dealt with via written procedure will be taken.	Inquiry for relevant questions to be discussed on the review of the RoP in the MSC-9 meeting will be sent out by MSC-S after the MSC-8 meeting.

	For MSC-10 in December, SVHC identification will be the main discussion point.	
11. CLP Regulation Presentation on the CLP Regulation - framework and classification of relevance to the MSC	Agenda item postponed to MSC-9	
12. Feedback from ECHA	Outcome of the MB meeting was recognised by the members: four new stakeholder organisations have been added to the list of eligible stakeholder organisations. New list will be uploaded to ECHA's website.	Based on the amended list, MSC will review the situation of the representation of stakeholder organisations on the MSC meetings in MSC-9 (27-29 October 2009).
13. AOB Workshop on dossier and substance evaluation Adoption of the minutes of MSC-8	The workshop on dossier and substance evaluation will be organised by ECHA on 22-23 September 2009. Only member state representatives will be invited. Pre-announcement for the workshop will be sent soon to the Member States, two representatives per MS will be reimbursed.	MSC-8 meeting minutes to be adopted via written procedure.
14. Adoption of conclusions and action points		All presentations and room documents as well as the Conclusions and action points to be uploaded on Circa (MSC-S/by 26/05/09).

V Declaration

Declaration
submitted by members of the Member State Committee from
the Czech Republic, Italy, Lithuania, Poland, Portugal and Slovenia
on prioritisation of HBCDD for inclusion in Annex XIV

Members of the MSC from the Czech Republic, Italy, Lithuania, Poland, Portugal, and Slovenia, recognizing that HBCDD meets at least two criteria for prioritisation of the three enlisted in Article 58(2) of REACH Regulation, in the spirit of fruitful co-operation, do not object prioritisation by ECHA of HBCDD for inclusion in Annex XIV, however, they believe that regarding this substance, actions taken under Title VIII of REACH Regulation would constitute more appropriate way to control the risk posed by HBCDD. At the 8th meeting of the Member States Committee these members of MSC raised their concerns, in particular indicating the following issues:

The majority of HBCDD is used in production of insulation panels/boards made of EPS and XPS, used in the construction works. EPS is also used in automotive industry (chairs), as packaging materials, in refrigerators and as boards used in advertisement. Minor volumes of HBCDD (about 10%?) are used for production of HIPS. Currently the use of HBCDD as a flame retardant for textiles is sharply diminishing and now seems to be small in comparison with other uses.

However, the release pattern is the opposite. Some amount of HBCDD is released during its production, during production of EPS, XPS, HIPS and polymer dispersion for textiles, as well as during production of articles from these kinds of polystyrene. Even smaller amounts of HBCDD may be released during construction works, when EPS or XPS is used (e.g. due to cutting of styrofoam plates). Although no adequate data is available, it may be expected that the release of HBCDD from construction panels/boards may be neglected. HBCDD is embedded in polystyrene. Articles made of EPS and XPS after their life cycle undergo recycling, incineration or are land filled. Taking into account the very long half life of these articles, much longer than it was expected when the XPS and EPS panels/boards were placed on the market for the first time, HBCDD release during the decay of the polystyrene wastes will be so slow that in situ degradation should occur and accumulation in the environment is highly improbable. Therefore such HBCDD release may also be neglected.

On the other hand, the large amounts of HBCDD are released from textiles coated with polymer dispersion containing HBCDD. Such textiles seems to be the major source of HBCDD found in the environment, even in remote areas. With such pattern of HBCDD release into the environment, only the minority of the use of HBCDD in the EU may be defined as the wide dispersive use. The vast majority of HBCDD use should be considered as “widespread”, but not as “wide dispersive”. It seems also obvious that with such pattern of HBCDD release into the environment, the restrictions for some uses of HBCDD should be much more appropriate than authorisation.

What is even more important, the application of authorization procedure in this case may be contrary to the objectives of REACH Regulation, as stipulated in the Article 1(1), both to a high level of protection of the environment and to enhancing competitiveness and innovation. The properties of insulation boards made of EPS and XPS make them also

difficult to substitute with other isolation materials. Therefore, it may be expected that the production of such boards will be removed from the EU and relocated to the closest EU neighboring countries, from where it will be exported to the EU. Considering the high standards of the protection of the environment in the EU it may be expected that in case of relocation of the production outside the EU, apart from negative consequences for the EU economy, the significant increase of the release of HBCDD to the environment in the global scale will be another negative result.

Having considered the above deliberations, especially the objectives of the REACH Regulation, as stipulated in the Article 1, the 6 members of the Member States Committee believe that the proper measure to limit the risk caused by HBCDD is to introduce a complete ban on using HBCDD in textiles, as well as to introduce measures that will limit the release of HBCDD to the environment in other uses, provided for in the environment law.

Some of the above mentioned members of the MSC raised also other concerns:

The use of HBCDD as a flame retardant in EPS and XPS insulation is very important in view of the fact that no suitable alternative to it exists as yet. EPS and XPS insulation for thermal insulation saves energy and also reduces CO_2 emissions. The positive benefit of HBCDD flame retardant for the environment is far greater than its negative environmental impact. HBCDD is contained as an additive in the structure of EPS and XPS boards (in an amount of less than 1% by mass), and in view of the nature of the substance it does not change and it is hardly released if at all from the boards when used.

The EU has an action plan for sustainable consumption and production and sustainable industrial policy - the foundation is an improvement in the energy and environmental performance of products and support for their use on the part of consumers. This approach will include products which could significantly reduce environmental impacts, for example reduce emissions to the environment. In the context of cross measures, some governments are implementing programmes for the thermal insulation of buildings. The implementation of such programmes will lead to a reduction in energy and CO_2 emissions. Without the broad use of EPS and XPS with flame retardant, these programmes, and in particular the target indicators up to the year 2020, are at serious risk.

The introduction of authorisation for the use of HBCDD as a flame retardant in materials made of polystyrene in insulation will in consequence endanger the production of insulation panels in hundreds of small enterprises across Europe, what goes against the intention of the European Union to save energy and reduce emissions to the environment. At the same time this puts manufacturers of these materials from EU Member States at a disadvantage compared with manufacturers from third countries to which the duty to apply for permission will not relate.

Article 58(2) of the REACH Regulation provides that certain use may be exempt from authorisation providing **the risk is properly controlled** on the basis of existing specific Community legislation imposing the minimum requirements relating to the protection of human health or the environment**.** Commission Regulation (EC) No 642/2005 and Commission Regulation (EC) No 2592/2001, imposing testing and information requirements on the importers or manufacturers of certain priority substances in accordance with Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of exist-

ing substances, **still apply**. In both regulations HBCDD is given for reasons of submitting further information and performing certain tests for the purposes of evaluating the risk to health and the environment. If necessary, a strategy is proposed for limiting these risks, including control mechanisms or supervision programmes, in compliance with these Commission Regulations. The possible alternative solution is thus the exemption of EPS and XPS insulation panels/boards from the authorisation regime.

Helsinki, 20th of May, 2009