MSC/M/026/2012
ADOPTED at MSC-27

Minutes
of the 26th Meeting of the Member State Committee (MSC-26)
23-24 October 2012

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 26th meeting of the Member State Committee (MSC) (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 provided for the meeting by the MSC Secretariat with an inclusion under AOB from a stakeholder observer (final Agenda is attached to these minutes).

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

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

Item 4 - Administrative issues

- Handling of members' declarations of potential interests at ECHA

The Secretariat (SECR) updated the MSC on progress in ECHA on this specific issue of conflict of interest. It was explained that the policy for managing potential conflicts of interest aims at prevention of conflict of interest. The scope of the policy is broad and covers all the people involved in the work of ECHA. The possibility of a public perception of a conflict of interest is included in the policy so as to prevent suspicion to be raised in the media regarding independency of individuals and ECHA and to secure the trust of our stakeholders. Provisional guidelines on eligibility have been endorsed by the Management Board (MB) (MB/33/2012/D(1)) and provisional document on general principles and guidance for the Committee members is under consultation. The audits by the European court of Auditors scrutinised the policies on potential conflicts of interest and their implementation in four Agencies and published the report in the third week of October 2012. Several points were highlighted by the European Court of Auditors which ECHA has started to improve and is doing its best to follow. However, the collaboration of the committee members is needed for proper implementation of the policy. The MSC was also reminded on the guidance accompanying the annual declarations and listed the interests that need to be declared by the members of the Committees in relation to the field of activity of ECHA.

SECR also informed MSC that SECR is screening the annual declarations and CVs and is contacting the members when further clarification is needed. A member sends in a declaration before becoming member and then on an annual basis during the membership.

Following some interventions by some members, SECR explained that the policy refers to individuals as members of the Committees and not to states.

MSC recognised that it is very important when MSCA appoints a member and alternate to look at the provisional guideline for eligibility criteria and consider that the person can work in the Committee without having frequently an issue of potential conflict of interest that needs to be declared at the meeting.

The Chair concluded that measures to be taken as a consequence of declaring a conflict of interest would be a record in the minutes together with the decision by the Chair on whether a member is able to take part in the vote or else in the discussion depending on the case.

- **CIRCABC security**

SECR explained that there has been a misuse of information which is also available in one of ECHA CIRCBC interest groups. As a security measure thus all MSC users of CIRCABC are requested to reset their passwords as soon as possible to limit any misuse of information from CIRCA BC interest group sites. This should be continued at least twice a year as a standard practice. Further instructions on how to do this would be sent in an email after the meeting.

Item 5 – Adoption of the minutes of the MSC-25 meeting

SECR presented the revised version of the MSC-25 minutes informing MSC that written comments on the draft minutes were received by two MSC members prior to the MSC-25 meeting. Three representatives of three Registrants for three dossier evaluation cases who had participated in MSC-25 have been also consulted for the respective parts of the draft minutes. One provided comments which were included in the minutes. In conclusion, the minutes were adopted with no further changes carried out at the meeting. SECR would upload the minutes on MSC CIRCABC and ECHA website.

Item 6 – Dossier evaluation

a. Written procedure report on seeking agreement on draft decisions on dossier evaluation

SECR gave a report on the outcome of the written procedure (WP) for agreement seeking on 16 dossier evaluation cases (see Section V for more detailed identification of the cases). WP was launched on 26 September and closed on 8 October 2012. For one case, draft decision (DD) was split thus resulting in two DDs for these cases and overall 17 DDs for the 16 cases. By the closing dates, responses to WP were received from 23 members with voting rights and from the Norwegian member. Unanimous agreement was reached on 13 DDs. For three DDs out of these 13 DDs, one MSC member did not vote. For one DD WP was terminated by the MSC Chair on the basis of MSC member's request and it was referred to the MSC-26 meeting for agreement seeking. One MSC member did not vote on this DD. For three DDs involving the standard information requirement for Annex X, 8.7.3, four votes were indicating disagreement, 18 votes were in favour of them and two MSC members did not vote. Thus, these three cases are to be referred to COM for further decision-making under Article 133 (3) of REACH.

b. Introduction to and preliminary discussion on draft decisions on testing proposals after MS-CA reactions *(Session 1, tentatively open session)*

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

TPE-145/2012 Dicyclohexylamine (EC No. 202-980-7)

Session 1 (open)

A representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in the DD, an open session was held.

One proposal for amendment (PfA) suggested to correct the explanation why a mammalian spermatogonial chromosome aberration test is required. Another PfA suggested requiring the Registrant to perform the 90-day repeated dose toxicity (RDT) study via inhalation route as no inhalation study and local inhalation DNEL (derived no-effect level) is available yet for this corrosive substance. This PfA further argued that vapour pressure is not low enough to exclude exposure via

vapours or aerosols and the chemical safety report (CSR) also indicated relatively high air concentrations even with respiratory personal protective equipment (PPE). Two other PfAs suggested requesting an extended one generation reproductive toxicity study (EOGRTS) for Annex X, point 8.7.3 with cohort 2 and 3 (DNT (developmental neurotoxicity)/DIT (developmental immunotoxicity)) but without cohort 1B (production of F2 generation) instead of ECHA's proposal to perform the two-generation reproductive toxicity test (EU B.35). A further PfA suggested providing also the option of EOGRTS but excluding from the request the extension of cohort 1B. Another PfA proposed to correct the interpretations of observations on weight of testes and ovaries, and on gestation index. Furthermore, the PfA expressed the opinion that the two-generation reproductive toxicity test should be rejected as the effects observed in the 28-day study and screening study (OECD 421) are not sufficient to trigger a full reproductive toxicity study. However, if a generation study will be required, they suggest requesting EOGRTS without cohort 1B instead of giving also the option of the two-generation reproductive toxicity test (EU B.35).

ECHA Secretariat modified DD based on PfA concerning the mammalian spermatogonial chromosome aberration test and the interpretation of observations on weight of testes. ECHA Secretariat also split the DD into TPE-145A and TPE-145B where TPE-145A addresses the information requirement for Annex X, point 8.7.3 (two-generation reproductive toxicity) and TPE-145B addresses the information requirement for an *in vivo* mammalian spermatogonial chromosome aberration study, PNDT and 90-day RDT study. ECHA Secretariat also modified the deadlines to be given to the Registrant to submit the required information. The split DDs modified and updated with procedural steps were provided to MSC for finding unanimous agreement.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs informed that they will cancel the testing proposal for the 90-day RDT study and due to lower number of testing animals needed, will perform the two-generation test. [1]

The representative of Registrant in the meeting concerning 90-day RDT study explained that the air concentration of the substance as included in CSR (0,22 mg/m3) is without the use of PPE. He also stated that as exposure is well controlled (i.e. the substance is used mainly in industrial settings, workers are trained several times a year) there is no significant inhalation exposure. This is also confirmed by measured values that are well below DNEL. He pointed out that in the meantime they have updated the dossier and cancelled the testing proposal (TP) for the 90-day study based on the weight of evidence (WoE) approach.

Concerning the generation study (as well as the prenatal developmental (PNDT) study for which no PfA was received), he confirmed the Registrant's intention to perform the two-generation (and PNDT) study after the chromosome aberration test if the tests are still warranted.

In the discussion on the 90-day study, ECHA clarified that as the dossier update came only recently (i.e. after the start of the CA (competent authority) consultation), MSC cannot take this update into account. Furthermore, ECHA pointed out that there is no waiving possibility for a 90-day study based on the results of the chromosome aberration test as these are standard information requirements.

MSC members representing the MSCA that submitted PfA for the inhalation route in the 90-day study maintained the PfA and highlighted that currently no local DNEL can be derived and therefore the inhalation route is needed. Furthermore, concerning inhalation exposure, it was deduced from the CSR that the exposure

[1] The Registrant's assumption that two-generation study uses less animals is incorrect.

information in the registration dossier only relates to the manufacture of the substance and that it is highly likely that exposure scenarios for downstream uses in CSR indicate much higher exposure concentrations than the measured ones for manufacture. For the three professional uses as downstream uses there were no measured but only modelled data available. One MSC member asked about irritation effects of other secondary amines in the literature while another one questioned whether the possible aerosol formation at high temperatures by downstream users of metal working fluids was taken into account for the potential inhalation exposure.

The representative of the Registrant admitted that they had not received any exposure information from downstream users and the exposure information in the registration dossier relates to manufacture of the substance. However, as in downstream uses (i.e. in formulation processes) the concentration of the substance approximately 10 times lower than that in the manufacturing, the Registrant does not think that there is any inhalation exposure in downstream uses. Also he expressed his view that their experts took account of all available information in the literature on irritation effects of similar substances. He pointed out the difficulties to get information on exposures of downstream uses.

ECHA highlighted that the model used by the Registrant (ECETOC TRA) is not particularly suitable for modelling aerosol formation. However, some data published in the context of biocide evaluation suggest that although it is very difficult to measure inhalation exposure during use of metal working fluids it is suggested by ECHA experts that it might be reasonably low. In the discussion on a PfA on the triggers for a generation study, the MSC member representing the MSCA that submitted the PfA maintained their opinion that a change in ovarial and testis weights without any histopathological change would not trigger a generation study. In his view, reproductive effects if any would be shown in a 90-day study and at this stage no generation study would be needed.

One MSC member pointed out that REACH talks about indication of an adverse effect and the change of organ weight is indeed an indication (i.e. a trigger for the generation study). Other MSC members and ECHA (mentioning that the Registrant proposed the generation study) supported this view. ECHA also added that indications for an effect on the gestation index can only be confirmed in a generation study.

MSC further considered the links between the need for a generation study and the route of administration in the 90-day study. Oral route would give information on systemic effects and on the possible need for the generation study while due to the uncertainty on inhalation exposure a further inhalation study might also be needed.

Session 2 (closed)

The information from biocide evaluation was challenged by some members as it was not clear whether the substance was water soluble or dissolved in oil and therefore it was not possible to conclude on potential exposure at use of metal working fluid based on the argument of biocide evaluation. Neither the information on exposure at biocidal use was made available to MSC in advance of the meeting and was therefore difficult for the members to verify.

Concerning the route of administration in the 90-day study, one MSC member further highlighted that based on clearly positive results of two *in vivo* micronucleus studies, the substance is a potential carcinogen. As potential carcinogenic effects (e.g. hyperplasia) might be expected and the inhalation route would provide a reduced exposure concentration compared to the oral route, a study via the inhalation route therefore would not support proper evaluation of systemic effects. The oral route is more likely to indicate possible carcinogenic effects. Therefore, in his view the oral route should be preferred. Several MSC members supported this view. However, some members still had a concern on local effects by inhalation at the use of metal working fluids.

Based on the above discussions, MSC concluded for the DD TPE-145B/2012 to require the 90-day study via oral route (as proposed by the Registrant). MSC also agreed to indicate in section III of DD the remaining concerns for inhalation exposure and local effects in the respiratory tract and the need for the Registrant to address them in the dossier update. In case these concerns cannot be clarified by other means the Registrant should submit a TP for an appropriate RDT study by the inhalation route. For DD TPE-145A/2012, MSC concluded to remind the Registrant in section II that the generation study should be carried out only if the results of the spermatogonial chromosome aberration test and the 90-day study are available and accounted for and in section III that an indication for an effect on the gestation index can only be confirmed in a generation study.

MSC found unanimous agreement on ECHA's DD addressing an *in vivo* mammalian spermatogonial chromosome aberration study, PNDT and 90-day RDT study (TPE-145B/2012) as provided for the meeting and amended based on the above conclusions.

The Chair recognised the results of voting on DD (TPE-145A/2012) relating to TP for a two-generation reproductive toxicity study, as provided for the current meeting and amended based on the above conclusions. As MSC did not reach a unanimous agreement on DD at the vote, the Chair invited the disagreeing MSC members to provide written justifications for their disagreement if the justification were different to those provided for previous similar cases (otherwise SECR would use the justification provided in previous similar cases). ECHA will refer the case (TPE-145A/2012) to the European Commission (COM) which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

TPE-147/2012 Reaction mass of 2,6-Octadien-1-ol, 3,7-dimethyl-, (E) and 2,6-Octadien-1-ol, 3,7-dimethyl-, (Z)- (List No. 906-125-5)

Session 1 (open)

A representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in the draft decision (DD), an open session was held.

Three PfAs suggested requesting an EOGRTS study for Annex X, 8.7.3 instead of ECHA's proposal to give two options for the Registrant either to perform the two-generation reproductive toxicity test (EU B.35) or EOGRTS (OECD 443) with the second generation. A fourth PfA suggested keeping the two options but excluding from the optional request for EOGRTS the extension of cohort 1B (production of F2 generation).

One of the three PfAs, on the top of the proposal for EOGRTS, agreed with the Registrant that data on the same endpoint for the other main constituent of the registered substance geraniol (60%) should be awaited and EOGRTS should be carried out not with the registered substance but with its other main constituent nerol (40%). ECHA Secretariat did not modify DD for the MSC-26 based on PfAs.

ECHA Secretariat split DD into TPE-147A and TPE-147B where TPE-147A addresses the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity) and TPE-147B addresses the information requirement for the PNDT study. ECHA Secretariat modified the deadline to be given to the Registrant to submit the test results of the PNDT study (from 24 to 12 months). The split DDs modified (only TPE-147B) and updated with procedural steps were provided to MSC for finding unanimous agreement.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs reconfirmed his views expressed in the written comments on ECHA's DD earlier that he would like to conduct the OECD 443 study with Cohort 1A only on geraniol first. Based on these results and the results of all available data on nerol they would like to decide on whether or

not further testing (i.e. EOGRTS or two-generation study) on the registered substance (consisting of nerol and geraniol) is necessary. The Registrant agreed with the approach of PfA concerning testing on nerol and referred to the intention of another company to conduct an OECD 422 study (combined repeated dose toxicity study with the reproduction/developmental toxicity screening test) on nerol. According to the Registrant the other company is intending to register nerol by 31 May 2013. Furthermore, the Registrant generally agreed with the two options (EU B.35 and OECD 443) in DD but disagreed with the inclusion of cohort 1B (production of F2 animals), cohort 2 and 3 (DNT/DIT studies).

The representative of the Registrant in the meeting confirmed their intention to use test results on the constituents of the registered substance to fulfil the relevant information requirements. He also explained that a reproductive toxicity screening study with the registered substance showed equivocal reproductive effects at mid and high doses. These results should be clarified with the generation study on geraniol first. Based on the data of the generation study with geraniol (and all available data of nerol at that time), it could be decided whether the registered substance should be further tested or a sound classification decision can be made based on those data, i.e. the data from geraniol could be read-across to the registered substance. Replying to a question he also stated that assuming no combination effects of the constituents, testing of the registered substance would also be possible but testing of the registered substance with the two constituents (mixture) may not reveal the effects as the concentration of each of the constituents would not be high enough to produce the adverse effects.

ECHA pointed out that the Registrant's testing strategy explained in the comments in writing and in the meeting is not contained in the registration dossier. DD currently includes merely unspecified TPs with the registered substance for "toxicity to reproduction" and "developmental toxicity/teratogenicity" without specifying the substance to be tested or the test method to be used. However, DD needs to be based on the information in the registration dossier. ECHA also highlighted that the separate DD on the generation study with geraniol was referred to COM as MSC did not reach unanimous agreement on that DD. COM will take the decision in Comitology but the time scale for this decision making is unknown.
MSC acknowledged the Registrant's testing strategy proposed in the written comments and in the meeting. However, MSC also recognised the procedural constraints as stressed by ECHA above.

Session 2 (closed)

It was recognised that the constituent geraniol of the registered substance was proposed to be tested only in a two-generation study and no test for PNDT was proposed by the Registrant. It was also concluded that the DD cannot be based on a potential testing proposal of a substance (nerol) by another company in the future. MSC concluded that as there is considerable uncertainty on the availability of relevant test data on both constituents (nerol and geraniol) of the registered substance, the Registrant should be required to perform a generation study and a PNDT study on the registered substance unless TPs for these studies are submitted to ECHA for both individual constituents. MSC also concluded to remind the Registrant that classification based waiving of both tests with the registered substance on the basis of test data of the components (e.g. results of the generation study with geraniol) might be applied if adequately and reliably documented and justified in the dossier. MSC furthermore concluded to set the timeframe to 24 months from 12 months (due to splitting of the DD) to submit the information required from the PNDT study.

MSC found unanimous agreement on ECHA's DD addressing the TPs for a developmental toxicity/teratogenicity study (TPE-147B/2012) as provided for the meeting and amended based on the above conclusions.

The Chair recognised the results of voting on the DD (TPE-147A/2012) relating to TP for a toxicity to reproduction study, as provided for the current meeting and amended based on the above conclusions. As MSC did not reach a unanimous agreement on DD at the vote, the Chair invited the disagreeing MSC members to provide written justifications for their disagreement if the justification were different to those provided for previous similar cases (otherwise SECR would use the justification provided in previous similar cases). ECHA will refer the case (TPE-147A/2012) to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

TPE 161/2012 Sodium N-lauroylsarcosinate (EC No. 205-281-5)

Session 1 (open)

The Registrant had not indicated interest to participate in the initial discussion and did not express objection to the presence of stakeholder observers during these initial discussions.

A PfA proposed to modify Section II of DD indicating that there is a data gap concerning reproductive toxicity in the dossier for standard information in accordance with Annex X, 8.7.3.

ECHA Secretariat did not modify DD for MSC-26 meeting. The DDs updated with procedural steps was provided to MSC for finding unanimous agreement.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfA intended to take the results of the OECD 414 study into account when deciding on further testing. Furthermore, the Registrant asked for an extension of the time set to submit the required information from 12 to 24 months, based on the test house's time estimation for the required test.

ECHA pointed out that a prerequisite to consider positively such requests for extension of the deadline to submit the required information is to provide some evidence for the basis of the request which the Registrant did in this case. ECHA proposed that as more similar cases are likely to come in future ECHA would accept these requests when appropriately justified even if no related PfA is submitted.

Session 2 (closed)

After careful consideration of potential consequences MSC supported ECHA's proposed approach. MSC concluded that the time set to submit the required information should be changed from 12 to 24 months, as requested by the Registrant. MSC found unanimous agreement on ECHA's DD as provided for the meeting and amended based on the above conclusion.

TPE 148/2012 Tert-butyl perbenzoate (EC No. 210-382-2)

Session 2 (closed)

SECR explained that agreement seeking on this DD was sought in WP. However, WP was terminated by the Chair of MSC on request of a MSC member. The member suggested an editorial change deleting a sentence from section III of DD which would not affect the information requirement of the DD. MSC concluded to amend section III of DD accordingly.

MSC found unanimous agreement on ECHA's DD as provided for the current meeting and amended based on the above conclusion.

d. General topics

1. Status report on ongoing evaluation work including reporting from expert workshop held at ECHA on Read-Across Assessment

SECR gave a detailed statistics and update on the status of evaluation work until end of September 2012. MSC took note of the report. SECR also introduced the Combo approach that is currently being employed. This is when two different types of DDs are submitted to the Registrant at the same time: substance identity compliance check (sCCH) DD and TP DD with one cover letter explaining the scope of each DD and the requirement of the Registrant to resolve first the sCCH DD and secondly the TP DD.

With regards to the expert workshop held at ECHA on Read-Across Assessment, SECR explained the structure of the two day workshop and briefly listed some conclusions, mainly that the Read-Across Assessment Framework (RAAF) as currently developed is helpful for the assessment of read-across cases; general structure / approach is supported; the key aspects in general are fine, but have to be further improved; more key aspects might be necessary; dealing with uncertainty still needs to be refined; terminology and assumptions to be clarified; approach for highly complex cases is still to be prepared; this is still work in progress and an exchange of expert views with MSCAs is underway.

2. Preliminary outline of recommendations and conclusions from a technical meeting on scientific adequacy of *in vivo* mutagenic assays held at ECHA

MSC took note of ECHA's presentation. Replying to questions ECHA agreed that based on the final recommendations/conclusions ECHA needs to further consider their implications for an update of the relevant ECHA guidance. However, timing for this task can currently not be estimated. ECHA also mentioned that not only ECHA but also CARACAL has to be consulted on prioritisation of guidance updates. Several MSC members expressed the wish that ECHA would present the conclusions of the workshop at the next CARACAL meeting. COM stressed that the technical meeting only discussed scientific issues. However, for a well grounded decision on the potential guidance update COM considers that also other factors (e.g. costs, availability of CROs - contract research organisations) should be taken into account. ECHA expressed its view that in relation to the tests discussed in the technical meeting, case by case discussion is needed both for dossier and substance evaluation until a generic policy line based on the final conclusions/recommendations can be established.

The Chair concluded that more discussion would obviously be needed at an appropriate forum how to provide information to the companies on the preferred test guidelines for mutagenicity testing *in vivo*.

3. Study report from ECHA related to evaluation - Scientific Discussion Paper on terrestrial plant toxicity

SECR introduced the revised version of the terrestrial plant toxicity scientific paper that was prepared by SECR and which was distributed for MSCA consultation prior to MSC-26 meeting. It was explained that comments were received from two MSCAs. In the consultation process a teleconference was organised with MSCAs and later EFSA was also contacted. The paper was then revised and made available to MSC for discussion and possible endorsement.

The paper compares the OECD technical guideline (TG) 208 with the ISO standard 22030. The OECD TG provides for more species whilst the ISO provides for more endpoints. The OECD TG leaves the number of test species open on purpose. Thus the ECHA scientific discussion paper suggests that the number of species for OECD TG should be specified for long-term studies as a minimum of 6 species whilst for short-term studies as a minimum of 3 species. The paper suggests that for CCHs an existing OECD TG 208 with a minimum of 3 species can be accepted as a long-term test.

During the discussion some members requested for the scope, status and content of the paper to be clarified since it was not clear to them what MSC needed to endorse and whether the paper is to be used as a guidance, since usually creation of a guidance follows a different path. A stakeholder observer showed a wish to contribute for a more scientific evaluation of the conclusions of the paper with regards to metals.

It was explained that the aim of the paper was for the MSC to endorse the approach of considering OECD TG as a long term test and the number of species required for long term and short term studies. Based on the proposal from the Chair to further clarify what MSC was asked to endorse this would be further clarified in a brief paper to be presented in MSC-27 meeting expressing the conclusions of the scientific discussion paper. As some members felt a need to explore the scientific discussion paper further and consider possible comments on it, it was suggested that the comments were invited by 3 November if possible.

SECR also presented a proposal for improving consistency in the evaluation of terrestrial testing proposals. Comments on this proposal were invited. This proposal was provided also for consultation by MSCAs until 3rd November.

e. Appeal cases – update (*closed session*)

The Secretariat provided an update to the recent appeal cases on ECHA dossier evaluation decisions.

It was noted that MSC will be further informed on the Board of Appeal's rulings for these cases once they are concluded.

Item 7 – ECHA's draft recommendations of priority substances to be included in Annex XIV

a) Progress report after closure of the public consultation on ECHA's Draft 4th Recommendation, Draft RCOMs and Draft Annex XIV entries for prioritised substances

SECR provided a progress report after closure of the public consultation on the draft recommendation for Annex XIV. Comments on all substances had been received. For the presentation the comments were grouped to those of general nature and priority, other regulatory routes, transitional arrangements, exemption requests and review periods. SECR explained ECHA's draft responses to all the main comments received during the public consultation. It was reported that after assessing the impact of the comments, some updating of the information in the background documents of some substances would be carried out but no changes in the draft recommendation itself were currently foreseen as necessary.

During the discussion it was emphasised that data in the registration dossiers was a primary source of information used by ECHA for the prioritisation. SECR also emphasised that no exposure or risk assessment is carried out during the recommendation step of the authorisation process . Rather, assessment of the information is not to conclude if there is a risk or not but if there is potential for exposures and risk cannot be excluded. Due to the comments received some discussion took place whether it would be possible to consider if other regulatory processes (e.g. restriction) should be used for the risk management instead of authorisation. After the discussion it was concluded that prioritisation should take place in accordance with the legal criteria of Article 58(3) and follow the jointly agreed prioritisation approach. All substances on the candidate list are subject to prioritisation and may eventually go to the authorisation list. Thus any consideration on the most appropriate process for risk management should take place early on. Some participants also reminded during the discussion that the

aim of authorisation, namely substitution, should be kept clear in the minds when the most appropriate risk management options are considered.

Stakeholders raised the issue of the complexity of the authorisation process and wanted ECHA to provide better guidance on which type of information would be useful at which stage of the process. SECR agreed that such further guidance on the website would be useful and reassured that this is already under consideration.

b) Preparations for the opinion on ECHA's Draft 4th recommendation of priority substances to be included in Annex XIV - Report by the rapporteur and discussion of the first draft opinion, exchange of views on comments received

The rapporteur presented the draft opinion as provided to the meeting. The main issues as indicated by the rapporteur were thoroughly discussed. As already discussed in the context of the report from SECR, MSC discussed further how to consider comments of the public consultation suggesting use of other regulatory measures than authorisation, like restriction process. It was concluded that MSC could reflect such comments in the opinion by stating that no such (other) regulatory initiative is available and therefore the prioritisation process for authorisation has to take place. While going through the comments and the substances in the draft opinion MSC provided some further feedback to be taken into account by the rapporteur in finalisation of the draft opinion. For the four chromates MSC felt it would be necessary to know the outcome of the REACH Committee for the other chromates before the MSC opinion could actually be finalised. The modified draft opinion will be provided for adoption in the December meeting of the MSC.

Item 8 – SVHC identification - **Information about the progress on SVHC identification**

SECR presented a statistical overview of the comments received on the SVHC proposals in the recently completed public consultation. MSC was informed that due to the high number of comments received (840 in total) and the very short period between the end of the public consultation and the current plenary presentation, it was not yet possible to carry out analyses of the type and nature of the comments received.

A MSC observer from industry pointed out that it would be useful for the industry to get further guidance what kind of comments are expected at which step of the authorisation process. The industry stakeholders have understood by now that it is beneficial to provide comments in the context of identification of SVHCs on aspects which will be useful only later in the authorisation process, like for prioritisation of substances from the candidate list to the authorisation list. The observer representing industry requested for ECHA's feedback whether by delivering comments on this improved manner has been considered helpful. SECR confirmed that the industry stakeholders' way of working is correct and further guidance on providing comments in public consultations is under preparation and will be made available on the ECHA website.

Further, SECR reminded the members of the procedural steps with regard to the forthcoming MSC involvement and the outlined timeframe for the ongoing SVHC round.

Item 9 – Substance evaluation

a) CoRAP - Introduction of the draft CoRAP by ECHA and first exchange of views on the draft CoRAP

SECR in its presentation informed the meeting participants that the final draft CoRAP containing 116 substances (48 substances planned for 2013, 46 - for 2014 and 22 - for 2015) was submitted to MSC and MSs as preliminary envisaged. It was also explained that one substance originally listed in the first CoRAP published on 29 February 2012, was removed and three substances were post-poned to later years for evaluation. The public draft CoRAP version was published on the ECHA website on 23 October 2012, this time also indicating at this early stage the MS contact details and the source of the substance. Non-confidential versions of the substance-specific justification documents were provided to StOs for 2013, 2014 and 2015- year substances by the time of the meeting. These will once again be checked for confidential business information (CBI) before being published in March 2013 together with the final CoRAP annual update.

A preliminary overview on the initial concern is provided in the justification documents and justification for selection of the substance for the draft CoRAP. Furthermore it was explained that because some of the substances that are listed in the draft CoRAP could be grouped together due to structural similarities with common concerns, a grouping approach is being considered for the following CoRAP update (2014-2016). The full presentation was made available to MSC members and stakeholders on MSC CIRCABC.

During the discussion some members asked some clarifying questions. A StO showed appreciation for publishing the MS contact details at this early stage. Another StO asked about the potential outstanding issues related to the old Existing Substance Regulation (ESR) program. SECR explained that those substances from ESR having a pending decision were published in a separate list but they are still part of the published CoRAP. For practical reasons this list was kept separate from the running CoRAP.

The rapporteur of the working group (WG) for the MSC opinion on the first CoRAP update gave an overview of the work of the WG at that stage and asked MSC members to inform rapporteur and SECR by 5 November 2012 on whether there were any changes to the content of the justification documents for the substances that were already in the first CoRAP.

b) Substance evaluation process

1) Draft MSC working procedure for MSC to process draft decisions in substance evaluation

SECR presented the main differences between the substance evaluation (SEv) process and the dossier evaluation process and compared the working procedures for the MSC for dossier evaluation with the draft working procedure for substance evaluation under discussion at this meeting. The main difference in the latter is the number of Registrants and downstream users involved compared to the former. This is also reflected in the potential number of case owners that could be invited for Session 1 of the MSC meeting where the substance evaluation case is being discussed. The working procedures explain that normally SECR will invite one case owner representative on behalf of all the Registrants but this will be decided on a case by case basis. One member indicated that this could have a negative effect on information exchange if certain information is considered confidential business information (CBI). SECR agreed with this observation and explained that the wording in the working procedures is quite general so as to allow SECR to decide on a case by case basis.

Regarding the choice of the agreement seeking route by evaluating MSCAs (eMSCAs) for the substances they are evaluating, the members showed that they would prefer if eMSCAs decide in collaboration with MSC-SECR whether to go for agreement seeking in written procedure or in the meeting rather than on their

own. SECR explained that they are available to assist the eMSCAs as much as possible throughout the whole SEv process but the main responsibility should remain by the eMSCA. A member asked whether the MSC member or MSC alternate member can be the expert appointed by eMSCA to present the substance evaluation case in the MSC meeting. One MSC member considered that as MCS members are representing their MS and may be under instruction, there can be no conflict of interest between the members of the MSC and the eMSCA. To this SECR explained that this needs to be discussed internally in view of any potential conflict of interest. The outcome of such internal discussions would be reported to MSC in MSC-27.

MSC adopted the working procedure for MSC to process draft decisions in substance evaluation and asked members to send any editorial comments by 31 October 2012. The RCOM template that was part of the presentation as well as the presentation itself was made available to MSC members and stakeholders on MSC CIRCABC. The working procedures would also be published on the ECHA website after the minor change in MSC RoPs has been adopted recognising the option to invite case owners also for MSC discussions on the substance evaluation draft decisions.

2) Introduction to the time planning for the decision making process in substance evaluation

SECR presented the table listing the 2012 substances for substance evaluation asking the eMSCAs through their MSC member to indicate their future planning for their substances i.e their planned MSCA consultation start date in 2013 which will determine to which MSC meeting the case would go to for agreement seeking if PfAs are submitted by eMSCAs or ECHA. It was highlighted that the November 2013 and February 2014 MSC meetings are the preferred meetings for SECR planning of MSC work, since in the other MSC meetings, MSC will be much occupied with the other REACH processes. It was also clarified that any indicative plans listed in the table can be changed at any point of time since this is a living document.

3) Updates to registration dossiers during substance evaluation (SEv) ***(Closed session)***

SECR gave some information to the meeting participants on the aggregated data sets that were generated to assist the MSCAs, the reports on CoRAP substances, the dossier updates and IUCLID MSCA. During the presentation it was clarified that if the eMSCA requires a new aggregated data set, this can be provided by ECHA upon request. SECR can also assist the eMSCA by providing information on how to compare the updates submitted by Registrants which were listed in the reports to identify new relevant information for SEv. 124 new or updated dossiers have been submitted for 18 out of the 36 substances. MSC was also informed that a IUCLID database hosted by ECHA containing all registration dossiers is available to MSCAs since 25 June 2012. This provides easier and more secure access to registration information. An Authority User Manual is also made available to MSCAs since September to assist them with the technical aspects required for SEv.

SECR also explained that a leaflet to Registrants and downstream users (already mentioned in MSC-25) was at that time of the meeting, under translation. In this leaflet SECR strongly recommends to update the dossier if needed as early as possible but preferably before the start of SEv. It is clarified that an update of the registration dossier triggered only by the listing of a substance in CoRAP, is not a legal requirement. An emphasis was also put on planned testing, i.e. not to submit a TP for a substance that is under SEv, instead the Registrant should

clarify and discuss their data gap and potential dossier updates with the eMSCA. The leaflet also asks Registrants to indicate to eMSCA when a dossier is updated.

Following this, a member presented the updated paper on their proposal on how to deal with dossier updates with the aim to reach a common position in MSC. ECHA expressed some legal concerns regarding the approach presented in the document. Some members showed sympathy or support to the proposal. However, some members indicated difficulties to support the proposal as presented in the document and several members did not express their view. It was generally recognised that the document reflects a real practical problem which needs to be solved. However, it was also mentioned that the cases may differ from each other a lot and therefore it may not be optimal to specify one deadline for updates to be taken into consideration. As it was recognised that some further policy reflections on the proposed approach would be needed, MSC agreed that no conclusion could be taken on this topic at this MSC meeting and therefore CARACAL would be a better forum for such a discussion.

Item 10 – Manual of Decisions (MoD) - New item for inclusion in MoD of MSC

MSC agreed to include the proposed item in MoD of MSC without discussion.

Item 11 – Report from other ECHA bodies and activities
Report from MB on topics relevant to MSC

SECR briefly reported on key topics of MSC relevance from the last MB meeting held on 27-28 September 2012 in Bucharest, Romania. Some highlights provided for members' information are, as follows: the appointment of the Swedish MB member Nina Cromnier as a new MB Chairperson for next 2-year term of office, the adoption of a new Policy on managing potential Conflicts of Interest, the provisional adoption of the new eligibility criteria for the appointment of members in the ECHA Committees and other bodies, the adoption of the terms of reference and the mandate of the new Advisory Committee on managing conflicts of interest, the endorsed cooperation agreements with OSHA and EFSA, the discussion held on the involvements of stakeholder organisations and of case owners in the new procedures for authorisation applications.

Following a member's request, SECR will make available in MSC CIRCABC the new guidelines for eligibility for candidates for membership the Member State Committee after the meeting

Item 12 – Any other business

a. MSCA Workshop on the role and future of the Candidate List

A MSC member informed the Committee of his CA's intention to organise a workshop on the role and future of the Candidate List. The aim will be for MSCAs to discuss relevant policy-related issues. It was clarified that the workshop is preliminary scheduled for 6 and 7 November 2012 and the invitations will be sent to MSCAs shortly.

b. Report from the Workshop on read-across & grouping as used by the metals sector for REACH purposes held in Helsinki in October 2012

The MSC observer from EUROMETAUX provided MSC with a brief report from the workshop on the read-across & grouping as used by the metals sector for REACH purposes organised by Industry and held in Helsinki on 1 October 2012. It was explained that in the workshop, some key elements of the WoE approach with regard to metals and inorganic compounds have been considered and concrete examples were given to the participants.

The Committee was informed that the final report from the workshop, as well as other relevant documentation, will be further provided to the Secretariat and uploaded to MSC CIRCABC for members' information.

Item 13 – Adoption of conclusions and action points

MSC adopted the conclusions and action points of MSC-26 at the meeting (See Section IV).

Signed
Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
ATTIAS, Leonello (IT) (alternate member)
BIWER, Arno (LU)
CONWAY Louise (IE) (altenate member on 24.10.)
COSGRAVE, Majella (IE)
CRUZ, Ana Lúcia (PT)
DEIM, Szilvia (HU)
DOUGHERTY Gary (UK)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
HUMAR-JURIC, Tatjana (SI)
KORENROMP, Rene (NL)
KULHANKOVA, Pavlina(CZ)
LUDBORZS, Arnis (LV)
LULEVA, Parvoleta (BG)
MAJKA, Jerzy (PL) (alternate member)
MARTIN; Esther (ES)
MIHALCEA-UDREA, Mariana (RO)
PEDERSEN, Finn (DK) (alternate member)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI)
VANDERSTEEN, Kelly (BE)
Representatives of the Commission
BINTEIN, Sylvain (DG ENV)
GARCIA JOHN Enrique (DG ENTR)
Observers
ANNYS, Erwin (CEFIC)
BASTIJANIC-KOKIC Biserka (HR)
DEL CASTILLO ROMAN Francisco (CONCVE)
FRANCHIOLI, Luigi (UEAPME)
SANTOS , Tatiana (EEB)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
ANDERSSON, Niklas
BALOGH, Attila
BROERE, William
CARLON, Claudio
DE COEN, Wim
DELOFF-BIAŁEK, Anna
DE WOLF, Watze
HALLING, Katrin
HIRVONEN, Tero
HUUSKONEN, Hannele
KARHU, Elina
KORJUS, Pia
KOULOUMPOS, Vasileios
LE CURIEUX, Frank
LE GOFF, François
LEPPER, Peter
NAUR, Liina
PREVEDOUROS, Konstantinos
REUTER, Ulrike
RODRIGUEZ IGLESIAS, Pilar
RUOSS, Jürgen
RÖCKE, Timo
RÖNTY, Kaisu
SOBANSKA, Marta
SUNDQUIST Anna-Liisa
TRNKA, Jan Peter
TARAZONA, José
VAHTERISTO, Liisa
VASILEVA, Katya

Proxies

- ATTIAS, Leonello (IT) also acting as proxy of CAMILLERI, Tristan (MT)
- DUNAUSKIENE, Lina (LT) also acting as proxy of VESKIMÄE, Enda (EE)
- LULEVA, Parvoleta (BG) also acting as proxy of KYPRIANIDOU-LEONTIDOU, Tasoula (CY) and KOUTSODIMOU, Aglaia (EL)
- MARTÍN, Esther (ES) also acting as proxy of DRUGEON, Sylvie (FR)
- RUSNAK, Peter (SK) also acting as proxy of KULHANKOVA, Pavlina (CZ) on Wednesday from 15:00 onwards

Experts and advisers to MSC members

BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
CATONE, Tiziana (IT) (expert to ATTIAS, Leonello)
CONWAY, Louise (IE) (expert to COSGRAVE, Majella on 23 October)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
LUNDBERGH, Ivar (SE) (expert to FLODSTRÖM, Sten)
LØFSTEDT, Magnus (DK) (expert to PEDERSEN, Finn)
MALKIEWICZ, Katarzyna (SE) (adviser to FLODSTRÖM, Sten)
MARTINS, Ana Lilia (PT) (expert to CRUZ, Ana Lúcia)
SCHWAEGLER, Mark (DE) (expert to FINDENEGG, Helene)
TRAAS, Theo (NL) (expert to KORENROMP, René)
ULDUKIENE, Vilma (LT) (expert to DUNAUSKIENE, Lina)

By WEBEX-phone connection:

- BERTATO Valentina, LUVARÀ Giuseppina, BORRAS HERRERO Anna, POPOVA Temenuzhka and HUALDE-GRASA Eva-Patricia from DG ENTR during agenda items 7 and 8; ROZWADOWSKI, Jacek from DG ENTR during agenda item 7 and STRECK, Georg from DG ENTR during agenda items 9a and 9b

Case owners:

Representatives of the Registrant were attending under agenda item 6b for TPE-145/2012 and TPE-147/2012.

Apologies:

Michal ANDRIJEWSKI (PL)
Tristan CAMILLERI (MT)
Sylvie DRUGEON (FR)
Aglaia KOUTSODIMOU (EL)
Tasoula KYPRIANIDOU-LEONTIDOU (CY)
Pietro PISTOLESE (IT)
Henrik TYLE (DK)
Enda VESKIMÄE (EE)

III. Final Agenda

Agenda
26th meeting of the Member State Committee

23-24 October 2012
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

23 October: **starts at 9:00**
24 October**: ends at 17:30**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/026/2012
For adoption

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

Item 4 – Administrative issues

- Handling of members' declarations of potential interests at ECHA

For information

Item 5 – Adoption of the draft minutes of the MSC-25

MSC/M/25/2012
For adoption

Item 6 – Dossier evaluation
Closed session for 6c & 6e
Indicative time plan for 6b is Day 1, for 6c Day 1& 2

a. Written procedure report on seeking agreement on draft decisions on dossier evaluation

ECHA/MSC-26/2012/001
For information

b. Introduction to and preliminary discussion on draft decisions on testing proposals after MS-CA reactions *(Session 1, tentatively open session)*

For discussion followed by agreement seeking under 6c:

ECHA/MSC-26/2012/010

<u>Testing proposals</u>

- TPE-145/2012 Dicyclohexylamine (EC No. 202-980-7)

ECHA/MSC-26/2012/002-004

- TPE-147/2012 Reaction mass of 2,6-Octadien-1-ol, 3,7-dimethyl-, (E) and 2,6-Octadien-1-ol, 3,7-dimethyl-, (Z)- (List No. 906-125-5)

ECHA/MSC-26/2012/005-007

- TPE 161/2012 Sodium N-lauroylsarcosinate (EC No. 205-281-5)

ECHA/MSC-26/2012/008-009

For information and discussion

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

As listed above under **6b** and cases returned from written procedure for agreement seeking in the meeting

- TPE 148/2012 Tert-butyl perbenzoate (EC No. 210-382-2)

ECHA/MSC/D/2012/0293

For agreement

d. General topics:

1. Status report on ongoing evaluation work including reporting from expert workshop held at ECHA on Read-Across Assessment

For information

2. Preliminary outline of recommendations and conclusions from a technical meeting on scientific adequacy of *in vivo* mutagenic assays held at ECHA

For information

3. Study report from ECHA related to evaluation

- Scientific Discussion Paper on terrestrial plant toxicity

ECHA/MSC-26/2012/016

For discussion and endorsement

e. Appeal cases – update (*closed session*)

For information and discussion

Item 7 – ECHA's draft recommendations of priority substances to be included in Annex XIV

Indicative time plan for item 7 is Day 1

a) Progress report after closure of the public consultation on ECHA's Draft 4th Recommendation, Draft RCOMs and Draft Annex XIV entries for prioritised substances

ECHA/MSC-26/2012/019 & 021-026

b) Preparations for the opinion on ECHA's Draft 4th recommendation of priority substances to be included in Annex XIV

- Report by the rapporteur and discussion of the first draft opinion, exchange of views on comments received

ECHA/MSC-26/2012/015

For discussion

Item 8 – SVHC identification

Information about the progress on SVHC identification

For information and discussion

Item 9 – Substance evaluation

(Closed session for 9b3)

a) CoRAP

- Introduction of the draft CoRAP by ECHA and first exchange of views on the draft CoRAP

ECHA/MSC-26/2012/011& 020
Justification document per substance, 117 documents in total
For information and discussion

b) Substance evaluation process

1) Draft MSC working procedure for MSC to process draft decisions in substance evaluation

ECHA/MSC-26/2012/012
For discussion and decision

2) Introduction to the time planning for the decision making process in substance evaluation

ECHA/MSC-26/2012/018
For information and discussion

3) Updates to registration dossiers during substance evaluation *(Closed session)*

ECHA/MSC-26/2012/013
For information

ECHA/MSC-26/2012/014
For discussion

Item 10 – Manual of Decisions (MoD)

- New item for inclusion in MoD of MSC

ECHA/MSC-26/2012/017
For discussion and decision

Item 11 – Report from other ECHA bodies and activities

- Report from MB on topics relevant to MSC

For information

Item 12 – Any other business

- MSCA Workshop on the role and future of the Candidate List

- Report from the Workshop on read-across & grouping as used by the metals sector for REACH purposes held in Helsinki in October 2012

For information

Item 13 – Adoption of conclusions and action points

- Table with conclusions and action points from MSC-26

For adoption

IV. Main Conclusions and Action Points (adopted at the MSC-26 meeting)

Main conclusions and action points
MSC-26, 23-24 October 2012
(adopted at the MSC-26 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
4. Administrative issues - Handling of members' declarations of potential interests at ECHA	
MSC recognised that it is very important when MSCA appoints a member and alternate to look at the provisional guideline for eligibility criteria and consider that the person can work in the Committee without having frequently an issue of potential conflict of interest that needs to be declared at the meeting. SECR is screening the annual declarations and CVs and contact the members when further clarification is needed. MSC recognised that measures to be taken as a consequence of declaring a conflict of interest would be a record in the minutes together with the decision by the Chair on whether a member is able to take part in the vote or else in the discussion depending on the case.	MSC-S to upload the provisional guideline for eligibility criteria on MSC CIRCABC by 26 October 2012.
5. Adoption of the minutes of MSC-25	
MSC adopted the draft minutes with modifications proposed by members in writing before the meeting.	MSC-S to upload final version of the minutes on MSC CIRCABC by 26 October 2012.
6. Dossier evaluation **6a. Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the report.	MSC-S to upload on MSC CIRCABC the final ECHA decisions on cases agreed in written procedure, as indicated in document ECHA/MSC-26/2012/001. MSC-S to provide COM for further decision making with documents (DD on generation testing, RCOM, minutes, outcome of the vote, justification for the position at the vote) of cases on which MSC did not reach agreement, as indicated in document ECHA/MSC-26/2012/001.
6b. Introduction to and preliminary discussion on draft decisions on testing proposals after MS-CA reactions *(Session 1, open)* **6c. Seeking agreement on draft decisions (DD) on testing proposals when amendments were proposed by MSCAs *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting where appropriate of: - *TPE-145B/2012 Dicyclohexylamine (EC No. 202-980-7)* - *TPE-147B/2012 Reaction mass of 2,6-Octadien-1-ol, 3,7-dimethyl-, (E) and 2,6-Octadien-1-ol, 3,7-dimethyl-, (Z)- (List No. 906-125-5)*	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
- TPE 148/2012 Tert-butyl perbenzoate (EC No. 210-382-2) *- TPE 161/2012 Sodium N-lauroylsarcosinate (EC No. 205-281-5)* MSC could not reach unanimous agreement on the following draft decisions as modified in the meeting: *- TPE-145A/2012 Dicyclohexylamine (EC No. 202-980-7)* *- TPE-147A/2012 Reaction mass of 2,6-Octadien-1-ol, 3,7-dimethyl-, (E) and 2,6-Octadien-1-ol, 3,7-dimethyl-, (Z)- (List No. 906-125-5)* on the information requirements for Annex X, point 8.7.3 due to different views of MSC members on the most appropriate generation test (B.35 (TG 416) or OECD TG 443) to be requested for fulfilling the standard REACH information requirements for this endpoint.	SECR to provide COM for further decision making with documents (DD on generation testing, RCOM, minutes, outcome of the vote, justification for the position at the vote) of cases TPE-145A/2012 and TPE-147A/2012. MSC members voting against ECHA's draft decisions to provide justification for their vote (in case they do not wish their standard justification to be used for this purpose).
6d. General topics	
1. Status report on ongoing evaluation work including reporting from expert workshop held at ECHA on Read-Across Assessment MSC took note of the report. **2. Preliminary outline of recommendations and conclusions from a technical meeting on scientific adequacy of *in vivo* mutagenic assays held at ECHA** MSC took note of the report. **3. Study report from ECHA related to evaluation - Scientific Discussion Paper on terrestrial plant toxicity** MSC agreed to decide in MSC-27 on the conclusions presented in the discussion paper.	SECR to inform MSC on 2013 plans for dossier evaluation and to provide 2012 dossier evaluation statistics in MSC-27. After finalisation of recommendations and conclusions ECHA to further consider their implications for the update of the relevant ECHA guidance. MSC to send in comments on the policy paper and on the proposal for improving consistency in the evaluation of terrestrial testing proposals preferably by 3 November 2012 directly to the ECHA presenter (e-mail address is on the last slide of the presentation).
7 – ECHA's draft recommendations of priority substances to be included in Annex XIV **7a. Progress report after closure of the public consultation on ECHA's draft 4th Recommendation, draft RCOMs and draft Annex XIV entries for prioritised substances**	
MSC took note of the report.	Comments/questions on ECHA's draft responses to be provided right after the meeting (where necessary).
7b. Preparations for the opinion on ECHA's draft 4th recommendation of priority substances to be included in Annex XIV - Report by the rapporteur and discussion of the first draft	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
opinion, exchange of views on comments received	
MSC took note of the report and provided feedback to be taken into account by the Rapporteur for the final draft opinion.	Rapporteur to finalise the draft opinion for adoption at MSC-27.
9 – Substance evaluation, CoRAP **9a. Introduction of the draft CoRAP by ECHA and first exchange of views on the draft CoRAP**	
MSC took note of the draft CoRAP presented by ECHA.	MSC members to send to Rapporteur information from their MSCAs whether changes to the content of JD (justification document) were made when JD was updated by 5 November 2012.
9b. Substance evaluation process **1) Draft MSC working procedure for MSC to process draft decisions in substance evaluation** MSC adopted the working procedure for MSC to process draft decisions in substance evaluation.	MSC members to send to MSC SECR any editorial comments by 31 October 2012. SECR to report on the outcome of internal discussions on dealing with potential conflict of interest in substance evaluation. SECR to upload the RCOM template on MSC CIRCABC in the substance evaluation folder by 31 October 2012.
2) Introduction to the time planning for the decision making process in substance evaluation MSC noted that the preferred MSC meetings for discussion of SEv DDs are the November 2013 and February 2014 MSC meetings.	MSC members to indicate already their internal planning of when to start the MSCA consultation for the substances they are evaluating.
3) Updates to registration dossiers during substance evaluation MSC agreed that no conclusion could be taken on this topic at this MSC meeting and therefore CARACAL would be a better forum for such a discussion.	MSCAs to send a written request to ECHA if they want an updated IUCLID5 aggregated dossier for their substance.
10 – Manual of Decisions (MoD)	
MSC agreed to include the proposed item in MoD of MSC.	MSC-S to upload the updated MoD on MSC CIRCABC by 26 October 2012.
12 – Any other business	
MSC took note of the report of Eurometaux.	
13 – Adoption of conclusions and action points	
MSC adopted the conclusions and action points of MSC-26.	MSC-S to upload the conclusions and action points on MSC CIRCABC by 26 October 2012.

V. Dossier evaluation cases referred for MSC agreement seeking in written procedures:

agreed by written procedure: CCH-049/2012 Cyclohexanone (EC No. 203-631-1); TPE-142/2012 A mixture of: tetrasodium-phosphonoethane-1,2-dicarboxylate; hexasodium-phosphonobutane-1,2,3,4-tetracarboxylate (EC No. 410-800-5); TPE 143/2012 Phosphonium, tetrakis(hydroxymethyl)-, chloride (1:1), reaction products with 1-tetradecanamine and urea (EC No. 436-230-7); TPE 144/2012 Ethyl 3,5-dichloro-4-hexadecyloxycarbonyloxybenzoate EC No. 404-740-9; TPE 149/2012 Di-tert-butyl 1,1,4,4-tetramethyltetramethylene diperoxide (EC No. 201-128-1); TPE 150/2012 Tris[4-(diethylamino)phenyl]methylium acetate (EC No. 263-974-8); TPE 152B/2012 1-Hexanol, 2-ethyl-, manuf. of, by-products from, distn. Residues (EC No. 271-832-1);TPE 154/2012 1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters (EC No. 290-754-9); TPE 155/2012 3-C12-14-(even numbered)-alkylamido-N,N-dimethylpropan-1-amino oxide (List No. 931-324-9); TPE 156/2012 Slimes and Sludges, blast furnace and steelmaking (EC No. 266-006-2); TPE 157/2012 Pentane-2,4-dione (EC No. 204-634-0); TPE 160/2012 Dibutyl fumarate (EC No. 203-327-9); TPE 161/2012 Sodium N-lauroylsarcosinate (EC No. 205-281-5); TPE 162/2012 Reaction mass of 1,3-Propanediol, 2-(hydroxymethyl)-2-[(methoxymethoxy)methyl]- and 1,3-dioxane-5,5-dimethanol (List No. 911-819-6)

referred to COM: TPE 146/2012 Geraniol EC No. 203-377-1, TPE 152A/2012 1-Hexanol, 2-ethyl-, manuf. of, by-products from, distn. Residues (EC No. 271-832-1), TPE 158/2012 3-Trimethoxysilylpropyl methacrylate (EC No. 219-785-8)

WP terminated and agreement sought in MSC-26 meeting: TPE 148/2012 Tert-butyl perbenzoate (EC No. 210-382-2)