MSC/M/025/2012
Adopted at MSC-26

Minutes
of the 25th Meeting of the Member State Committee (MSC-25)
19-21 September 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 25th 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 (final Agenda is attached to these minutes).

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

One MSC member (Helene Findenegg) declared potential conflict of interest in respect to agenda points *6c* and *d* concerning the discussions and agreement seeking on case CCH-035/2012. The Chair concluded that based on the declaration of potential conflict of interest the member in question will not participate in the vote on seeking agreement on CCH-035/2012.

Item 4 - Administrative issues - MSC Rules of Procedure (RoPs)

The Chair informed the members that in August the MSC RoPs were agreed by the Management Board (MB) and are now available on MSC CIRCABC and on ECHA website. Following the newly adopted RoPs also the MSC stakeholder observers (STOs) and case owners attending the meeting had been provided with short presentations for the dossier evaluation cases, in advance of the meeting.

Item 5 – Adoption of the minutes of the MSC-24 meeting

The Secretariat (SECR) presented the revised version of the MSC-24 minutes informing MSC that written comments on the draft minutes were received by one MSC member prior to the MSC-25 meeting. One representative of a Registrant for a dossier evaluation case who had participated in MSC-24 has been also consulted for the respective parts of the draft minutes and has not provided any comments. In conclusion, the minutes were adopted with a minor change suggested by one STO and done at the meeting. SECR would upload the minutes on MSC CIRCABC and ECHA website.

Item 6 – Dossier evaluation

a. General topics:

1. Issues in REACH related to CMR classification category 1 and the implemented risk management measures

ECHA gave a detailed presentation on why in its view adaptation possibilities and their justification relating to CMR classification should be left to the Registrant and why ECHA by default does not reject testing proposals (TPs) as suggested by several proposals for amendments (PfAs) of MSCAs on some of the cases on the agenda of MSC-25 based on potential column 2 classification-related adaptations. The presentation also reviewed the consequences that the Registrant needs take care of when classifying his substance (MSC members/STOs can find the full presentation on MSC CIRCABC).

Some MSC members pointed out that REACH seems insufficient in not giving MSC an explicit mandate to deal with classification and labelling (C&L) although TPs where classification may be an issue need to be discussed in MSC. Several MSC members acknowledged ECHA's view that TPs normally should not be rejected based on PfAs suggesting potentially applicable classification if the Registrant does not use this adaptation possibility and that to decide on harmonised C&L is

not the task of MSC but of the Risk Assessment Committee (RAC) and Commission (COM). However, in some specific scenarios when the classification based on available data seems to be likely, MSC should be able to at least refer to the adaptation possibility of column 2 of 8.7 of Annex VIII/IX/X in the draft decision (DD). One MSC member proposed to reject TPs where despite of harmonised C&L a test is proposed.

ECHA further explained that it would be questionable whether the right of testing could be denied from the Registrant even if harmonised C&L is available for the substance. ECHA also emphasized that both classification *and* adequate risk management measures (RMM) for carcinogens (C) and mutagens (M) or data sufficient for a robust risk assessment for reprotoxicants (R) are needed for a valid adaptation according to column 2 of Annex VIII, IX or X, 8.7. So far PfAs of MSCAs have focused only on the classification part. ECHA also clarified that if MSCAs or MSC members are not satisfied with the classification used in the context of a TP, MSCAs can always make a proposal for harmonised C&L. If there is no harmonised C&L yet for the substance, also the Registrant can initiate the process. In both cases, RAC will give an opinion on the proposal and COM will take the final decision. ECHA emphasised that it would against the procedures set up for establishing harmonised classification to give a role to MSC. Harmonised C&L would be a task for RAC, not for MSC. MSC must not be used as a kind of fast track for harmonised C&L and can not impose in a decision on a TP any self classification on the Registrants. It was proposed by several members that collaboration between RAC and MSC should be improved to make members of each Committee aware of the practical connections between the registration dossiers, TP examinations and compliance checks (CCH) as well as proposals for harmonised C&L.

COM generally agreed with ECHA's approach expressed on the topic but acknowledged that there is room for improvement concerning division and coordination of tasks between MSC, RAC and COM.

The Chair concluded that no general approach can be agreed and applied to DDs where classification is a concern and therefore there is a need to handle these cases and to consider different scenarios on a case-by-case basis in this context. However, MSC can not impose on the Registrant application of any specific self-classification but could invite the Registrant to consider classification based on available data. The Chair also reminded that adaptation of information requirements of Annex VIII/IX/X, 8.7 would require two conditions: that the substance is a known CMR category 1 *and* RMM have been implemented (for C and M) or data are sufficient for robust risk assessment (for R). Co-operation between RAC and MSC, COM can be improved on these matters but practical aspects of such collaboration have to be further considered.

2. Applicability of testing proposals using a read across (RA) approach (closed session)[1]

After a similar discussion on the same topic in MSC-24 meeting, ECHA gave a presentation summarising its main arguments for its approach to handle as TPs the indications in dossiers by Registrants that testing is proposed on an analogue substance. The presentation was mainly motivated by one MSCA's concerns raised in PfAs to the two categories to be discussed by the current meeting. One of the MSCA's concerns was that if a Registrant does not indicate testing of an analogue substance as a TP but just includes RA based waivers for tests still to be performed ECHA would not have the chance to treat these dossiers in a similar way as if treated as TPs. In the MSCA's view such RA cases should possibly be prioritised for CCH later when test data would be available for the substance to be RA to (source substance). On the other hand, ECHA will treat them as TP cases if

[1] Please find a MSC member's statement relating to the agenda point in Annex V.

they have been indicated as TPs by the Registrant and prepare decisions on them. Consequently, in the MSCA's view there may be a possibility that similar cases are not treated equally. Moreover, MSCA considered that when the test on the source substance that will provide the data for RA is still to be performed, ECHA may be prejudging on a RA without having the data available on the source substance for drawing definite conclusions. Thus, the MSC member from the MS that submitted the PfAs expressed the view that normally the optimal option providing equal treatment would be to handle cases with TPs on analogue substances as CCHs. In his view the only exception to consider the case as a TP should be when the TP on an analogue substance refers to a non-registered substance. He also pointed out that ECHA's approach by treating all these cases as TPs is resource intensive with very short deadlines for DDs to be prepared while the proposed CCH approach could be timely more flexible. Instead ECHA should focus on making targeted CCHs on dossiers of concern, e.g. where the RA applied is clearly not justified and furthermore the unjustified application of the postulated RA is of particular concern for the chemical safety.

ECHA replied that the Agency does not prejudge whether the proposed RA approach will be accepted later when test results on the source substance have been made available. ECHA in DDs only communicates its view to the Registrant on the plausibility of the testing strategy and makes clear in statement of reasons (SoRs) of DDs if RA does not seem plausible and what the potential insufficiencies in the Registrant's argumentation for RA are. Also ECHA in its formal and informal communication with the registrants always clarifies whether the Registrants wanted to make TPs based on a RA testing strategy. When making TPs (even based on testing of an analogue substance) the Registrants have legitimate right to expect ECHA's decisions on any TPs. When responding in DD to the Registrant's RA strategy, i.e. RA hypothesis and documentation provided for support of RA, ECHA may give to the Registrant a possibility to improve the RA argumentation by updates to the registration dossiers. If the proposed RA approach would fail ECHA would be able to give feedback to the Registrant on this aspect in DD. It was noted that all TPs will be addressed for third party consultation contrary to the CCHs.

ECHA furthermore explained that according to ECHA's current interpretation of REACH reference to testing of an analogue substance is not a valid waiver which therefore cannot be recommended for Registrants to be used. The acceptable waivers are only those which have been indicated in columns 2 of Annexes VII-X and in Annex XI.

ECHA explained that in the follow-up phase ECHA-S will check at the same time all dossiers whether results of the tests make indeed the RA-based approach valid and justified.

While several MSC members realised the relevance of suggestions and issues raised in the discussion, MSC acknowledged also the time constraints for the currently processed TP cases in dossiers from the 2010 registration deadline and could agree with ECHA's approach for these cases (deadline to issue DDs on these TPs is 1 December 2012). MSC agreed that communication to Registrants on RA cases should be continuously improved and that a new discussion on the approach will take place after more experience with the ongoing cases has been gained.

3. Selection of first species for prenatal developmental toxicity (PNDT) study if other reproduction toxicity (RDT) studies are required

One MSC expert gave a presentation based on comments of the corresponding MSCA submitted to some of ECHA's recent DDs where ECHA requested both PNDT in the first species and two-generation reproductive study/extended one

generation reproductive study (EOGRTS) in rats. Based on the REACH text and the ECHA guidance, the presentation suggested that as the two-generation reproductive study/EOGRTS is always requested in rats, the first species for a PNDT study in these cases should be the rabbit. This approach could potentially provide additional information for reproductive/developmental toxicity while both studies conducted in the same species may not.

ECHA in its response acknowledged the rationale behind the approach proposed and that neither ECHA guidance nor REACH does clearly specify the species for PNDT studies. Therefore, ECHA suggested for CCHs and TPs by default to leave the choice between rat and rabbit to the Registrants' discretion. ECHA would accept other species than rats and rabbits with adequate justification.

MSC generally agreed with ECHA's default approach after ECHA explained that with a PfA the species could be raised for discussion in a specific case e.g. based on a substance specific sensitivity of a certain species.

The Chair pointed out that as the issue was raised in comments and not in PfAs to certain cases, these current cases can not be amended according to the agreed approach. ECHA will apply ECHA's default approach however for future similar cases.

4. Status report on ongoing evaluation work

SECR gave a detailed statistics and update on the status of evaluation work until end of August 2012. MSC took note of the report.

b. 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 24 dossier evaluation cases (see Section VI for more detailed identification of the cases). WP was launched on 22 August and closed on 3 September 2012. For six cases, DDs were split thus resulting in two DDs for these cases and overall 30 DDs for the 24 cases. By the closing dates, responses to WP were received from 24 members with voting rights and from the Norwegian member. Unanimous agreement was reached on 20 DDs. For four DDs WP was terminated by the MSC Chair on the basis of MSC member's request and they were referred to the MSC-25 meeting for agreement seeking. For six DDs involving the standard information requirement for Annex X, 8.7.3, four votes were indicating disagreement, 20 votes were in favour of them and one MSC member did not vote. Thus, these six cases are to be referred to COM for further decision-making under Article 133 (3) of REACH.

c. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MSCA reactions

d. Seeking agreement on draft decisions on compliance checks and testing proposals when amendments were proposed by MS's

TPE-127/2012 Diammonium dihydrogen ethylenediaminetetraacetate (EC No. 244-063-4)
TPE-128/2012 Edetic acid (EC No. 200-449-4)
TPE-129/2012 Disodium dihydrogen ethylenediaminetetraacetate (EC No. 205-358-3)
TPE-130/2012 Tetraammonium ethylenediaminetetraacetate (EC No. 245-022-3)
TPE-131/2012 Tetrasodium ethylenediaminetetraacetate (EC No. 200-573-9)
TPE-132/2012 Triammonium hydrogen ethylenediaminetetraacetate (EC No. 240-073-8)

Session 1 (open)

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

The above listed substances are considered to form a group or category by the Registrant. The substance which has been proposed by the Registrant to be read-across to is covered by TPE-129/2012 (testing for 90-day RDT via inhalation has been proposed).

SECR explained the three PfAs related to the 90-day RDT study and one PfA on the dossier evaluation process applied by ECHA.

Regarding TPE-129, one PfA, made also for TPE-127, -128, -130, -131 and -132, suggested testing in 90-day RDT study another substance of the proposed category (tetra-ammonium EDTA, TPE-130) to take into account the potential effects of ammonium and use the data to RA to other substances within the proposed category. It also suggested adding a text to DD indicating that only plausibility for RA has been assessed and the final conclusion on the proposed RA approach can only be drawn when the test results are available.

The other PfA on 90-day RDT testing by inhalation on TPE-127, -128, -131 and -132 proposed to further clarify in DD that the remaining concern is related to 90-day RDT by inhalation as there is already an oral 90-day study available on Na_2H_2EDTA (TPE-129). Another PfA on TPE-130 pointed out that the substance is registered on the tonnage level of Annex VII and therefore no 90-day RTD testing requirement exists. As the TP has been addressed for Na_2H_2EDTA (TPE-129) and the results only to be RA to the substance under TPE-130, any contrary decision for tetra-ammonium-EDTA (TPE-130) would not make a difference. MSCA proposed to make clear in DD the circumstances under which this TP was agreed and to modify the text of DD accordingly. Another PfA suggested correcting a reference in DD of one of the substances to the appropriate Annex of REACH.

A last PfA was made on all cases (TPE-127, -128, -130, -131, -132) but TPE-129, suggesting that TP should be rejected because the test proposed concerns another substance registered under REACH than the substance in question and proposes instead that only the TP on the registered substance (i. e. substance covered by TPE 129/2012) should be treated as a TP. The MSCA considered that in principle it would not be warranted to pre-judge the validity and acceptability of a RA argument related to another structurally analogous substance where testing has not yet been performed, and that the RA cases would potentially constitute future CCH cases.

SECR modified DD for MSC-25 based on some of the PfAs.

Registrant's comments on PfAs of CAs and discussion

The Registrant in his written comments on PfAs agreed to perform the subchronic inhalation study with Na_2H_2-EDTA (TPE-129) as representative for the EDTA-category, for three reasons: 1. The EDTA-anion is the main toxicophore according to their hypothesis. 2. Effects of ammonium-ions mentioned by NL-CA would be taken into account by reaching a NOAEC that is comparable to the threshold limit value of ACGIH or NIOSH, or recommended exposure limit for ammonium chloride fume or derived no effect levels (DNELs) for other soluble ammonium compounds. 3. Further animal testing can be avoided since a 5d-dose range finder inhalation study was already performed with Na_2H_2-EDTA. ECHA was of the view that the Registrant's comments would not affect the content but rather support the approach of DD.

MSC considered the Registrant's comments on PfAs.

During the meeting the representative of the Registrant stressed their point in the written comments that they expected the NOAEC for sub-chronic inhalation of the substance to be identified by TPE 129/2012, will be in the range of 1 to

10mg/m3. Due to subsequent application of assessment factors (AF), the expected DNEL for the inhalation route would then be lower than 1 mg/m3.

The member representing the MSCA that submitted PfA regarding the dossier evaluation process to be applied (which ECHA did not agree) advocated for an alternative approach to evaluating RA TPs. However, at the end the member agreed not to oppose ECHA's approach as the category proposed by the Registrant was well justified and obvious.

The member representing the MSCA that submitted PfA on testing on another substance of the proposed category whose PfA was not introduced in DD explained that their concern was triggered by the possibility of the Registrant overlooking the local effect of the ammonium ion. To this concern, the Registrant further explained that if a DNEL of above 10mg/m3 is obtained, they would not only look at the EDTA but at the ammonia as well.

There was a general agreement with ECHA's approach in the six DDs.

Session 2(closed)
MSC found unanimous agreement on ECHA's DDs for TPE-127/2012, TPE-128/2012, TPE-129/2012, TPE-130/2012, TPE-131/2012 and TPE-132/2012 as provided for the current meeting without further modifications.

TPE-101/2012 2,2'-[oxybis(methylene)]-bis[2-ethylpropane-1,3-diol] (EC No. 245-509-0)
TPE-102/2012 2,2,2',2'-Tetrakis(hydroxymethyl)-3,3`-oxydipropan-1-ol (EC No. 204-794-1)
TPE-103/2012 2,2-Bis(hydroxymethyl)-1,3-propanediol (pentaerythritol) (EC No. 204-104-9)

Session 1 (open)
No representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DDs, an open session was held.

SECR pointed out that the above listed substances together with the case TPE-104/2012[2] were considered by the Registrant to form a group or category. The substance which has been proposed by the Registrant to be RA to is covered by TPE-104/2012 (where testing for PNDT oral route was required) for which MSC agreement was reached in WP on 3 September 2012. ECHA's view as expressed in DD on the cases was that RA within the proposed category would not be plausible based on the arguments provided by the Registrant.

One PfA referring to all three cases suggested the TP to be rejected because the test proposed concerns another substance registered under REACH than this substance in question and proposed instead that only TP on the registered substance (i.e. substance covered by TPE-104/2012) should be treated as a TP. The second PfA pointed out that the Registrant had not been given the opportunity to respond to the remaining ECHA's concerns based on the updated RA argumentation by the Registrant and proposed some modifications in DD referring to the outstanding concerns as a reason to require testing. The third PfA on DDs of TPE-102 and -103 proposed that RA would be possible based on PNDT tests on trimethylolpropane (TMP) or on registered substance because of structural similarities, likely common metabolites, the observed low toxicity of the registered substance and the worst case approach when TMP is used.

SECR modified DDs for MSC-25 based on the PfA suggesting to further clarify the remaining concerns for plausibility of the proposed RA.

Registrant's comments on PfAs of CAs and discussion

[2] TPE 104/2012 Propylidynetrimethanol (EC No. 201-074-9)

The Registrant in the written comments on PfAs did not comment on them, but provided responses to the SoR of ECHA's DDs further justifying why RA should be accepted tackling each of the arguments used by ECHA in DD for rejecting RA.

MSC considered the Registrant's comments on DDs noting that the comments were not on PfAs but on DD itself.

The plausibility of the proposed RA was discussed in the light of REACH, Annex XI, 1.5. Some members advocated for sufficient structural similarities between the substances as a possible basis for RA. However, it was pointed out by SECR that the likelihood of common break-down products was based only on assumptions without further documentation. Information on possible metabolites of the substances was based on one prediction model without information on the likelihood of common breakdown products and without information on validity of the prediction model. Also information on absorption showed differences between the members of the proposed category. A constant pattern in changing of the potency of the properties was not demonstrated as the results of RDT study on one member of the proposed category showed toxic effects whereas no toxic effects were seen in other studies on other members of the proposed category. The explanation and documentation provided by the Registrant was not considered sufficient regarding the seen differences in RDT studies.

It was proposed by one MSC member that further clarification for the rejection of RA would be needed in the DD thus providing a possibility for the Registrant to pursue this route for meeting the standard information requirements for the substances of the proposed category. However, DD would clearly state that the proposed RA was not considered plausible based on the argumentation provided by the Registrant in the registration dossier, and that the substances of the proposed category should be tested for PNDT.

MSC concluded that on the basis of the argumentation provided by the Registrant, the proposed category would not be plausible and the suggested RA could not be accepted for any of the cases in the category.

Session 2 (closed)

In response to a question, SECR pointed out that no request for further testing for generating toxicokinetic data has been made in DDs, but just an indication to the Registrant has been included to consider by which means the RA argumentation could be further improved.

As the RA proposed by the Registrant was not sufficiently justified and considered plausible the substances of the proposed category need to be tested for PNDT. MSC modified Section III (SoR) to reflect the above conclusions by further specifying the reasons why RA was not considered plausible. The responsibility to further consider the RA option, amend and substantiate the RA and category justification according to Annex XI, 1.5 would remain with the Registrant.

MSC found unanimous agreement on these ECHA's DDs as provided for the meeting and amended during the meeting discussion as described above.

CCH-034/2012 Hydrogenated dimerization products of 1-decene, 1-dodecene and 1-octene (List No. 700-308-1)

Session 1(open)

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

Based on effects seen in the 28-day RDT study one PfA proposed to reconsider specification of NOAEL. Another PfA proposed to request PNDT study on the second species in rabbits. Furthermore it proposed to request EOGRTS to comply with the information requirement for the two-generation study in accordance with Annex X, 8.7.3.

Three MSCAs proposed to request the Registrant to justify deviation from the ECHA guidance when using different AFs in calculation of DNELs. Furthermore another PfA suggested specifying DNEL also for consumers via dermal route.

Regarding exposure assessment one PfA proposed the Registrant to justify the process temperatures indicated in the registration dossier.

Another PfA proposed to request information on long-term toxicity on invertebrates, long-term toxicity on plants and long-term toxicity on sediment organisms because the MSCA did not consider the Registrant's waiving arguments for these tests justified. This PfA also proposed to specify PNEC-sediment and exposure assessment for the sediment compartment.

Another PfA proposed to review and correct CSA for consumers to use correct DNELs and to provide risk characterisation to be performed both for the inhalation and dermal routes.

SECR modified DD before MSC-25 based on PfAs regarding PNDT testing on the second species, long-term toxicity testing on invertebrates, plants and sediment organisms as well as specification of PNEC-sediment and exposure assessment in sediment compartment and choice of AFs for DNEL derivation.

Registrant's comments on PfAs of MSCAs and discussion

The Registrant did not provide written comments on PfAs.

The Registrant during the meeting discussion showed their regret of missing the opportunity to comment on PfAs by MSCAs and explained that due to the intended limited uses of this product and the presence of no reactive groups in the chemical any further testing at this stage is not justified. In their view the PNDT and two-generation study are already provided in the dossier and are sufficient. The data on the first species of PNDT were provided to fulfil the information requirements outlined by REACH and they did not receive any information from ECHA on the inadequacy of the tests. Thus the additional second study is not necessary. The Registrant also considered the request for long-term toxicity in soil as unjustified at this time, since further testing has been proposed in 2011 update, which seems that such proposals have not been taken into consideration by ECHA and MSCAs. In their view, completion of the shorter term test needs to be performed in order to know whether long term test is needed. Regarding sediment testing, Registrant still stressed to use the predictive model as a first screen before testing in sediment is done so as to determine if sediment testing is actually needed.

Members from the MSC explained to the Registrant that the Registrant's interpretation of the Regulation in relation to PNDT is not correct. PNDT in the second species is a standard information requirement in REACH under Annex X thus the test will be needed. It was further explained that the data gap for the two-generation study referred to in PfA was proposed to be filled in by an EOGRTS. However because the discussion on application of EOGRTS under REACH is still ongoing at the Commission level, the data gap concerning this information requirement was not addressed in ECHA's CCH DD and this PfA is not reflected in DD as presented in MSC-25. This will be further clarified in the cover letter accompanying the final decision so that the Registrant will be aware that this particular endpoint is not covered by the decision. Apart from that, it is always indicated in ECHA's decisions that the dossier can be revisited and checked at any point of time.

Regarding the use of AFs for DNEL derivation it was explained to the Registrant that any deviation from AFs of the ECHA guidance would need to be justified based on substance specific reasons.

Regarding long-term toxicity testing in invertebrates, it was explained that adaptation of the standard information requirement under Annex X of REACH would not be possible based on short-term toxicity testing. Thus long-term testing on invertebrates is required. DD is further clarified by explaining that if the long-term test on invertebrates is performed the short-term test is not needed because the test will be the same but more species need to be tested for the long-term toxicity.

Clarification was also provided on how and when to use the Equilibrium Partitioning Method (EPM). The Integrated Testing Strategy (ITS) described in the guidance were explained in order to help the Registrant understand why the predictive model cannot be used to determine PNEC-soil and PNEC-sediment when the PNEC-aquatic is not available. If a PNEC-aquatic is not derived, the absence of long-term effects on aquatic organisms can be used as part of a Weight-of-evidence (WoE) approach in the assessment of effects on terrestrial organisms, but the ITS table based on hazard categories cannot be applied. Thus long-term testing on terrestrial plants is also required.

Session 2 (closed)
MSC found unanimous agreement on ECHA's DDs as provided for the current meeting with a slight modification carried out at the meeting.

TPE-105/2012 Hydrogenated dimerization products of 1-decene, 1-dodecene and 1-octene (List No. 700-308-1)
Session 1(open)
Representatives of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

The submitted TP was on short-term toxicity testing on plants. One PfA was submitted by one MSCA proposing to add after the procedural steps in DD a special disclaimer reminding the Registrant about a possible CCH and suggesting not to refer to the "present" dossier.

SECR modified DD before MSC-25 based on PfA.

Registrant's comments on PfAs of MSCAs and discussion

The Registrant did not provide written comments on PfA.

The Registrant, who was the same as for CCH-034/2012, during the meeting discussion showed their regret of missing the opportunity to comment on PfA. Their intervention in the meeting focused on PfAs received for CCH-034/2012 as explained above and not on PfA received for this TP. It was explained by SECR how the information requested for long-term toxicity testing on plants under CCH is related to TP for short-term toxicity testing on plants. As the Registrant proposed short-term toxicity testing on 'radish' this species was considered in CCH DD as one species to be included in the long-term toxicity testing on plants.

Session 2(closed)
MSC found unanimous agreement on ECHA's DD as provided for the current meeting without any modifications.

CCH-035/2012 2-Dimethylaminoethyl methacrylate (EC No. 220-688-8)
Session 1 (open)
A representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

One PfA questioned whether the inhalation route is the most relevant route of exposure in 90-day RDT study and indicated uncertainties regarding the mechanisms leading to the observed neurotoxicity in an oral study, but not in an inhalation study. This PfA suggested that exposure in a 90-day inhalation study may not achieve a sufficiently high internal dose to cause neurotoxic effects.

Another PfA indicated that the Registrant had not followed the harmonised classification and hence the advised risk management measures (RMMs) in exposure scenarios and extended safety data sheets are not based on all known hazards.

Regarding DNEL derivation, exposure assessment and risk characterisation for workers' short-term inhalation exposure a PfA raised a concern that the Registrant does not classify the substance as a skin sensitizer which is a harmonised classification but bases the classification on a negative test result of the registered substance. The same PfA further indicated that Section III of DD should point out that the substance has a harmonised classification, and that the primary route of occupational exposure is via inhalation and dermal contact. Another PfA suggested that, because of the skin sensitising properties, the substance may present a concern for sensitisation by inhalation. On the same information requirements and on missing elements for consumer exposure two other PfAs suggested modifying DD for inhalation exposure and exposure scenarios so that the harmonised classification would be taken into account both in Section II, 2 c) and d) respectively and in Section III. Furthermore for C&L (Annex VI, section 4) two PfAs indicated that the registration dossier should be made compliant with the existing and legally binding harmonised C&L for the registered substance. Regarding missing elements for consumer exposure a PfA suggested modifying Section III by deleting a sentence on the discrepancy in the CSR between the various product uses and only one product type covered in the exposure assessment.

SECR modified DD for MSC-25 based on all PfAs but the one related to the most appropriate route of administration and the one related to the sensitisation by inhalation.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs expressed the intention to consider the issues related to CSR in the next update of the registration dossier. Concerning C&L of the registered substance, the Registrant claimed that (1) a C&L dossier to modify the harmonised C&L would be submitted soon to a CA (2) acute toxicity by oral and dermal route is not supported by data available for the Registrant. The Registrant to one PfA also argued that (1) actual test data do not indicate classification as skin sensitiser and (2) no evidence indicates respiratory sensitisation potential. The Registrant agreed with PfA to perform the 90-day RDT study via oral route (instead of inhalation as requested by DD).

In the meeting, the Registrant expressed a wish to get hold of the data which were used as the basis of the harmonised classification of the substance for acute toxicity and as a skin sensitiser. Concerning the 90-day study, they highlighted the low vapour pressure of the substance which would make inhalation testing technically difficult. Also, with the strong eye irritation described in a study, it is questionable whether the concentration needed to observe systemic effects could be reached via inhalation.

MSC considered the Registrant's comments on PfAs.

MSC members representing MSCAs that submitted PfAs concerning CSR and C&L accepted the way DD was amended by ECHA for the meeting.

The MSC member representing MSCA that submitted PfA for the oral route maintained his position in the discussion and generally agreed with the Registrant's position and arguments for the oral route. ECHA claimed that both inhalation and oral route could be used to see potential systemic effects (particularly neurotoxicity) as the irritant effects seen in a study from the 1970's are not described in sufficient detail to be able to conclude that inhalation could not be used as route of administration due to irritation of the eyes or of the respiratory tract. Furthermore, it is the Registrant's responsibility to set the

proper dose e.g. via a range finding study so that concentrations causing corrosive effects are avoided. There are definitely uncertainties for both routes due to the different outcomes of available studies that could be explained by several variables e.g. different doses, length of exposure, route-specific metabolism (first pass effect). ECHA also noted that according to the CSR, inhalation is the major concern for human exposure.

Considering all arguments above, MSC agreed there was residual uncertainty about the inhalation route and discussed further whether extrapolation from the oral to the inhalation route would be reliable enough to establish a safe DNEL for inhalation.

Session 2 (closed)

MSC agreed that the route of administration in the 90-day RDT study should be oral. The study OECD 424 or EU B.43 should be combined with the OECD 408 study focusing on neurotoxic effects. The Registrant shall be reminded that as there is residual uncertainty for the route-to-route extrapolation and consequently in establishing DNEL for inhalation, the Registrant is required to satisfactorily address this uncertainty. Sections II and III of DD were modified accordingly.

MSC found unanimous agreement on ECHA's DD as provided for the meeting and amended during the meeting discussion as described above.

TPE-108/2012 Dilauroyl peroxide (EC No. 203-326-3)

Session 1 (open)

No representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

One PfA proposed modification in Section II of DD for indicating the existing data gap concerning reproductive toxicity in the dossier for standard information in accordance with Annex X, 8.7.3. The second CA proposed to reject the testing proposal for 90-day sub-chronic RDT study because the adaptation in accordance with column 2 of Annex IX, 8.6.2 should apply.

SECR modified DD for MSC-25 based on the comment of the Registrant which indicated acceptance of the adaptation proposed by one PfA.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs agreed with the first PfA concerning reproductive toxicity. Further, he also agreed with the second PfA saying that the testing proposal for the 90-day study should be eliminated.

MSC considered the Registrant's comments on PfAs. ECHA SECR amended DD for MSC-25 taking into account the Registrant's comments which indicated acceptance to follow PfA which would provide a possibility to adapt the standard information requirement for the 90-day study. The modification to DD was to clarify for the Registrant why the proposed adaptation was not acceptable and the testing would be required.

An expert from CA with PfA suggesting the TP rejection and use of an adaptation for fulfilling the standard information requirements for this endpoint agreed with ECHA's response on their PfA and further clarified the rationale behind their initial considerations when PfA was made.

MSC concluded that DD as modified for the meeting could be acceptable for MSC agreement seeking.

Session 2 (closed)

MSC found unanimous agreement on ECHA's DD as provided for the current meeting without further modifications.

TPE-135/2012 Hexane-1,6-diol (EC No. 211-074-0)

Session 1 (open)

No representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

One PfA proposed to indicate that there is a data gap in the dossier for standard information in accordance with Annex X, 8.7.3. Two other PfAs suggested providing in DD an alternative to the Registrant to consider WoE approach instead of testing the substance for 90-day RDT, taking into account the existing 28-day RDT data on pentane 1,3-diol and pentane 1,5-diol as well as the findings from the 90-day study required by ECHA decision to be carried out on a structurally related substance pentane 1,2-diol. Furthermore, PfA proposed to use another species, rabbit or mouse instead of rat in PNDT study. As an argument for another species PfA referred to information available for a number of C2-C6 diols on rat where no evidence on developmental toxicity was observed. Thus, WoE approach could be used to predict that a developmental toxicity study on hexane-1,6-diol in the rat would not show any toxicologically significant adverse effects and therefore an alternative species should be used. Based on available information on rabbit and mouse studies on other diols the PfA suggested that the mouse rather than the rabbit may be the most sensitive species for detecting developmental toxicity on hexane-1,6 diol.

ECHA Secretariat did not modify DD based on PfAs.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs did not agree with PfA to consider WoE approach for waiving the 90-day RDT study. The Registrant explained that the available data for hexane-1,6-diol and pentane-1,5-diol are largely consistent, indicating generally low toxicity and showing that both substances can be considered in a RA approach. Furthermore, to execute proper risk assessment and to verify the RA approach an oral sub-chronic toxicity study should be performed with hexane-1,6-diol which is representative for terminal aliphatic diols with medium chain length. Concerning the species, according to the Registrant's view studies suggest that the sensitivity for detecting developmental toxicity of diols is not increased in mice. Since there are no PNDT data available for terminal aliphatic diols with medium chain length and the rat is according to OECD TG 414 the recommended rodent species, the proposed PNDT study should be performed in rats.

MSC considered the Registrant's comments on PfAs.

The MSC member representing MSCA that submitted PfAs with WoE approach for the 90-day RDT study and the suggestion to perform PNDT study in mice maintained his position in the discussion. Some MSC members pointed out that while the suggested WoE approach has merits, it would not give the certainty on the effects of terminal aliphatic diols with medium chain length and the Registrant's right to test can not be denied. Concerning the choice of the species, ECHA emphasised that there is no positive scientific or legal reason to change the species from rat to mice. The only reason against the rat is that a related substance showed less potent effects in earlier studies in rats, but it was argued that this information was not informative for the registered substance. It is however true that if the PNDT study in rats will be negative, then Registrant needs to do the test on a 2nd species. Several MSC members supported ECHA's view for DD.

Session 2 (closed)

MSC concluded that the 90-day RDT study should be requested and the PNDT study should be performed in rats as indicated in DD submitted to MSC.

Based on the above conclusions, MSC found unanimous agreement on ECHA's DD as provided for the current meeting without further amendments.

TPE-116/2012 Sodium permanganate (EC No. 233-251-1)
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 suggesting to make it clear in the decision that the decision does not take into account the update of the dossier made by the Registrant after the MSCA consultation on ECHA's DD started (14 June 2012). MSC concluded to amend section I of DD accordingly. SECR explained that the update will be recognised in the cover letter attached to the final decision.

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

TPE-124A&B/2012 Hexaboron dizinc undecaoxide (EC No. 235-804-2)
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 three MSC members. They suggested MSC discussion on the possible classification of the registered substance due to the harmonised classification of boric acid (Toxic to reproduction, category 1B) that is a hydrolysis product of the registered substance. One of these three MSC members suggested also requesting the Registrant to do the 90-day RDT test first. If the toxicity profile of the registered substance will be similar to that of boric acid based on the results of this test, the registered substance can be classified as toxic to reproduction, category 1B and further RDT (i.e. PNDT or two-generation/EOGRTS) testing would not be necessary due to classification-based waiving.

In the discussion ECHA pointed out that even if the sequence of testing will be required by the decision as suggested, the Registrant can not be obliged to self-classify the substance based on the results of the 90-day study.

MSC supported the suggested order of testing and concluded that the 90-day RDT study should be performed first. The Registrant should also be reminded in DD that based on the results of the 90-day study classification of the registered substance may be possible and further PNDT/generation testing may not be necessary. As the original DD was split into two DD documents (TPE-124A/2012 relating to TP for a two-generation RDT study and TPE-124B/2012 relating to the TPs for a 90-day toxicity, a PNDT and a carcinogenicity study (which was rejected), MSC concluded to amend the section I of both split DDs accordingly.

The Chair recognised the results of voting on DD (TPE-124A/2012) relating to TP for a two-generation RDT study, as provided for the current meeting and amended in the meeting by MSC 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 from that for previous similar cases (otherwise SECR would use the justification provided by the four members before in similar cases). ECHA will refer the case (TPE-124A/2012) to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

Concerning DD (TPE-124B/2012) relating to TPs for a 90-day toxicity, a PNDT and a carcinogenicity study (which was rejected), MSC found unanimous agreement on ECHA's DD as provided for the current meeting and amended in the meeting by MSC based on the above conclusions.

TPE-139/2012 A mixture of: α-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl-ω-hydroxypoly(oxyethylene); α-3-(3-(2H-benzotriazol-

2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl-ω-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)-propionyloxypoly(oxyethylene) (EC No. 400-830-7)

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 three MSC members suggesting to add a reminder to the Registrant that effects seen in available RDT studies may already be sufficient for classification of the substance as toxic for reproduction category 1B and that PNDT study on the second species may not be needed. MSC supported this suggestion and concluded to add the suggested reminder to DD. MSC also concluded based on the discussions under agenda point *6a1* to clarify in the reminder that if the classification is possible and available toxicity data are adequate to support a robust risk assessment, the information requirement for a PNDT study in the second species could be adapted according to column 2 of 8.7, Annex X.

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

e. Update of MSC working procedures on dossier evaluation

MSC adopted the working procedures without any changes. SECR replied to questions that although not part of the working procedures (1) information on appeal cases will be provided to MSC as appropriate and (2) dossier evaluation DDs as agreed in MSC meetings will be uploaded to MSC CIRCABC without undue delay.

f. Update on appeal cases

MSC took note of ECHA's report.

Item 7 – Substance evaluation

1) CoRAP

a) Report by ECHA on the work for draft annual CoRAP update

SECR in its presentation informed MSC that the preliminary draft CoRAP as it stands during the time of the meeting, has a total of 117 substances out of which 65 substances are new. 15 MS expressed their interest to evaluate these additional 65 substances for the years 2013-2015. The draft CoRAP would be submitted to MSC to prepare its opinion on it on 12 October 2012 and published on ECHA website (a public version) by end of October. Final opinion of MSC would be adopted at MSC-28 meeting (beginning of February 2013). SECR also informed MSC on the complementary part to CoRAP based on Articles 135 and 136 of REACH that was published on 5 September 2012 on the ECHA website including 44 pending NONS cases and 7 pending existing substance cases.

During the discussion reference was made to the 100 substances originally communicated by COM that should be present in CoRAP for evaluation per year. However SECR explained that this is not a legal requirement and that the number of substances per year is dependent on the capacity of the MSs in relation to how many substances they can evaluate and on the finding of meaningful substances to evaluation, i.e. substances with a potential concern of causing risk.

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

SECR briefly introduced the draft mandate of the rapporteur and co-rapporteur. This followed the same mandate adopted for the previous opinion drafting. MSC adopted the mandate as proposed by SECR.

c) Appointment of Rapporteur

SECR explained that two members volunteered one for rapporteur and the other one for co-rapporteur. MSC appointed the volunteering members as rapporteur and co-rapporteur.

d) Establishment of a working group to support the Rapporteur

MSC agreed that based on the experience from the previous opinion writing, the establishment of a working group (WG) is beneficial. Thus MSC decided to establish the WG, adopted its mandate as proposed by SECR and agreed on its members. Three members had volunteered in writing whilst six volunteered orally. Thus the WG including the rapporteur and co-rapporteur consists of a total of nine members.

2) Substance evaluation process

a) Case owners' participation to MSC discussions

SECR explained in the introduction that because of the upcoming webinar to Registrants on substance evaluation, the lead registrant workshop, the development of a leaflet giving tips to Registrants and Downstream Users (DUs) on substance evaluation and the drafting of the working procedures for MSC consultation on substance evaluation, SECR would need to know whether MSC agrees in principle to invite case owners during MSC discussions on substance evaluation. MSC agreed to invite case owners for such discussions and to hold such discussions in the same way as for dossier evaluation DDs, where the Registrant is invited for Session 1 of the discussion held in an open session but not for Session 2 of the discussion which is held in a closed session. Some observers highlighted the complication of the substance evaluation process over the dossier evaluation process. SECR recognised such a complication especially when more than one Registrant or DU is affected by the substance evaluation decision. However, how to tackle this in practice still needs further discussion in the upcoming MSC-26 meeting in the context of the working procedure on MSC consultation for substance evaluation discussion.

b) Updates to registration dossiers during substance evaluation

A member introduced a memo that was submitted as a room document to MSC presenting their proposal of how to deal with updates to registration dossiers, especially when a large number of registration dossier updates are received on the substance that is being evaluated by the MS. The member proposed that updates to the registration dossiers would not be taken into account during the substance evaluation, i.e. between the time when evaluation was started and when the first DD was prepared and submitted to Registrants/DUs. The updates would be considered only when comments were provided by the Registrants/DUs on the DD and when the evaluating MS would prepare the response to comments document based on Registrant's comments. It was suggested that in any case there should be a cut-off date by when such updates could be considered by the evaluating MS. Updates received after that cut-off date would then be considered by the evaluating MS after the Registrant(s)/DUs have submitted their comments on the first substance evaluation DD. It was pointed out that some legal considerations would also be needed to examine whether the proposed approach would be possible.

It was recognised that a cut-off date is needed. However, the point at which such a cut-off point should be established was still left open. Industry representatives highlighted the importance of upfront communication of the evaluating MS with the registrants/DUs involved and the agreement of such a cut-off date. Since REACH is a Regulation it is directly applicable to all MS and the line to be taken should be consistent amongst all MS.

Chair concluded that no position could be taken at this stage and that further discussion on the matter will take place in the next MSC meeting, MSC-26.

Item 8 – SVHC identification

a. Information about new SVHC proposals

SECR informed MSC about SVHC proposals submitted in the 2nd round for 2012 for which the public consultation is currently ongoing. It was pointed out that some of the proposals may require specific attention of MSC, such as the SVHC proposals to identify five PBT/vPvB, three respiratory sensitisers to be identified under Article 57 (f), a group of substances degrading to an identified SVHC and two proposed endocrine disruptors posing probably adverse effects to the environment to be identified under Article 57 (f). It was also mentioned that based on COM request, ECHA has prepared SVHC Annex XV proposals for 37 CMR substances listed in Annex VI of CLP Regulation.

Several members and industry observers expressed their concern as regards the submission of 37 SVHC proposals on COM request without RMO analyses and not having the substances included in the Registry of Intention but shortly before the start of the public consultation. It was suggested to SECR to consider possible extension of the public consultation deadline for providing the industry with more time for consideration and commenting. SECR explained that due to the tight legally binding deadlines extension of the public consultation period would not be possible. It was also pointed out that the role of the Candidate List should be re-discussed between the MSs. Some observers representing NGOs and worker protection organisations expressed their satisfaction with the step undertaken.

SECR pointed out that the RMO analysis will be developed for these 37 substances. However, this will not happen before the end of the SVHC process and it would not affect ID of SVHCs which has to be based on the criteria of Article 57.

MSC agreed that the issue and concerns regarding COM request to ECHA to submit SVHC Annex XV dossiers for 37 substances are more relevant for CARACAL consideration than for MSC. The task of MSC is to deal with the SVHC proposals if they are to be addressed in the MSC process.

The COM observer further explained the reasons for their request to ECHA, pointing out on the importance to meet the political target for inclusion of 136 SVHC in the Candidate List by end of 2012 and clarifying that RMO analyses on the 37 substances will be prepared and considered in the RiME group. Members were also informed that COM intends to be in close contact with MSCAs during the ongoing process.

In conclusion, the Chair noted that MSC will be further informed of the outcome of the public consultation and further steps to be taken under the ongoing SVHC process.

b. Identification of sensitisers as SVHCs under Article 57 (f) of REACH

SECR presented the draft paper explaining the general approach on how to identify sensitisers as SVHC under Article 57 (f) of REACH. It is proposed that starting point for such identification would be a substance with harmonised C&L under the CLP Regulation due to its sensitising properties and other elements, such as substance potency, dose-response relationship and reactivity should be further considered. Some generic aspects were also suggested to be considered when a substance is identified as SVHC based on skin or respiratory sensitisation.

MSC members and observers expressed their appreciation with the presented document. It was noted that in practise it is difficult to divide the respiratory sensitisers into sub-categories 1A or 1B as there is currently no standardised test guideline for such experimental testing; thus, it is not become clear whether such division could be used as basis of identification under Article 57 (f) until such time as validated animal models for testing of respiratory sensitisation are available; if

Art. 57 (f) should be used for identification of SVHC based on the sensitising property case-specific argumentation should be presented justifying why the substance is considered to be of 'equivalent level of concern'. All sensitisers would most likely not qualify to be identified as SVHCs under Article 57 (f). Some further comments were mentioned such as: whether societal concerns should be covered under SVHC process or later on in the authorisation process; when comparing level of concern between reprotoxicants and sensitisers, delay between the exposure and effect is not always relevant argument due to the fact that the adverse health effects caused by some reprotoxicants occur instantly; the SVHC identification of respiratory sensitisers might be easier than skin sensitisers, thus it might be useful to further compare skin and respiratory sensitisers.

Several MSC observers representing worker protection organisations and NGOs welcomed the proposed approach that will allow the identification and inclusion of sensitisers in the Candidate List, pointing out that these substances are of great concern for workers causing in many cases skin and/or respiratory sensitisation. SECR was also requested to consider developing similar approaches for SVHC identification of substances due to their neurotoxicity and for which threshold could be specified. The industry observers also highlighted that sensitisers are of significant concern for companies and actions are taken to eliminate the risk. Some other arguments as regards SVHC identification of sensitisers were suggested to be considered as additional criteria, such as whether a substance is causing effects to healthy workers or only to ones with asthma diseases; whether a threshold (and even cut-off values) can be defined for a sensitiser and whether effective RMMs are already implemented.

SECR agreed with comments and stressed the importance of case-by-case assessment for SVHC identification of sensitising substances is the approach to be followed. SECR noted that according to the proposed approach, different aspects related to intrinsic properties (sensitising) of the substance should be considered in a holistic way when identification of such a substance under Article 57 (f) is proposed.

The MSC Chair thanked MSC for the good suggestions and invited the Committee to send their written comments on the draft paper by 8 October 2012.

Item 9 – Preparations for the opinion on ECHA's 4th draft recommendation of priority substances to be included in Annex XIV

SECR gave some statistical data and a preliminary analysis of the comments received (204 in total) during the public consultation that ended on 19 September 2012. It was explained that most of the comments were received from the concerned industry and the most commented substance was DMAC, followed by the chromate compounds.

Thanks were expressed by SECR to the industry representatives that the industry associations and companies had combined their comments and there were only some repeated/copied comments.

An industry observer pointed out on the streamlined industry commenting, requesting for serious attention to be paid to each comment, as one single comment may represent the concerns of hundreds companies.

- **Development of MSC opinion on draft recommendation of priority substances to be included in Annex XIV – Initial plan by the Rapporteur**
    - Possible exchange of views on the draft recommendation and comments received

The MSC Rapporteur informed MSC of the work plan for developing an opinion on the 4th draft recommendation and of the start of the WG work on the 1st draft opinion that should be available for Committee's discussion at MSC-26 in October 2012. Members were requested to send their comments on the 4th draft recommendation and public consultation comments received by 1 October 2012 for their further uptake in the MSC opinion development.

Item 10 – Implementation of ECHA's Conflicts of Interest policy

a) Eligibility criteria for ECHA bodies

SECR explained to MSC the draft proposal on eligibility criteria for ECHA bodies focusing on potential conflict of interest aspects that would be presented to MB at its meeting on 28-29 September 2012. These criteria were well received especially by some STOs since according to them reputation takes quite a long time to be built but it can be easily lost. The Chair explained that MSC has already had in place rules regarding conflict of interest declarations since each member of MSC had to fill in declarations of interest from the start of their appointment. ECHA has recently, however, complemented the documents setting up its conflict of interest policy which would provide further guidance for assessment of potential conflict of interest. It was further explained that even though these eligibility criteria will be applicable for newly appointed members and renewals, MB will be provided with a preliminary assessment on the impact of these criteria on the current membership.

b) General principles and guidance for committee members

SECR introduced the general principles and guidance for Committee members regarding potential conflict of interest and explained that these are a follow up action arising from the visit of the Court of Auditors. These principles outline some responsibilities to the members. Some of the elements stem from existing documentation like the code of conduct for the members of MB that was recently adopted by MB. This document is not trying to overwrite REACH or RoPs. It was explained to members that these principles need to be applied with an element of common sense. Example if a member in his/her capacity as MSCA is being asked about a dossier that is under discussion at MSC, the member should refrain from such contact or else contact MSC SECR for advice. There may be some other more generic tasks of MSCAs which are not dossier specific that would not interfere with the member's role despite a specific dossier is under discussion at the Committee. An example of such tasks is to provide advice to the companies from the CA Help Desk. SECR also confirmed that these principles apply also to alternate members.

As follow-up actions, MSC was given one week to comment on the meeting document. This document would then have been discussed and commented by the three ECHA Committees. After improvement of the text and finalisation, these principles and guidance will become an ECHA decision and made available on the ECHA website.

Item 11 – Any other business

- Information about a study report on Costs and Practicalities of Two New OECD Guidelines

The Chair informed MSC about the recently released study report that deals with costs and practicalities of two new OECD guidelines that are relevant to MSC work (OECD 443 EOGRTS and OECD 488 Transgenic Rodent Somatic and Germ Cell Mutation Assay). It was also clarified that the Committee may also find the report on ECHA website where it was published with a brief note.

Two members, an expert and an industry observer expressed their views on the released study report and their willingness to discuss the study in a proper forum. The Chair pointed out that the study report was intended for MSC for information at this meeting, not for discussion and concluded that the report might be useful for MSC when considering some specific dossier- and/or substance- evaluation cases.

- Suggestions from members

No suggestions have been received by members under this agenda item.

Item 12 – Adoption of conclusions and action points

MSC adopted the conclusions and action points of MSC-25 at the meeting.

Signed

Anna-Liisa Sundquist

Chair of Member State Committee

II. List of attendees

Members/Alternate members
BIWER, Arno (LU)
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
HUMAR-JURIC, Tatjana (SI)
KORENROMP, Rene (NL)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina(CZ)
LUDBORZS, Arnis (LV)
LULEVA, Parvoleta (BG)
MARTIN; Esther (ES)
MIHALCEA-UDREA, Mariana (RO)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)[5]
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
Representatives of the Commission
KOBE,Andrej (DG ENV)
STRECK Georg (DG ENTR)
Observers
ANNYS, Erwin (CEFIC)
BUONSANTE, Vito A. (ClientEarth)
DROHMANN, Dieter (ORO)
FRANCHIOLI, Luigi (UEAPME)
LIGTHART, Jerker (ChemSec)
MUSU, Tony (ETUC)
SANTOS , Tatiana (EEB)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
BALOGH, Attila
BELL, David
BORNATOWICZ, Norbert
BRAUNSCHWEILER, Hannu
BROERE, William
CESNATIS, Romanas
CARLON, Claudio
DE COEN, Wim
DELOFF-BIAŁEK, Anna
DE WOLF, Watze
DOYLE, Simone
FEEHAN, Margaret
HUUSKONEN, Hannele
KARHU, Elina
KOJO, Anneli
KORJUS, Pia
LE CURIEUX, Frank
MÜLLER, Birgit
NAUR, Liina
PELLIZZATO, Francesca
REUTER, Ulrike
ROSSI, Laura
RUOSS, Jürgen
RÖCKE, Timo
RÖNTY, Kaisu
SCHÖNING, Gabriele
SIMON, Rupert
STILGENBAUER, Eric
SUMREIN, Abdel
TARAZONA, José
VAHTERISTO, Liisa
VASILEVA, Katya
VESENTINI, Damiano

Proxies

- PISTOLESE, Pietro (IT) also acting as proxy of CAMILLERI, Tristan (MT)
- COSGRAVE, Majella (IE) also acting as proxy of DOUGHERTY, Gary (UK)
- MARTÍN, Esther (ES) also acting as proxy of DRUGEON, Sylvie (FR)
- KOUTSODIMOU, Aglaia (EL) KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
- RUSNAK, Peter (SK) also acting as proxy of ANDRIJEWSKI, Michal (PL)
- DUNAUSKIENE, Lina (LT) also acting as proxy of STESSEL, Helmut (AT) on Thursday afternoon and on Friday
- TYLE, Henrik (DK) also acting as proxy of KORENROMP, René (NL) on Friday

Experts and advisers to MSC members

ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BLOM, Cécile (NO) (expert to REIERSON, Linda)
GRACZYK, Anna (PL) (expert to MAJKA, Jerzy)
INDANS, Ian (UK) (expert to DOUGHERTY, Gary)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
LUNDBERGH, Ivar (SE) (expert to FLODSTRÖM, Sten)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
ROSENTHAL, Esther (DE) (adviser to FINDENEGG, Helene)
RÜHL, Dana (DE) (expert to FINDENEGG, Helene)
TRAAS, Theo (NL) (expert to KORENROMP, René)
ULDUKIENE, Vilma (LT) (expert to DUNAUSKIENE, Lina)

By WEBEX-phone connection:

- DOUGHERTY, Gary (UK) during agenda items 6a1, 6a2 and general discussions on TPE 101-103/2012 and TPE 127-132/2012
- MICHEL, Cécile (FR) during item 6 a) and dossier evaluation on case TPE-139/2012,
- BERTATO Valentina, LUVARÀ Giuseppina, and BORRAS Anna from DG ENTR during agenda items 8 and 9
- GARCÍA-JOHN, Enrique from DG ENTR during open sessions

Case owners:

Representatives of the Registrant were attending under agenda item 6c for category for TPE-127-132/2012, CCH-034/2012, TPE-105/2012 and CCH-035/2012.

Apologies:

Michal ANDRIJEWSKI (PL)
Tristan CAMILLERI (MT)
Ana Lúcia CRUZ (PT)
Gary DOUGHERTY (UK)
Sylvie DRUGEON (FR)
Tasoula KYPRIANIDOU-LEONTIDOU (CY)

III. Final Agenda

Agenda

25th meeting of the Member State Committee

19-21 September 2012
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

19 September: **starts at 9:00**
21 September**: ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/025/2012
For adoption

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

Item 4 – Administrative issues

- MSC Rules of Procedure (RoPs)

For information

Item 5 – Adoption of the draft minutes of the MSC-24

MSC/M/24/2012
For adoption

Item 6 – Dossier evaluation
Closed session for 6a2, 6d & 6g
Indicative time plan for 6c is Day 1& 2, for 6d Day 2 & 3

a. General topics:

3. Issues in REACH related to CMR classification category 1 and the implemented risk management measures

For discussion and conclusion

2. **Applicability of testing proposals using a read across approach *(Closed session)***

For discussion and conclusion

3. **Selection of first species for prenatal developmental toxicity study if other reproduction toxicity studies are required**

For discussion

4. **Status report on ongoing evaluation work**

For information

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

ECHA/MSC-25/2012/001

For information

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

For discussion followed by agreement seeking under 6d:

- TPE-127/2012 Diammonium dihydrogen ethylenediaminetetraacetate (EC No. 244-063-4)
  ECHA/MSC-25/2012/018-19
- TPE-128/2012 Edetic acid (EC No. 200-449-4)
  ECHA/MSC-25/2012/020-21
- TPE-129/2012 Disodium dihydrogen ethylenediaminetetraacetate (EC No. 205-358-3)
  ECHA/MSC-25/2012/022-23
- TPE-130/2012 Tetraammonium ethylenediaminetetraacetate (EC No. 245-022-3)
  ECHA/MSC-25/2012/024-25
- TPE-131/2012 Tetrasodium ethylenediaminetetraacetate (EC No. 200-573-9)
  ECHA/MSC-25/2012/026-27
- TPE-132/2012 Triammonium hydrogen ethylenediaminetetraacetate (EC No. 240-073-8)
  ECHA/MSC-25/2012/028-29
- TPE-101/2012 2,2'-[oxybis(methylene)]-bis[2-ethylpropane-1,3-diol] (EC No. 245-509-0)
  ECHA/MSC-25/2012/008-9
- TPE-102/2012 2,2,2',2'-Tetrakis(hydroxymethyl)-3,3`-oxydipropan-1-ol (EC No. 204-794-1)
  ECHA/MSC-25/2012/010-11
- TPE-103/2012 2,2-Bis(hydroxymethyl)-1,3-propanediol (pentaerythritol) (EC No. 204-104-9
  ECHA/MSC-25/2012/012-13

- CCH-034/2012 Hydrogenated dimerization products of 1-decene, 1-dodecene and 1-octene (List No. 700-308-1)
ECHA/MSC-25/2012/002-3

- TPE-105/2012 Hydrogenated dimerization products of 1-decene, 1-dodecene and 1-octene (List No. 700-308-1)
ECHA/MSC-25/2012/014-15

- CCH-035/2012 2-Dimethylaminoethyl methacrylate (EC No. 220-688-8)
ECHA/MSC-25/2012/006-7

- TPE-108/2012 Dilauroyl peroxide (EC No. 203-326-3)
ECHA/MSC-25/2012/035-36

- TPE-135/2012 Hexane-1,6-diol (EC No. 211-074-0)
ECHA/MSC-25/2012/030-31

For information and discussion

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

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

- TPE-116/2012 Sodium permanganate (EC No. 233-251-1)
ECHA/MSC/D/2012/244

- TPE-124A&B/2012 Hexaboron dizinc undecaoxide (EC No. 235-804-2)
ECHA/MSC/D/2012/258 & 259

- TPE-139/2012 A mixture of: α-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl-ω-hydroxypoly(oxyethylene); α-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl-ω-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)-propionyloxypoly(oxyethylene) (EC No. 400-830-7)
ECHA/MSC/D/2012/272

For agreement

e. Update of MSC working procedures on dossier evaluation

ECHA/MSC-25/2012/016

For adoption

f. Update on appeal cases *(Closed session)*

For information and discussion

Item 7 – Substance evaluation

1) CoRAP

a) Report by ECHA on the work for draft annual CoRAP update

For information

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

ECHA/MSC-25/2012/033

For discussion & decision

c) Appointment of Rapporteur

For discussion & decision

d) Establishment of a working group to support the Rapporteur

ECHA/MSC-25/2012/034

For discussion & decision

2) Substance evaluation process

- **Case owners' participation to MSC discussions**

For discussion

Item 8 – SVHC identification

a. Information about new SVHC proposals

For information

b. Identification of sensitisers as SVHCs under Article 57 f of REACH

ECHA/MSC-25/2012/032

For information and discussion

Item 9 – Preparations for the opinion on ECHA's 4th draft recommendation of priority substances to be included in Annex XIV

- **Development of the MSC opinion on draft recommendation of priority substances to be included in Annex XIV – Initial plan by the Rapporteur**
  - Possible exchange of views on the draft recommendation and comments received

For discussion

Item 10 – Implementation of ECHA's Conflicts of Interest policy

a) Eligibility criteria for ECHA bodies

For information

b) General principles and guidance for committee members

ECHA/MSC-25/2012/017

For information

Item 11 – Any other business

- Information about a study report on Costs and Practicalities of Two New OECD Guidelines

ECHA/MSC-25/2012/037

- Suggestions from members

For information

Item 12 – Adoption of conclusions and action points

- Table with conclusions and action points from MSC-25

For adoption

IV. Main Conclusions and Action Points (adopted at the MSC-25 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
5. Adoption of the minutes of MSC-24	
MSC adopted the revised draft minutes with a minor modification done at the meeting.	MSC-S to upload final version of the minutes on MSC CIRCABC by 24 September 2012.
6. Dossier evaluation **6a) General Topics**	
4. Issues in REACH related to CMR classification category 1 and the implemented risk management measures MSC concluded that no general approach can be agreed and applied to draft decisions where classification is a concern and therefore these cases need to be handled on a case-by-case basis and different scenarios considered in that context. However, MSC acknowledged that MSC does not have the remit to impose on the registrant to apply any specific self-classification. MSC can invite the registrant to consider classification based on available data. It was recognised that adaptation of information requirements of Annex IX, 8.7 would require two conditions: that the substance is a known CMR cat 1 and the risk management measures have been implemented (CM)/data are sufficient for robust risk assessment(R). **5. Applicability of testing proposals using a read across approach** MSC agreed that concerning read-across in testing proposals ECHA can apply the present approach and treat as testing proposals (as indicated in the dossiers by the registrants) indications that testing is proposed on an analogue substance. When experience has been gained on the cases in the pipeline a new discussion on the approach will take place. **6. Selection of species for prenatal developmental toxicity study if other reproduction toxicity studies are required** MSC agreed that in future decisions concerning PNDT study, the decision on selection of the first species, rat or rabbit, for a PNDT study should be left up to the discretion of the registrant. Exceptional selection of the species by MSC will require case specific assessment and justification. Selection of other species by the registrant has to be specifically justified. **4. Status report on ongoing evaluation work** MSC took note of the report.	MSC to keep the current approach for testing proposals for high-production volume chemicals (1 December 2012 deadline).
6. Dossier evaluation **6b) 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-25/2012/001.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	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-25/2012/001.
6c) Introduction to and preliminary discussion on draft decisions (DD) on compliance checks after MSCAs' reactions *(Session 1, open session)* **6d) Seeking agreement on draft decisions (DD) on compliance checks when amendments were proposed by MSCAs *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions as revised during the meeting where appropriate of: - TPE-127/2012 Diammonium dihydrogen ethylenediaminetetraacetate (EC No. 244-063-4) - TPE-128/2012 Edetic acid (EC No. 200-449-4) - TPE-129/2012 Disodium dihydrogen ethylenediaminetetraacetate (EC No. 205-358-3) - TPE-130/2012 Tetraammonium ethylenediaminetetraacetate (EC No. 245-022-3) - TPE-131/2012 Tetrasodium ethylenediaminetetraacetate (EC No. 200-573-9) - TPE-132/2012 Triammonium hydrogen ethylenediaminetetraacetate (EC No. 240-073-8) - TPE-101/2012 2,2'-[oxybis(methylene)]-bis[2-ethylpropane-1,3-diol] (EC No. 245-509-0) - TPE-102/2012 2,2,2',2'-Tetrakis(hydroxymethyl)-3,3`-oxydipropan-1-ol (EC No. 204-794-1) - TPE -103/2012 2,2-Bis(hydroxymethyl)-1,3-propanediol (pentaerythritol) (EC No. 204-104-9 - CCH-034/2012 Hydrogenated dimerization products of 1-decene, 1-dodecene and 1-octene (List No. 700-308-1) - TPE-105/2012 Hydrogenated dimerization products of 1-decene, 1-dodecene and 1-octene (List No. 700-308-1) - CCH-035/2012 2-Dimethylaminoethyl methacrylate (EC No. 220-688-8) - TPE-108/2012 Dilauroyl peroxide (EC No. 203-326-3) - TPE-135/2012 Hexane-1,6-diol (EC No. 211-074-0) - TPE-116/2012 Sodium permanganate (EC No. 233-251-1) - TPE-124B/2012 Hexaboron dizinc undecaoxide (EC No. 235-804-	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
2) - TPE-139/2012 A mixture of: α-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl-ω-hydroxypoly(oxyethylene); α-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl-ω-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)-propionyloxypoly(oxyethylene) (EC No. 400-830-7) MSC could not reach unanimous agreement on the following draft decision: - TPE-124A/2012 Hexaboron dizinc undecaoxide (EC No. 235-804-2) 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 case TPE-124A/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).
6f) Update of MSC working procedures on dossier evaluation	
MSC adopted the updated working procedures without changes.	MSC-S to upload the adopted document to MSC CIRCABC and ECHA website. MSC-S to upload agreed versions of the modified DDs on CIRCABC after the meeting.
7 Substance evaluation	
1) CoRAP ***a) Report by ECHA on the work for draft annual CoRAP update***	SECR will present to MSC the leaflet being drafted to give tips to Registrants and Downstream Users on substance evaluation in MSC meeting in October.
b) Tasks of the Rapporteur in drafting the opinion of the MSC MSC adopted the tasks of the Rapporteur and Co-Rapporteur in drafting the opinion of the MSC on the draft annual CORAP update of ECHA as presented in the meeting.	
c) Appointment of Rapporteur MSC appointed a Rapporteur and Co-Rapporteur for the drafting of the opinion of the MSC on the draft annual CORAP update of ECHA.	SECR to send the letters of appointment to Rapporteur and Co-Rapporteur. Rapporteur and Co-Rapporteur to fill in and sign the declaration of commitment and the declaration of absence of any conflict of interest after receipt of the letter of appointment.
d) Establishment of a working group to support the Rapporteur MSC established a working group to support the Rapporteur and Co-Rapporteur. The working group is made up of a total of	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
nine MSC members including the Rapporteur and Co-Rapporteur.	
2) Substance evaluation process **a) Case owners' participation to MSC discussions** MSC agreed in principle to invite case owners to participate in the MSC discussion for substance evaluation draft decisions. **b) Updates to registration dossiers during substance evaluation**	MSC to discuss the details and practicalities on case owner participation, in MSC-26 in October 2012 in the context of the working procedures for MSC on substance evaluation. The member that submitted the initial paper for this meeting to prepare a second paper based on the discussion in MSC-25 to be further discussed in MSC-26 in October.
8. SVHC identification	
b) Identification of sensitisers as SVHCs under Article 57 f of REACH MSC took note of the presented draft paper on identification of sensitisers as SVHCs under Article 57 (f).	Members to provide written comments on the draft paper by 8 October 2012.
9. Preparations for the opinion on ECHA's 4th draft recommendation of priority substances to be included in Annex XIV **- Development of the MSC opinion on draft recommendation of priority substances to be included in Annex XIV – Initial plan by the Rapporteur** - Possible exchange of views on the draft recommendation and comments received	
	MSC members to send their comments on the 4th draft recommendation and comments received to MSC-S by 1 October 2012. Input to be considered by the Rapporteur in the MSC opinion development.
10. Implementation of ECHA's Conflicts of Interest policy	
a) Eligibility criteria for ECHA bodies **b) General principles and guidance for committee members**	SECR to take note of the discussion and to consider the appropriate way to document the proposals. Members to provide any further comments by 28 September 2012.
15. Adoption of conclusions and action points	
MSC adopted the conclusions and action points of MSC-25.	MSC-S to upload the MSC-25 conclusions and action points by 24 September 2012.

V. STATEMENT OF DK MSC MEMBER

(TO AGENDA POINT 6a2)

The Danish preference to handle testing proposals is the following:

- accept TP on the substance which has been proposed to be tested
- reject TP on the analogues which the Registrant has proposed
- to apply read across in the future and at the same time deem the cases inadmissible as TP cases because the TPs do not concern the substance on which the TP has been made
- share with the Registrant in a communication letter the concern regarding the validity and acceptability of the plausibility of the intended read across as judged based on the currently available information
- inform the Registrant that a final judgement of the validity of the intended read across can not be made but may be considered and concluded if this read across case will be prioritised for a future targeted CCH

However DK has decided not to vote against the DDs of cases TPE 101-103/2012 in MSC-25 even though it is maintained as a TP-case but also made clear that this did not imply that DK is of the opinion that this is the optimal solution or that similar cases should be dealt with in this way in the future. DK encouraged ECHA to consider this generic issue in relation to how such cases should be treated at the next tonnage band but accepted ECHA's approach at this tonnage band because of ECHA's reference to practicalities with ongoing dossier evaluation work in ECHA.

VI. Dossier evaluation cases addressed for MSC agreement seeking in WP

Cases unanimously agreed by MSC in WP:

MSC ID number	Substance name used in draft decision	EC No
TPE 099/2012	N,N-dimethyldecan-1-amide (Decanamide, N,N-dimethyl-)	238-405-1
TPE 100/2012	N-(C16-C18)alkyl(C16-C18)alkane-1-amine (Amines, di-C16-18 (even numbered) alkyl)	To be defined
TPE 104/2012	Trimethylolpropan [Propylidynetrimethanol]	201-074-9
TPE 106B/2012	2,2'-(octadec-9-enylimino)bisethanol (Bis(2-hydroxyethyl) oleyl amine)	246-807-3
TPE 107/2012	N-butyltin trichloride	214-263-6
TPE 110/2012	Tricyclodecanedimethanol	248-096-5
TPE 112/2012	1,3-dioxepane	208-015-6
TPE 115/2012	Benzyldimethylamine	203-149-1
TPE 117B/2012	Bis(2-(2-butoxyethoxy)ethoxy)methane	205-598-9
TPE 119/2012	N,N,N',N',N'-Pentamethyl-N-C16-18 (even numbered) C18 unsat.-alkyl-1,3-propanediammonium chloride	629-716-7
TPE 122/2012	Amides, C8-18(even-numbered) and C18(unsatd.), N-(2-hydroxypropyl)	931-596-9
TPE 123B/2012	Vinyl neononanoate	259-160-7
TPE 125/2012	N-Butylbenzene-sulphonamide	222-823-6
TPE 126/2012	N-[2-(piperazin-1-yl)ethyl]C18-unsatured-alkylamide	629-767-5
TPE 133B/2012	Alkenes, C11-12, hydroformylation products, distn. residues	292-427-6
TPE 134/2012	Alkyl dimethyl betaine	931-700-2
TPE 136/2012	List No 920-762-6	920-762-6
TPE 138/2012	Ammonium iron(3+) hexakis(cyano-C)ferrate(4-)	247-304-1
TPE 140/2012	Alcohols, lanolin	232-430-1
TPE 141B/2012	N-methylaniline	202-870-9

Cases to be referred to COM:

MSC ID number	Substance name used in draft decision	EC No
TPE 106A/2012	2,2'-(octadec-9-enylimino)bisethanol (Bis(2-hydroxyethyl) oleyl amine)	246-807-3
TPE 117A/2012	Bis(2-(2-butoxyethoxy)ethoxy)methane	205-598-9
TPE 118/2012	Potassium cyanate	209-676-3
TPE 123A/2012	Vinyl neononanoate	259-160-7

TPE 133A/2012	Alkenes, C11-12, hydroformylation products, distn. residues	292-427-6
TPE 141A/2012	N-methylaniline	202-870-9

Cases for which WP was terminated (with further agreement seeking in the MSC-25 meeting):

MSC ID number	Substance name used in draft decision	EC No
TPE 116/2012	Sodium permanganate	233-251-1
TPE 124A/2012	Hexaboron dizinc undecaoxide	235-804-2
TPE 124B/2012	Hexaboron dizinc undecaoxide	235-804-2
TPE 139/2012	A mixture of: α-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl)propionyl-ω-hydroxypoly(oxyethylene); α-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl) propionyl-ω-3-(3-(2H-benzotriazol-2-yl)-5-tert-butyl-4-hydroxyphenyl) propionyloxypoly(oxyethylene)	400-830-7