



MSC/M/05/2010
Adopted at MSC-16 meeting on 1 February 2011

Final Minutes

Minutes of the 15th Meeting of the Member State Committee (MSC-15)
1-3 December 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 15th meeting of the Member State Committee (MSC).

For this 15th meeting, apologies were received from eight MSC members. Three of them had notified the Chair as to their proxy. Further proxies were then given during the meeting due to last minute changes in the flights of the members because of a Finnair strike (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 Secretariat (SECR) with the deletion of Item 11 – Report from other ECHA bodies and activities. The final Agenda is presented in Part III to these minutes.

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

No conflicts of interest were declared in respect to any Agenda point of the meeting. However, the Chair took the opportunity to raise for discussion with the participants an issue of concern not necessarily directly connected to the Agenda item under discussion.

She reminded everyone the objective of these meetings and that the Committees are of paramount importance in the implementation of REACH and to ensure ECHA is independent and transparent. Reminder of these values is among other things mentioned in the Work Program of ECHA just recently adopted by the Management Board. The organisation of the work of the MSC is such to respect these values. In fact, public consultations to the proposals made and response to comments are organised in a transparent way. The stakeholder observers can distribute comments to MSC by contacting SECR and request for their transmission and can be accompanied by one expert according to the code of conduct. The Chair reminded all participants that ECHA does not have a mandate of basing its work on policy considerations and that the committee participants need to base their discussions and agreements on scientific and technical arguments.

It was emphasised that when information is shared between parties outside the Committee, that information should be shared equally amongst all the members of the Committee for transparency's sake and for everyone in the Committee to have a common basis.

Following this reminder, the members explained that they have two hats, the hat as a member state representative and that as a MSC member. When they receive information from different stakeholders, they welcome such information, however,

they always receive it and reply to it as representatives of the member state competent authority and not as MSC members.

It was agreed that there is a need to further clarify on the ECHA website the MSC processes on SVHC identification and ECHA's draft recommendation. Further emphasis should be put on the procedures ensuring transparency and credibility of MSC processes like clarifying the importance to provide information via public consultations, to contact the MSC-S if additional documents or information is wanted to be distributed to MSC members and to avoid circulation of case related information directly to the MSC members. The objective is to ensure that all MSC members have the same information basis when making decisions.

Item 4 – Administrative issues

- Satisfaction survey

SECR reminded the members that such a survey was distributed during December 2009. This would be repeated by all the ECHA Committees soon after this meeting. The webropol link would be open until early January 2011. Responses to the survey will be appreciated by SECR as they would provide good basis to identify needs for improvement of performance of SECR.

- Renewal of memberships - oral status report

ECHA invited the Member States (MS) to renew their memberships in the ECHA Committees and Forum. Mostly all the MSs sent ECHA the appointments or renewal. The next invitation would be sent in June, since some members would have their membership expiring during the second half of 2011. Thereafter such invitations would be sent twice per year. Most of the MSC memberships would expire on 26 February 2011. 16 MSC members renewed their memberships, three are now new members (one already attended the MSC-15 meeting), two MSs did not respond yet whilst the eight remaining members would continue as per their membership until it expires. During this renewal process four more alternate appointments were received thus having a total of 16 alternates appointed. RAC and SEAC memberships would be decided in the Management Board meeting on 16 December 2010.

Item 5 - Draft minutes of the MSC-14

SECR explained that following the request for comments on the draft minutes no comments were received from the members but comments were received from the Commission (COM). Their comments were included and the amended minutes were provided to MSC on 19 November.

Minutes were adopted without changes in the meeting. They would be uploaded to CIRCA as per usual practice.

The action points from the MSC-14 meeting were referred to by SECR. All points had been covered by the agenda items of MSC-15 meeting.

One MSC member expressed a wish to have more detailed minutes reflecting better the scientific discussions. MSC-S promised to consider how the minutes could best incorporate the information related to the decision making at MSC.

Item 6 – Identification of SVHC

a) Reporting back on identification of SVHCs in written procedure

SECR shortly informed MSC of the outcome of the written procedure. Responses from 26 members with voting rights were received, all of which were in favour and none were against the proposed agreements. Also the Norwegian member responded positively. This response rate is well above the quorum of 60% i.e. 17 members. Two substances (2-methoxyethanol, 2-ethoxyethanol) were identified as SVHC in accordance with Article 57(c) owing to their classification as toxic for reproduction category 2 with unanimous agreement of the MSC members on 25 November 2010. Agreements and support documents of these two substances would be posted on the ECHA MSC webpage as well as the response to comments tables (RCOMs) prepared by the MSCAs who submitted the Annex XV proposals, indicating that they are MSCA documents.

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

The Chair explained that for each substance proposed to be identified as SVHC there are draft agreements (DAs), support documents (SDs) and response to comments tables (RCOMs) available. She also explained that SECR always prepares the DAs based on the assumption that the SVHC proposals of the Member State Competent Authorities (MSCAs) find agreement by the MSC. However, both DAs and SDs can be modified in the meeting. SECR has made some editorial formal changes in the SDs and included these also in the DAs in order to reflect the provisions of the new Classification, Labelling and Packaging (CLP) Regulation. From 1 December 2010 both old and new classifications need to be reported simultaneously until 2015.

Following this introduction, the representatives of the dossier submitting MSCAs presented their SVHC proposals for the following nine substances for agreement by the MSC during this meeting:

- **Chromium trioxide**
- **Acids generated from chromium trioxide and their oligomers**
- **1,3,5 Trichlorobenzene**
- **1,2,3 Trichlorobenzene**
- **1,2,4 Trichlorobenzene**
- **Cobalt (II) sulphate**

- **Cobalt (II) dinitrate**
- **Cobalt (II) carbonate**
- **Cobalt (di)acetate**

Summary of the discussion held per substance during the meeting:

- **Chromium trioxide**
- **Acids generated from chromium trioxide and their oligomers**

The representative of the German CA introduced the Annex XV proposals for chromium trioxide and acids generated from chromium trioxide and oligomers as well as the main comments and the responses of the German CA to these comments. Details can be found in the presentation, which has been made available to the meeting participants. The SVHC proposal was made to complete the set of chromium(VI) compounds already included in the candidate list. Numerous comments were provided during public consultation by the industry using these substances. Many comments repeated the same view that it would be unjustified to identify chromium trioxide as an SVHC. The comments stressed that risks were already assessed under the former Existing Chemicals Regulation (ESR) and no further actions would be needed. The German CA responded to the comments of the industry that under ESR the conclusion indicated risk, in particular, for workers. The harmonised classification as carcinogen (and mutagen) and the identified risk were the basis for making the proposal for identification of chromium trioxide as an SVHC. According to the German CA the authorisation process would be a proper tool to introduce further risk reduction measures, including considerations for substitution.

SECR complemented the presentation of the German CA representative by explaining that the acids generated from chromium trioxide and their oligomers are considered as a substance different from chromium trioxide. In fact both chromium trioxide, chromic acid and dichromic acid have different EC numbers. Chromic acid and its Oligomers might be regarded as a substance generated during end use of chromium trioxide and therefore exempted from the obligation to register. This is to reply to the comments received during the public consultation that acids are regarded as mixtures of chromium trioxide and water. SECR further explained that, however, chromic acids would be exempted from registration in accordance with Annex V(3) of REACH. ECHA did not receive any registration dossiers for chromic acids.

A member raised the concern that he received information from industry that there is almost no exposure from the chromate industry. However, the German CA representative explained that they have considered information from more than 2000 quite recent exposure measurements carried out by the German insurance organisation, Berufsgenossenschaft, that indicate high exposure. The trade union representative pointed out the recognised relationship between the chromium trioxide exposure and occupational diseases.

Another participant asked MSC to note that when the chromium trioxide goes to the next step of authorisation industry had some concerns that there are no proper alternatives for some critical uses.

It was noted by the Chair that at the SVHC identification step of the authorisation process information on exposures, uses or alternatives is not considered. Identification of SVHCs is taking place on the basis of hazard information and the criteria set out in Article 57. Information related to uses, exposures and alternatives as included in the Annex XV dossier or provided during public consultation will be considered in the later steps of the authorisation process.

Conclusion: The MSC unanimously agreed on 2 December 2010 that chromium trioxide and the acids generated from chromium trioxide and their oligomers meet the criteria of Article 57 (a) and (b) and Article 57 (a) respectively. Therefore, these substances are identified as SVHCs. Agreements and SDs for both substances were unanimously agreed after some minor modifications.

- **Cobalt (II) sulphate**
- **Cobalt (II) dinitrate**
- **Cobalt (II) carbonate**
- **Cobalt (di)acetate**

The representative of the Dutch CA introduced the Annex XV proposals, the main comments and the responses of the Dutch CA to the comments. The details can be found in the presentation, which has been made available to the meeting participants. The rationale why the dossiers were proposed are the classification of these cobalt-substances and the results of the RMO analysis carried out before making the proposal. It was also considered important to complete the candidate list with further cobalt substances that are similar to cobalt dichloride, which had already been placed on the candidate list earlier, in order to allow for a group approach to manage the risk of these cobalt substances together. This rationale was questioned by many comments from industry that were in most cases considering the current uses of the cobalt salts as intermediate uses, which is contrary to the understanding of intermediate uses by the competent authorities and ECHA as explained in the document agreed upon by CARACAL and published on ECHA website. The Dutch CA considered that the Annex XV dossiers of the cobalt salts do not demonstrate unacceptable risk because that is not required in the SVHC identification process or for subjection of substances to authorisation. More information will become available to be able to assess the risk when the substances have been placed on the candidate list.

A member said that the four substances would not meet the criteria for the future Annex XIV because it seems that there is a low volume for non-intermediate uses. Also the grouping approach cannot be used since the salts are used in very different processes and there are no alternatives. It would have been useful to get more information on real uses of these substances. Thus when proposing substances for inclusion in the candidate list it should be with a view to be prioritised to Annex XIV in the future and not just to be listed in the candidate list.

The Chair however reminded the MSC that at the current stage of the process the issue is not prioritising substances for Annex XIV but to consider whether they fulfil one or more of the criteria set out in Article 57. When a proposal is made to identify a substance as SVHC the MSC cannot start considering whether the proposal should

have been made or not. This should have been done by the submitting MSCA as part of their Risk Management Option (RMO) analysis.

Conclusion: MSC unanimously agreed on 2 December 2010 that the four cobalt substances meet the criteria of Art 57(a) and (c), and therefore these substances are identified as SVHC. The agreed SDs and Agreements will be posted on ECHA website as well as the RCOMs, which had been developed by the Dutch CA.

- **1,3,5 Trichlorobenzene**
- **1,2,3 Trichlorobenzene**
- **1,2,4 Trichlorobenzene**

The Chair explained that this is the first time that MSC receives Annex XV proposals for substances that are proposed to meet the criteria of Article 57 (f) for PBT-like substances. Thus, it was necessary to consider whether there is enough scientific evidence to conclude as such. The Annex XV dossier/report needs to demonstrate on the basis of a scientifically solid argumentation supported by relevant data that there is scientific evidence of probable serious effects to human health or the environment which gives rise to an equivalent level of concern to those of other substances listed under Article 57 (a)-(e). The scientific argumentation needs to be fully documented and the case discussed using a weight of evidence approach and expert judgement. The importance of assessing all available information properly was emphasised by the Chair because the conclusion in this first case will always be seen as a precedent. It was noted by one member that the concern of making a precedent should not be overestimated because each case has to be assessed separately.

The representative of the German CA introduced the Annex XV proposals for the trichlorobenzenes as well as the main comments and the responses of the German CA to these comments. Details can be found in the presentation, which has been made available to the meeting participants. The rationale why the dossiers were proposed are the PBT like properties of the substances. Trichlorobenzenes are considered to be persistent, fulfilling the criterion of Annex XIII. The substances show bioaccumulation and ecotoxicity, though not fulfilling the respective criteria of Annex XIII. Furthermore, trichlorobenzenes have a very high potential for long-range transport. Some comments questioned the bioaccumulative properties of the trichlorobenzenes; as a response, the respective section in the dossier was reworked and a field study on bioaccumulation was included. Some comments stated that the justification for the “equivalent concern” was not adequate; the German CA responded by giving a more detailed discussion on the issue.

In the discussion it was recognised that identification of SVHCs under Article 57 (f) does not require that a substance fulfils the criteria of Annex XIII. However, as the trichlorobenzenes were suggested to be “PBT-like” substances, it was deemed necessary to consider which of the available information would justify a conclusion that the substances either meet the PBT-criteria or are only close to meeting the criteria. It was indicated that when the PBT or vPvB criteria are not met there should be some supplementary information available that in a weight of evidence approach would suffice to justify using Article 57 (f) as the identification basis. Therefore the discussion focused on the kind of supplementary data and information that would

allow a conclusion that the criteria of Article 57 (f) are met. It was a common understanding in the meeting, that the three isomers of trichlorobenzenes (TCBs) do not fulfil the toxicity criterion (T) of Annex XIII but they would meet e.g. the classification criteria as dangerous for the environment. In this context, the information on the long range transport potential (LRTP) of the trichlorobenzene isomers was discussed.

An expert assisting one MSC member delivered a presentation on their position regarding these three substances (Room Document 52). The presentation has been made available to the meeting participants through CIRCA. He indicated that the available studies on 1,3,5-trichlorobenzene (1,3,5-TCB) show that after lipid normalisation the BCF is well below 2000 and hence the substances do not meet the B criterion. Moreover, as many of the studies referred to in the SVHC proposals are not considered reliable they should not be used as justification for the proposal. In addition, studies on biomagnification found in the literature reveal no signs of biomagnification of 1,3,5-TCB. Support was expressed by some members to this view.

A MSC member asked whether there is any monitoring data available showing that the substance can be found in the environment or biota in remote areas. It was mentioned that these substances are listed as priority substances under the Water Framework Directive and therefore monitoring data should be available.

The submitter CA explained that there are not many monitoring studies for TCBs in remote areas available. However, the models used to assess long range transport potential and presented in the support document are considered reliable. Two different modelling approaches were used, and both resulted in the same conclusion that TCB has a high LRTP.

A different MSC member agreed with the conclusion of the submitting CA that the substance has a high LRTP. He also argued that lack of measured data should not prevent from concluding on the LRTP of the substances.

However, another MSC member stated that without dispersive use of the substances, LRTP as such is not an issue.

Doubts were expressed by several members whether, on the basis of the available information, TCBs are good candidates to be identified under Article 57 (f) as they would remain very borderline cases for which the evidence of properties giving rise to an equivalent level of concern than PBT substances is vague.

A stakeholder representative expressed concern that with a negative decision the MSC would establish a very high level of burden of proof concerning the information needed to put a substance on the candidate list under 57 f: Trichlorobenzenes are persistent compounds with significant bioaccumulation potential as well as chronic aquatic toxicity; they have long range transport potential and have been found in wildlife in remote regions.

An explanation was given by SECR why Article 57 (f) specifically mentions PBT-like substances. The text of Article 57 (f) was agreed in the political process of REACH decision making to be able to ensure that substances having PBT properties can be identified on the basis of scientific arguments in a weight of evidence approach using

expert judgment. The original proposal made by the regulator presented criteria to be analysed to check whether the substance accumulates in higher mammals. However during the negotiations this was reduced to accumulation in fish which are based on strict numerical values that do not allow such considerations. So then Article 57 (f) was introduced to reflect the accumulation in higher mammals and compensate for the lack of flexibility given by the strict criteria of Annex XIII. The current assessment approach of Annex XIII are being revised. When the revised Annex XIII criteria taking into account the above mentioned arguments and introducing more flexibility as well as the use of the weight of evidence will enter into force it may not be necessary to use any more Article 57(f) for identifying PBT-like substances.

Conclusion of the first discussion: Following this discussion the Chair concluded that there seemed to be doubts whether the substances would meet the criteria of Art 57(f), mainly because they are not T, they do not meet the criterion for B and may not even be close to meeting the criteria according to the present way of assessing bioaccumulation. The data on biomagnification seems to be on studies that do not necessarily measure biomagnification. The substances are persistent and could be vP in sediments and soil. With regard to LRTP it was concluded that even though the substances do have a very high potential for being transported via the environment to remote areas, this was not enough to consider them as fulfilling art. 57 (f), when also taking their P-, B- and T-properties into account.

An ad-hoc group was set up to continue the discussion after closing the Plenary. The ad-hoc group was asked to report back to the Plenary.

Second discussion:

As result of the discussion in the ad-hoc group on 2 December 2010 it was proposed that agreement should be sought along the rationale that it is not possible to conclude on the basis of the available data whether the substance meets the criteria of Article 57 (f).

The MSC unanimously agreed on 3 December 2010 (at 11:15 -11:35 when quorum was confirmed to be present by the MSC-S when counting the proxies that were given by the members that had left the meeting as well as the alternates present) that it is currently not possible to conclude on the identification of the three isomers of Trichlorobenzene as substances of very high concern in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH). The agreements and the support documents were unanimously agreed upon based on the changes made during the meeting corresponding to the final conclusion.

It was also concluded that the trichlorobenzene isomers will not be included in the candidate list but the agreed documents will be published on the ECHA MSC website under heading 'other agreements', where the agreement and support document on cyclododecane is located.

The Chair and the members expressed their appreciation to the German CA for making the proposals available as they provided a good basis for discussion and greatly helped the Committee to understand better what evidence would be needed for identification of a PBT-like substance under Article 57 (f). There seemed also to be support for a proposal that it would be useful in the future to have a workshop where Article 57(f) could be discussed together with examples of the different types of

substances that could be identified under Article 57(f). The member from Germany informed MSC about the workshop that the German CA is organising in early December on endocrine disruptors where the criteria for these substances would be discussed. The Chair also asked for members to volunteer for organising this potential workshop on identification of a PBT-like substance under Article 57 (f). ECHA SECR would also consider this option. Another suggestion was to involve the RIMEDE group of CARACAL in discussions related to the Article 57(f) criteria.

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

- a) Responses of ECHA to the comments received in the public consultation on ECHA's draft recommendation and draft Annex XIV entries for prioritised substances**

- b) Introduction of changes in the draft recommendation and background documents following the consultation outcome**

SECR gave a presentation on the recommendation and the responses given to the comments received during the public consultation. ECHA indicated that even though additional information had been provided by industry to ECHA as part of the conclusions and action points of MSC-14 meeting, ECHA still maintained its opinion that the uses of arsenic trioxide in the glass industry and in Zn production are not uses of this substance as an intermediate. In the room document provided by ECHA it is indicated that arsenic trioxide in the glass production is considered as a processing agent. Following this, a stakeholder representative commented that the glass industry does however believe that in the information provided it was sufficiently explained that the arsenic trioxide added is not only functioning as a processing agent, as after the introduction of the As_2O_3 in the furnace it decomposes to Arsenic that is becoming an integral part of the glass.

With regard to the manufacture of zinc, the same stakeholder representative wanted to clarify the process a little bit further. He explained that the process starts with the complex zinc solution which however contains a range of other metals beside zinc. In order to use the natural resources to the extent possible arsenic trioxide is added to the solution of metals in order to separate the different metals by precipitation of as metal arsenates and to increase the concentration/purity of the zinc solution to maximise the efficiency of the electro refining process. The precipitated metal arsenates are further processed into the respective pure metals in other processes. Therefore, the use of arsenic trioxide in the electro-refining process of zinc is considered as intermediate by the industry.

The same stakeholder representative continued by stating that for the process of glass manufacture, arsenic trioxide is added under controlled conditions, observing all required safety measures. With regard to the Murano district situation, he stated that the situation has considerably improved in recent years. The occupational exposure levels to arsenic have been lowered to a level similar to that of the general public, as illustrated by the information provided to the MSC. As with regard to artisan glass manufacture only a low volume of diarsenic trioxide is used, therefore, the

prioritisation is questionable. It was also stated that industry welcomes the longer application dates of 18 months, since 12 months to apply for authorisation is very challenging to be met.

Following this intervention, the Chair, even though grateful for such information, highlighted that the MSC would have appreciated to receive this information during the public consultation, since it would be very difficult to analyse this information before the recommendation, as the MSC opinion on the recommendation needs to be finalised.

With regard to use of arsenic trioxide in the Murano district a member explained that, following a visit to this district, where he and colleagues from his institution met with staff of the Italian experimental station for glass, they understood that the experimental station's research on alternatives is in an advanced stage. However, more time is still required to fully understand the best of the alternatives in terms of safety and cost. They realised also that the main enterprises are working under strictly controlled conditions, however, the concern for small industry still remains. The same member remarked that the study demonstrating that exposure levels are decreasing, referred to by industry, has not yet been published.

A stakeholder representative asked the Commission representative present at the meeting whether the assumption made by ECHA on the entry into force of the second amendment of Annex XIV (i.e. January 2012) is correct. COM replied that this assumption is deemed to be correct since a twelve month period is needed for the final COM decision by comitology procedure.

Some questions were raised with regard to the application dates recommended by ECHA since for some substances 18 months after entry into force is recommended whilst for other substances the recommendation is 21 months. SECR explained that the recommended timing was chosen to comply on time with the guidance that should be conceded for preparing authorisation applications of good quality and to avoid overload of the Agency and its Committees with incoming authorisation applications in the time provided for.

The SECR also explained that so far there is no available overview of the registrations on the substances recommended for Annex XIV. With regard to planning for the next recommendation, the SECR explained that it is planned to start another recommendation process in 2011, provided there are enough suitable substances on the candidate list.

c) Opinion of the MSC on the draft recommendation of priority substances to be included in Annex XIV

1) Discussion on the draft opinion based on the (updated) draft recommendation of priority substances to be included in Annex XIV

2) Adoption of the MSC opinion

The Rapporteur presented the contents of the draft opinion to the MSC. In the discussion that followed the following main points were raised:

1. What is covered by the current EINECS number for 2,4-Dinitrotoluene.

A member raised the concern that since there are two different EC numbers for Dinitrotoluene, it would be interesting to know how these EC numbers relate to each other. One EC number is specific for “pure” 2,4-Dinitrotoluene (EC number 204-450-0; mono-constituent substance) whilst the other (EC number 246-836-1) is a generic entry for isomeric mixtures (reaction masses). To this the SECR prepared a very detailed reply in the form of a presentation. The SECR explained that 2,4-Dinitrotoluene, which is identified as a SVHC and now listed in the recommendation is the “pure” substance (mono-constituent substance) and according to the guidance for identification and naming of substances under REACH, its entry (EC number 204-450-0) covers substances that contain at least 80% of 2,4-Dinitrotoluene (the remaining 20% could consist of other Dinitrotoluene isomers or other constituents). The second substance (EC number 246-836-1) is a generic entry for isomeric mixtures (reaction masses) of dinitrotoluene for which the compositions might be variable or unknown. This EC entry might cover more than one substance in accordance with the guidance for identification and naming of substances under REACH. Industry is using this EC number for the technical grade of Dinitrotoluene that is composed of 70-80% of the isomer of 2,4-Dinitrotoluene, 20% of 2,6-Dinitrotoluene, and a small percentage of other isomers. This substance is regarded as a well-defined multi-constituent substance of the two main-constituents (main isomers), namely 2,4- and 2,6-Dinitrotoluene. This technical grade is used as intermediate in the synthesis of toluene di-isocyanate.

This multi-constituent substance however, is not covered by the entry (EC number 204-450-0) that is currently listed in the recommendation. This however should not be a point of concern since it appears that the technical grade dinitrotoluene is only used as an intermediate. In fact, registration data submitted so far for the technical grade of Dinitrotoluene refer only to uses as intermediate. So far, no registration dossier has been submitted for the mono-constituent 2,4-Dinitrotoluene.

It is not clear whether the technical grade substance can replace the mono-constituent 2,4-Dinitrotoluene in its uses. If such replacement was notified by updating the registration dossier of the technical grade, another Annex XV dossier covering the generic entry for the isomeric mixtures (reaction masses) of Dinitrotoluene could be developed.

The Chair concluded that since only EC number 204-450-0 is on the candidate list the mono-constituent 2,4-dinitrotoluene is the only substance that can be included in the recommendation of substances to be included in Annex XIV.

2. PPORD exemption

Due to the request received from one company, the Committee discussed exemptions from authorisation for PPORD uses of lead chromate pigments (C.I. Pigment Yellow 31 and C.I. Pigment Red 104).

As stated in the MSC opinion, MSC agrees with ECHA’s response to the request that PPORD exemption is not warranted in the specific case addressed during the public consultation.

In general, MSC is of the opinion that the impacts of exemptions for PPORD on human health and environment are difficult to address in this phase of preparation of a

recommendation for Annex XIV. The issue of inconsistency between the possibility of optional PPORD exemptions and the aims of authorisation formulated in Article 55 (that these substances are progressively replaced by suitable alternative substances or technologies) was discussed. MSC had the view that the conflicting objectives of the legislation to substitute a substance subject to authorisation and at the same time to allow the use of such substances for development of new uses are difficult to address. It was also noted that formulation of a PPORD exemption in such a way that it would be specific enough but applicable to all possible similar cases would be a challenge. A PPORD exemption to be included in the legislation cannot be addressed only to one company.

3. Route of authorisation/ application

Since in the first recommendation, as a footnote to some substances the route of authorisation was indicated, a discussion took place in MSC whether this information should be provided in the recommendation also this time. SECR explained that despite of that, it considered that as the COM had not included the route in Annex XIV (because it is not required by the legal text) it was not necessary to do so for this recommendation. Thus, ECHA decided not to include any information on the potential route of authorisation in the 2nd recommendation. It is clear that on the basis of the legislation (Art 60(3) and Art 60(4)) for PBT/vPvB substances only the “socio-economic route” could be chosen for granting authorisation. For the other SVHC substances (CMRs/ substances of equivalent concern) the possible route of authorisation depends on adequate control of risks. If an effect threshold (e.g. DNEL, NOEC) can be specified, normally the “adequate control route” (Art 60(2)) could be chosen for granting authorisation. However, also in case of substances with effect thresholds, if the applicant cannot prove that the risk is adequately controlled, the Commission may consider granting authorisation on the basis of the “socio-economic route”(Art 60(4)). If no effect threshold can be defined, granting of authorisation is only possible via the “socio-economic route” (Art 60(4)). Eventually, it may be the Risk Assessment Committee (RAC) who, taking account of the information on toxicity provided in the authorisation application by the applicant, would provide an opinion for the substance in question and effects threshold can be specified. However, the fact that there is a toxicological threshold alone does not mean that the authorisation can be granted by the Commission based on Article 60(2).

It was then overall agreed to remove any reference to the route of authorisation/application from the opinion since there is no such reference in the recommendation.

4. Whether to prioritise diarsenic trioxide and diarsenic pentaoxide

A MSC member explained that during the discussion in the working group, he had some reservations regarding the prioritisation of the diarsenic oxides since diarsenic trioxide is with regard to zinc production only used at two sites in the EU and is claimed to be used under strictly controlled conditions. Thus there appears to result no widespread exposure from this use. With regard to glass production, diarsenic trioxide appears to be normally used under strictly controlled conditions. In the Murano district relevant exposure to workers occurred but it seems that exposure significantly declined in recent years. He thus was wondering what was the relevant volume the

MSC should consider when prioritising these arsenic oxides. However, in the end the working group had agreed that there is not enough information available to decide that exposure to arsenic in the artisan glass industry is no relevant issue anymore and there was insufficient time to reopen the debate in the plenary meeting. The MSC thus agreed with the prioritisation of the arsenic oxides. Still, the issue of the relevant volume and the estimated exposure potential due to this volume is a general one and the member would like the MSC to reflect on this in the next prioritisation round.

Conclusion: MSC adopted unanimously its opinion on 3 December 2010 (at 10:05 when quorum was confirmed to be present by MSC-S when counting the proxies that were given by the members that had left the meeting as well as the alternates present) as provided for by the rapporteur and amended in some details in the current meeting. The MSC's favourable opinion was given on the draft second recommendation of ECHA published on 1 July 2010, and as updated on 19 November 2010, to include in Annex XIV the following substances:

- *Diisobutyl phthalate (DIBP)* (EC number 201-553-2)
- *Diarsenic trioxide* (EC number 215-481-4)
- *Diarsenic pentaoxide* (EC number 215-116-9)
- *Lead chromate* (EC number 231-846-0)
- *Lead sulfochromate yellow* (C.I. Pigment Yellow 34) (EC number 215-693-7)
- *Lead chromate molybdate sulfate red* (C.I. Pigment Red 104) (EC number 235-759-9)
- *Tris (2-chloroethyl) phosphate (TCEP)* (EC number 204-118-5)
- *2,4-dinitrotoluene (2,4-DNT)* (EC number 204-450-0)

Item 8 – Evaluation tasks

- a. **Exchange of views on the role of the MSC in the discussion of the criteria for prioritising the substances in substance evaluation**
 - o **Reporting back on MSCA written comments on prioritisation criteria for substance evaluation (*closed session*)**

The SECR gave a presentation on the written comments received on prioritisation criteria for substance evaluation (a proposal for criteria was discussed previously in the October 2010 workshop). The presentation explaining the comments and the way forward has been circulated to the MSC members and their experts.

SECR explained that the real work would start when the chemical safety report (CSR) would be opened to screen if the substance fulfils the criteria. Many MSs in their comments said that known CMR or PBT properties are not as important as the suspected ones.

With regards to access to the IT databases by the MSs, SECR explained that ECHA discussed the access to data several times in the workshop and CARACAL. ECHA appreciates that access to data is needed for MSs to do their work, thus SECR is working on ways how to give access to such data. On ECHA's website there is already the list of substances that have been registered (3400 phase-in substances). There is also a list of those substances that were intended to be registered. ECHA

checked this list with the registrations and placed the information of whether ECHA received a full registration dossier for such substances or a dossier for an intermediate. SECR looked at how many dossiers for CMRs were received. A total of 380 substances listed on Annex VI of CLP were registered. ECHA looked at the self classification by industry and at how many R50/53 substances were registered. Such information would be sent to MSs.

b. Status report on ongoing evaluation work

○ **Statistics**

SECR gave an overview on the situation of the dossier evaluation work in ECHA. Details of this work are available on the Evaluation CIRCA. The presentation has been made available to the meeting participants. The members showed concerns about the high numbers of the draft decisions predicted for the future. It was noted that 66 dossier evaluations were assigned to the DEGs in November. SECR explained that this would mean that the draft decisions would be sent to the registrant in May or June 2011, so the MSCAs will receive them only after summer.

COM requested for a cumulative number of substances that are evaluated and not only a cumulative number of dossiers. To this the SECR explained that the number of substances is almost the same as the number of dossiers evaluated since not many joint submissions have been looked at yet.

There was also a question on the communication policy launched by ECHA in CARACAL. SECR explained that during the last CARACAL meeting at the end of October 2010, it asked for MSs to volunteer for a pilot project to test the suggested policy. One outcome of the pilot would be to identify what level of detail would be necessary to communicate to MSs during the decision making process. ECHA would evaluate what can be most optimally provided to MSs.

○ **Benchmark case on use of read across**

SECR presented a read across case that was accepted by ECHA and for which MSCAs did not propose amendments to ECHA's draft decision. The presentation has been made available to the meeting participants. It was presented to MSC since the final decision was sent to the registrant without coming to the MSC. SECR had included in the RCOM the strengths and weaknesses analysis to show MSCAs the considerations made for the draft decision. This approach reflects the different views of also the ECHA experts that was hoped to be helpful also for the MS experts for coming to a conclusion what the justified content of the draft decision should be.

It was mentioned by one member that some MSCAs may not have prioritised this draft decision for commenting. One should therefore be cautious with drawing general conclusions. However, SECR approach to make an analysis of strengths and drawbacks was appreciated.

c. Reporting on ECHA observations in organising open sessions for discussing draft evaluation decisions

The Chair introduced this item by explaining that the Rules of Procedure (RoPs) and working procedures introduce the presence of stakeholders during the initial discussion of draft evaluation decisions, while respecting the confidentiality rules. It was requested at the Management Board meeting that confidentiality claims should be validated and only then conclusion made whether an open or closed session on a draft dossier evaluation decision would be held. Therefore MSC should revisit the working procedure on dossier evaluation to take this into account. As according to the RoPs and working procedures all confidentiality rules (not only the claims under Article 119(2)) need to be respected ECHA should therefore, check all of them to be able to decide whether MSC should have an open session or not. SECR checked the 8 draft decisions that potentially could be addressed in the February MSC meeting. SECR has checked the contents of the draft decisions against the provisions of Article 118, Article 119(1) and Article 119(2). The aim of this agenda point was to reflect with the MSC on the legal basis the MSC should look at. In fact the SECR in their presentation (presentation has been made available to the meeting participants) showed the MSC that it is quite a complex exercise especially since in this round there are a lot of former or unfinished notified new substances (NONs) for which ECHA has not information available on the confidentiality claims made under the old legislation. SECR has come to a conclusion that in these cases SECR will ask the registrant whether he/she can accept the presence of the stakeholder observers at the meeting during the initial discussion.

A stakeholder representative asked if there can be discussions without mentioning the use of the substance, especially since Article 118 (2) of REACH refers to the word 'normally'. The Chair explained that if the exact precise use is mentioned in the draft decision then such use may be very critical in the discussion. Also, even if the legal text uses the word 'normally', still the SECR prefers to take a conservative approach.

Item 9 – Manual of Decision (MoD)

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

Based on the discussions at MSC-14 and on the comments received from the members in writing, two topics out of the four proposed in the MSC-14 were maintained. The two items are the following:

1. Clarity in proposals for amendment that the registrant can comment on and the consequent draft decisions in the dossier evaluation process
2. Requests to registrant in the draft decision to update the CSR in the registration dossier

The MSC agreed on 3 December 2010 on the inclusion of these two items in the MoD following some slight editorial changes.

Item 10 – Update on provisional work plan for MSC

- **Provisional meeting dates of MSC for 2011**

SECR presented the workplan for 2011 and highlighted that the schedule for recommendation is still provisional. A member noted that the workload for the MSC for 2011 is going to increase so other ways how to organise these meetings need to be thought of. A suggestion was to include more video conferencing. The Chair welcomed proposals of the members how to improve the efficiency of the MSC work.

Item 11 – Any other business

- **Suggestions from members**

Some members made new proposals for the manual of decisions to which in turn the Chair asked them to send them in writing. Others asked whether the comments made by MSCAs on draft decisions were actually sent to the registrant. SECR replied that only the proposals for amendment were sent to the registrant, however, this would be further confirmed internally. SECR promised to come back to this issue in the coming meetings.

The conclusions of the UBA workshop on current topics of PBT/vPvB assessment under REACH held in Germany on 03-05 Nov 2010 were presented. The presentation has been made available to the meeting participants. It was agreed that once the minutes of this workshop are finalised, they would also be made available to the MSC.

Item 12 – Conclusions and Action Points

The conclusions and action points of the meeting (in Annex IV) could not be adopted during the meeting, since at that time of the meeting, no quorum was available any more. It was thus agreed that they would be adopted in the February 2011 MSC meeting together with the MSC-15 minutes.

Signed

Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

<u>Members</u>	<u>Observers</u>
COSGRAVE Majella (IE) (on 2 – 3 December)	ANNYS, Erwyn - CEFIC
DEIM, Szilvia (HU) (on 1-2 December)	LEENAERS, Joeri - EUROMETAUX
DOUGHERTY, Gary (UK) (on 1-3 December until 10:53)	MUSU, Tony – ETUC
DUNAUSKIENE, Lina (LT)	REINEKE Ninja - WWF
FINDENEGG Helene (DE)	
FLODSTRÖM, Sten (SE)	<u>ECHA staff</u>
HEISKANEN, Jaana (FI) (on 1-2 December)	AJAO, Charmaine
KORENROMP, René (NL)	BALOGH, Attila
KYPRIANIDOU-LEONITIDOU Tasoula (CY) (on 1 December)	BRAUNSCHWEILER, Hannu
LUDBORZS Arnis (LV) (on 1 and 2 December)	BROERE, William
LULEVA, Parvoleta (BG)	CARLON, Claudio
MAJKA Jerzy (PL)	DE BRUIJN Jack
MARTIN, Esther (ES) (on 2 – 3 December)	DE COEN, Wim
MIHALCEA-UDREA, Mariana (RO)	FEDTKE, Norbert
REIERSON, Linda (NO)	GRADZKA, Agnieszka
RUSNAK, Peter (SK)	KOJO Anneli
STESSEL, Helmut (AT)	KORJUS Pia
TYLE, Henrik (DK)	KOULOUMPOS, Vasileios
VANDERSTEEN, Kelly (BE)	KREBS Bernhard
VESKIMÄE, Enda (EE)	LEPPER Peter
	MÜLLER, Birgit
<u>Alternate</u>	NAUR, Liina
ATTIAS, Leonello (IT)	RÖCKE, Timo
BIWER Arno (LU)	RODRIGUEZ IGLESIAS Pilar
TALASNIEMI Petteri (FI) on 3 December	RUOSS, Jurgen
<u>Representatives of the Commission</u>	SUNDQUIST, Anna-Liisa
Sylvain BINTEIN (DG ENV)	TISSIER, ChrysteLe
HANSEN Bjorn (DG ENV) via webex on 2 December	VAHTERISTO, Liisa
KOBE Andrej (DG ENV) via webex on 2 December	
ROZWADOWSKI Jacek (DG ENTR)	YLÄ-MONONEN, Leena
<u>As dossier presenters:</u>	
FÖST Ulrich (DE)	
BÖHNHARDT Anna (DE)	
GOMEZ CONTRERAS Jeannette (NL)	

Proxy's

BIWER Arno (LU) also acting as proxy of DRUGEON, Sylvie (FR);

STESSEL, Helmut (AT) also acting as proxy of HUMAR-JURIC Tatjana (SI)

RUSNAK, Peter (SK) also acting as proxy of GEUSS Erik (CZ)

MARTIN, Esther (ES) also acting as proxy of PALMA Maria do Carmo Ramalho Figueira (PT) for the duration of the whole meeting; of ATTIAS, Leonello (IT) for 3 December.

COSGRAVE Majella (IE) also acting as proxy of DOUGHERTY, Gary (UK) on 3 December from 10:53 and of DEIM, Szilvia (HU) on 3 December.

VESKIMÄE, Enda (EE) also acting as proxy of LUDBORZS Arnis (LV) on 3 December.

Experts and advisers to MSC members

ANDERSSON Lars (expert to FLODSTRÖM, Sten)

ARTUS, Hannela (expert to VESKIMÄE, Enda)

BALCIUNIENE Jurgita (LT)

DE KNECHT Joop (adviser to KORENROMP, René)

KOZMIKOVA, Jana (expert to GEUSS, Erik)

MAURER Luc (expert to DRUGEON, Sylvie)

PECZKOWSKA Beata (expert to MAJKA Jerzy)

PEDERSEN Finn (expert to TYLE, Henrik)

RÁCZ, Éva (expert to DEIM, Szilvia)

TRAAS, Theo (expert to KORENROMP, René)

TALASNIEMI Petteri (adviser to HEISKANEN, Jaana) on 1-2 December

Apologies:

ANGELOPOULOU, Ioanna (EL)

CAMILLERI Tristan (MT)

DRUGEON, Sylvie (FR)

GEUSS Erik (CZ)

HUMAR-JURIC Tatjana (SI)

PALMA Maria do Carmo Ramalho Figueira (PT)

PISTOLESE Pietro (IT)

WELFRING, Joëlle (LU)

III Final agenda



Final Agenda

15th meeting of the Member State Committee

1-3 December 2010
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

1 December: **starts at 14:00**
3 December: **ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/015/2010

For adoption

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

Item 4 – Administrative issues

- Satisfaction survey
- Renewal of memberships - oral status report

Item 5 – Draft minutes of the MSC-14

- Adoption of draft minutes of MSC-14

MSC/M/04/2010

For adoption

Item 6 – Identification of SVHC

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

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

<i>Substance</i>	<i>EC number</i>	<i>Documents</i>
- Chromium trioxide	215-607-8	ECHA/MSC-15/2010/001-003
- Acids generated from chromium trioxide and their oligomers	231-801-5 & 236-881-5	ECHA/MSC-15/2010/004-006
- 1,3,5 Trichlorobenzene	203-608-6	ECHA/MSC-15/2010/019-021
- 1,2,3 Trichlorobenzene	201-757-1	ECHA/MSC-15/2010/022-024
- 1,2,4 Trichlorobenzene	204-428-0	ECHA/MSC-15/2010/025-027
- Cobalt (II) sulphate	233-334-2	ECHA/MSC-15/2010/007-009
- Cobalt (II) dinitrate	233-402-1	ECHA/MSC-15/2010/010-012
- Cobalt (II) carbonate	208-169-4	ECHA/MSC-15/2010/013-015
- Cobalt (di)acetate	200-755-8	ECHA/MSC-15/2010/016-018
- 2-Methoxyethanol*	203-713-7	
- 2-Ethoxyethanol*	203-804-1	

For discussion and agreement

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

a) Responses of ECHA to the comments received in the public consultation on ECHA's draft recommendation and draft Annex XIV entries for prioritised substances

* If concluded via written procedure, the substance will be removed from the draft agenda.

ECHA/MSC-15/2010/032-039
For members only: ECHA/MSC-15/2010/049
For information

- b) Introduction of changes in the draft recommendation and background documents following the consultation outcome

ECHA/MSC-15/2010/028
ECHA/MSC-15/2010/042-048
For information

- c) Opinion of the MSC on the draft recommendation of priority substances to be included in Annex XIV
- 1) Discussion on the draft opinion based on the (updated) draft recommendation of priority substances to be included in Annex XIV
 - 2) Adoption of the MSC opinion

ECHA/MSC-15/2010/029
For discussion and adoption

Item 8 – Evaluation tasks

- a. Exchange of views on the role of the MSC in the discussion of the criteria for prioritising the substances in substance evaluation
- Reporting back on MSCA written comments on prioritisation criteria for substance evaluation

For information & discussion

- b. Status report on ongoing evaluation work
- Statistics
 - Benchmark case on use of read across

For members only: ECHA/MSC-15/2010/041
For information

- c. Reporting on ECHA observations in organising open sessions for discussing draft evaluation decisions

For information

Item 9 – Manual of Decisions (MoD)

- Discussion on next new specific entries for the MoD

ECHA/MSC-15/2010/030
For discussion & decision

Item 10 – Update on provisional work plan for MSC

- Provisional meeting dates of MSC for 2011

For information

Item 11 – Any other business

- Suggestions from members

For information

Item 12 – Adoption of conclusions and action points

- Table with action points and decisions from MSC-15

For adoption

IV Main conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

MSC-15, 1-3 December 2010

(Adopted at the MSC-16 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
5. Draft minutes of MSC-14	
The minutes were adopted without further changes in the meeting.	MSC-S to upload the adopted minutes on MSC CIRCA and to publish them on ECHA website.
6. Identification of SVHC	
6a) Reporting back on identification of SVHC's in written procedure	
<p>The following two substances were identified as SVHCs in written procedure:</p> <ul style="list-style-type: none"> - <i>2-Methoxyethanol</i> (EC number 203-713-7) unanimously identified as SVHC (reprotoxic substance) because it fulfils the criteria of Art. 57 (c) of REACH Regulation. - <i>2-Ethoxyethanol</i> (EC number 203-804-1) unanimously identified as SVHC (reprotoxic substance) because it fulfils the criteria of Art. 57 (c) of REACH Regulation. 	MSC-S to upload the agreements and support documents (SD) on MSC CIRCA and the MSC section of the ECHA website after final editing. RCOM tables to be published on the MSC section of the ECHA website without any confidential information.
6b) Seeking agreement on Annex XV proposals for identification of SVHC	
<p>MSC agreed on the text of the SD and on that of the agreement as presented in the respective meeting documents and as amended in the meeting for the following substances:</p> <ul style="list-style-type: none"> - <i>Chromium trioxide</i> (EC number 215-607-8) unanimously identified as SVHC (carcinogenic and mutagenic substance) because it fulfils the criteria of Art. 57 (a) and (b) of REACH Regulation. - <i>Acids generated from chromium trioxide and their oligomers</i> (EC number 231-801-5 & 236-881-5) unanimously identified as SVHC (carcinogenic substance) because it fulfils the criteria of Art. 57 (a) of REACH Regulation. - <i>Cobalt (II) sulphate</i> (EC number 233-334-2) unanimously identified as SVHC (carcinogenic and reprotoxic substance) because it fulfils the criteria of Art. 57 (a) and (c) of REACH Regulation. - <i>Cobalt (II) dinitrate</i> (EC number 233-402-1) unanimously identified as SVHC (carcinogenic and reprotoxic substance) because it fulfils the criteria of Art. 57 (a) and 	SECR to upload the MSC agreements and SDs on MSC CIRCA and the MSC section of the ECHA website after final editing. RCOM tables to be published on the MSC section of the ECHA website without any confidential information.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
<p>(c) of REACH Regulation.</p> <p>- Cobalt (II) carbonate ((EC number 208-169-4) unanimously identified as SVHC (carcinogenic and reprotoxic substance) because it fulfils the criteria of Art. 57 (a) and (c) of REACH Regulation.</p> <p>- Cobalt (di)acetate (EC number 200-755-8) unanimously identified as SVHC (carcinogenic and reprotoxic substance) because it fulfils the criteria of Art. 57 (a) and (c) of REACH Regulation.</p> <p>Based on the information available in the support documents, the comments received and the discussions in MSC, MSC agreed that it cannot be concluded that trichlorobenzenes (1,3,5 Trichlorobenzene (EC number 203-608-6), 1,2,3 Trichlorobenzene (EC number 201-7571), 1,2,4 Trichlorobenzene (EC number 204-428-0)) should be considered as substances of very high concern in accordance with Article 57 (f).</p>	<p>SECR to upload the MSC agreements and SDs on MSC CIRCA and the MSC section of the ECHA website (<i>Other agreements of MSC</i>) after final editing. RCOM tables to be published on the MSC section of ECHA website without any confidential information.</p>
<p>7. (Updated) Draft recommendation for inclusion of priority substances in Annex XIV</p>	
<p>7c) Opinion of the MSC on the draft recommendation of priority substances to be included in Annex XIV</p>	
<p>MSC has adopted its opinion as provided for and amended in the current meeting on the draft second recommendation of ECHA published on 1 July 2010 and as updated on 19 November 2010, to include in Annex XIV the following substances:</p> <ul style="list-style-type: none"> - <i>Diisobutyl phthalate (DIBP)</i> (EC number 201-553-2) - <i>Diarsenic trioxide</i> (EC number 215-481-4) - <i>Diarsenic pentaoxide</i> (EC number 215-116-9) - <i>Lead chromate</i> (EC number 231-846-0) - <i>Lead sulfochromate yellow</i> (C.I. Pigment Yellow 34) (EC number 215-693-7) - <i>Lead chromate molybdate sulfate red</i> (C.I. Pigment Red 104) (EC number 235-759-9) - <i>Tris (2-chloroethyl) phosphate (TCEP)</i> (EC number 204-118-5) - <i>2,4-dinitrotoluene (2,4-DNT)</i> (EC number 204-450-0) 	<p>MSC-S to publish the final opinion of MSC on ECHA website. ECHA to take into account the opinion of MSC in the final recommendation.</p>

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
8. Evaluation tasks	
8a) Exchange of views on the role of the MSC in the discussion of the criteria for prioritising the substances in substance evaluation	
MSC took note of the report given by SECR.	SECR to present the refined draft prioritisation criteria at MSC-16 meeting. MSC-S to present the first draft working procedure on MSC involvement in CoRAP development. SECR to organise a workshop in May 2011 to agree upon the prioritisation criteria and their publication. SECR to provide MSCAs with compilation of data in a form of spreadsheets extracted from REACH-IT enabling them to make decisions for substance evaluation notifications.
8c) Reporting on ECHA observations in organising open sessions for discussing draft evaluation decisions	
MSC took note of the report given by SECR.	MSC-S to finalise the confidentiality analysis of the five dossier evaluation cases to be discussed in the MSC-16 meeting. MSC-S to invite stakeholders to the MSC-16 meeting based on the results of this analysis.
9. Manual of Decisions (MoD)	
MSC decided to include two entries as presented by MSC-S and amended in the meeting in the MoD of MSC.	MSC-S to include the two entries into the MoD of MSC. MSC to provide new proposals for the MoD.
13. Adoption of conclusions and action points	
The conclusions and action points were provisionally adopted.	MSC-S will upload the provisional conclusions and action points on MSC CIRCA together with the presentations delivered at the meeting, by 7 December 2010.