MSC/M/028/2013
ADOPTED by written procedure
on 28 March 2013

Minutes
of the 28th Meeting of the Member State Committee (MSC-28)
5-7 February 2013

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 28th 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

Following a member's request, a sub-item was included under Item 10 AOB for ECHA feedback on the follow-up of the expert workshop on TGR versus UDS in genotoxicity testing. The Agenda was then adopted as provided for the meeting by the MSC Secretariat with one small cancellation (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

- **Satisfaction survey – oral report**

SECR thanked all the respondents and provided an oral report of the results. It was explained that responses were received from 26 members or alternate members and seven out of 14 stakeholder observers (StOs). This 2012 survey included more questions that are more targeted to MSC than the previous one. Overall, satisfaction of members was high on all aspects of MSC work except for the support provided by ECHA as regards training where 'medium satisfaction' was reached. Outcome for StOs was 'medium satisfaction', except for the level of transparency and publication of the MSC outcomes was 'low' (28% were very satisfied or satisfied, and actually 43% were dissatisfied or very dissatisfied). Written feedback was considered very useful and can help SECR to improve in its work and explain often the reasons for some responses.

Following the meeting a written report would be provided on CIRCABC and SECR would need to pick up any lessons learnt and apply them in an action plan as appropriate. Then SECR asked the Committee for feedback on the type of training that they wish to get.

The Chair reminded the Committee that there are specific confidentiality reasons why some of the documents are not provided to StOs, however, an improvement was made since now the presentations of the dossier evaluation cases are being provided to the StOs before the meeting.

- **Annual declarations for the membership**

The Committee was reminded to fill in, sign and hand-in to SECR the commitment declarations and the annual declaration of interest forms during the meeting.

- **General principles and guidance for Committee members**

SECR informed the Committee that the commenting round of the document has been finalised and is available on CIRCABC under general documents and would soon be made available on ECHA website.

Item 5 – Adoption of the minutes of the MSC-27 meeting

SECR presented the revised version of the MSC-27 minutes informing MSC that written comments on the draft minutes were received by four MSC members prior to the MSC-28 meeting. Two representatives of two Registrants for two dossier evaluation cases who had participated in MSC-27 have also been 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 few slight 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 nine dossier evaluation cases (see Section V for more detailed identification of the cases). WP was launched on 11 January and closed on 21 January 2013. For two cases, the draft decision (DD) was split thus resulting in two DDs for these cases and overall 11 DDs for the nine cases. By the closing date, responses to WP were received from 25 members with voting rights and from the Norwegian member. Unanimous agreement was reached on six DDs. For three DDs involving the standard information requirement for Annex X, 8.7.3, four votes indicated disagreement, 19 votes were in favour of these three DDs 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. For two DDs the WP was terminated by the MSC Chair on 21 January 2013 on the basis of Article 20.6 of the MSC Rules of Procedure as one MSC member for case requested meeting discussion at the MSC-28 meeting.

b. General topics

- **Current Chronic aquatic toxicity testing approach for Testing Proposals**

ECHA in a presentation introduced the concerns of a Competent Authority (CA) submitted in a proposal for amendment (PfA) for case TPE-176 and as a comment for case TPE-179. This CA stated that in cases like the above two where due to low water solubility the substance is difficult to test, no conclusion can be made from acute aquatic toxicity tests regarding the sensitivity of Daphnia or fish which could be used for determination of the most sensitive species for long-term tests. Therefore, in the view of the submitting CA both chronic fish and Daphnia study needs to be conducted. ECHA also noted that according to the currently applied approach that had also been agreed upon by MSC earlier, in similar cases of testing proposal (TP) examinations first the Daphnia test is required. When based on the results of the Daphnia test a risk is indicated, the Registrant in the draft decision (DD) is reminded to consider submitting a TP for the chronic fish test as well.

In the discussion, the MSC expert representing the Member State (MS) of the submitting CA maintained their PfA. She also pointed out that the above scenario is not covered by the current guidance document. Also she clarified that the main driver for their proposal was rather the low water solubility and the fact that consequentially no inter-species difference in sensitivity for long-term tests can be established but not the specific mode of action of some constituents of the registered substance.

ECHA and some MSC members acknowledged the relevance of the issue raised in PfA. One MSC member also proposed that as the fish flow through test is technically more reliable than Daphnia, it could be justified that the fish test should be carried out first. The same member also proposed not to refer in these scenarios for CSA with a specific assessment factor (AF) 50 as indicated by the guidance for another type of situation (where sensitivity can be established) but rather to leave the choice of the appropriate AF with the Registrant.

ECHA agreed that the scenario at hand is not covered by the guidance and therefore, the relevant guidance needs updating as soon as possible in accordance with the relevant guidance update procedures. ECHA also pointed out that in TP DDs the chronic fish test cannot be required unless proposed by the registrant. However, a compliance check (CCH) can be opened on the dossier and the fish test can be required in the CCH process if considered appropriate.

MSC agreed that ECHA's present standard approach shall be changed. In future similar scenarios where based on the low solubility of the substance no difference in sensitivity between Daphnia and fish in acute aquatic toxicity testing can be made no reference to

a specific assessment factor (AF) under CSA should be made but the choice of the appropriate AF should be left with the Registrant. MSC also agreed that in similar cases a sentence should be added in the statement of reasons (SoR) of DD highlighting that in case a risk is indicated based on the Daphnia study, a TP for a long-term fish test needs to be submitted.

Some MSC members expressed their wish to revise the agreed changes any time if needed based on more experience gained with similar cases.

The Chair concluded that ECHA will apply the agreed change in the approach as an interim standard approach in the future from the current meeting onwards (including case TPE-176). However, MSCAs can always submit PfAs if they think the approach is not applicable in a specific case.

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

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

TPE-176/2012 Vegeflux soy (EC No. 483-980-6)

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.

ECHA explained that one PfA to ECHA's DD had been submitted suggesting to request a long-term toxicity study not only on *Daphnia magna* (as proposed by the Registrant) but also on fish based on the justification that no clear difference in the sensitivity of aquatic species could be concluded from the results of acute aquatic toxicity tests. The same PfA had also indicated that the substance contains a small amount of epoxides and therefore chronic fish toxicity cannot be excluded.

ECHA Secretariat did not modify DD based on PfA. The DD updated with procedural steps was provided to MSC for finding unanimous agreement.

The Registrant did not provide any comments on PfAs.

In the discussion, in accordance with the outcome of the discussions under agenda point 6 (b), MSC supported ECHA's view that only the chronic Daphnia test should be requested. Also, MSC concluded that according to the interim standard approach agreed under agenda point 6(b), the reference to AF 50 should be removed from DD and a sentence saying that in case a risk is indicated based on the Daphnia study, a TP for a long-term fish test needs to be submitted should be added.

MSC also agreed that similar cases flagged by MSC as illustrative for a need for future guidance update should be collected by MSC Secretariat and made available on MSC CIRCABC. The MSC expert representing the MSCA that submitted the PfA agreed to prepare a thought starter for MSC for the future update of the relevant guidance based on the current case.

Session 2 (closed)

MSC found unanimous agreement on ECHA's DD as amended in the meeting based on the above conclusions.

TPE-182/2012 Shale oils, heavy (List No. 930-690-7)

TPE-183/2012 Shale oils, light (List No. 923-592-0)

TPE-184/2012 Shale oils, middle (EC No. 269-646-0)

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.

ECHA explained that two PfAs to ECHA's DD had been submitted. One PfA suggested MSC discussion on whether the testing strategy proposed by the Registrant (performing

PNDT study for all three substances and deciding based on the results whether read-across can be applied to fulfil the other information requirements) is the most appropriate one. The second PfA suggested rejecting the PNDT studies based on the self-classification of the substances as carcinogenic category 1B and the implemented risk management measures (RMMs). MSC was asked to discuss application of Column 2 adaptations to information requirements for such substances.

ECHA Secretariat did not modify DD based on PfA. The DD updated with procedural steps was provided to MSC for finding unanimous agreement.

The Registrant in the comments on PfAs welcomed the PfAs and also felt that based on self-classification and the adequate RMMs in place additional data further exploring the hazards of the substances would not be of any ultimate benefit for the safe use of the substances. However, the Registrant acknowledged that some data on repeated dose toxicity should be gained on each of the three substances to decide whether and to which extent read-across can be applied to fulfil the other information requirements (SECR: no testing proposals for repeated dose toxicity are included in the dossiers). The Registrant also wondered whether further reduction of the use of animals could be reached if already the results of range finding studies could adequately demonstrate a similar toxicological profile of the three substances in a repeated dose regime.

In the discussion, the MSC expert representing the MSCA that submitted the PfA maintained the view that as the substance is self-classified as carcinogen category 1B according to CLP Regulation and proper risk management measures (RMM) are described in the registration dossier, a column 2 adaptation of the standard information requirements should be applied and the PNDT study should be rejected. He also argued that additional testing would not add anything to the safe use of the substance.

In his view, it is clear that the Registrant did not consider all the existing data particularly the conclusions of the review of the International Agency for Research on Cancer (IARC) identifying the shale oils as *carcinogenic to humans* with some evidence for a genotoxic mechanism. He also highlighted that the Registrant himself in the CSR does not exclude a non-threshold genotoxic mechanism.

ECHA and an MSC member reminded MSC that in earlier similar cases, where the Registrant despite of a self-classification proposed a test to verify the assumed properties of the registered substance the proposed tests had not been rejected. ECHA also highlighted that shale oils can considerably vary in composition according to the geographical location of the origin so the IARC status for shale oils might not be absolutely relevant for the registered substance. Also, as there is no clear evidence in the dossier that the substance is genotoxic and as the Registrant himself did not use the waiver either, in ECHA's view it would not be correct to take over the Registrant's responsibility to waive the PNDT test.

ECHA also mentioned that there are no intentions available at ECHA for a proposal for harmonised classification and labelling, and that the Registrant is a lead registrant and there is no guarantee that members of the joint registration will use the same classification. ECHA also noted that the question of non-threshold genotoxicity is relevant for the REACH authorisation process.

Based on the above discussions, MSC supported ECHA's view that there are doubts whether there is sufficient information available in the dossier to use the column 2 waiver and to reject the PNDT test proposed by the Registrant.

However, MSC generally supported and developed further the idea suggested in a room document (by the MSC member representing the MS of the CA that submitted the two PfAs) that the Registrant should be reminded that based on available information on the potential genotoxicity of the registered and related substances, a column 2 adaptation of the standard information requirements of 8.7.2 of Annex X might be applied. Also representatives of an industry stakeholder organisation (STO) and an NGO supported this idea. ECHA however emphasised that, in their view, it is not the task of ECHA to give advice to registrants of specific substances in the decisions how to use column 2 adaptations.

Session 2 (closed)

MSC concluded based on the above discussions that a paragraph in SoR should be added explaining why the conditions for an Annex X, 8.7 column 2 adaptations are currently not fulfilled and thus information was provided to the Registrant in the decision why MSC did not support the proposed PfA to reject the testing proposals.
MSC found unanimous agreement on ECHA's three DDs as amended in the meeting based on the above conclusion.

TPE-190/2012 Terphenyl, hydrogenated (EC No. 262-967-7)

Session 1 (open)

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

ECHA explained that two PfAs were submitted to ECHA's DD. Based on the PBT assessment of the substance carried out pursuant to Commission Regulation (EC) 465/2008, both PfAs suggest requesting the Registrant (1) to update the registration dossier with existing data relevant for PBT assessment and (2) to carry out the long-term Daphnia study not on the registered substance but on its representative constituents so that the data could be used for a PBT assessment. Also, both PfAs suggest requesting the Registrant considering sediment testing (e.g. on Chironomid or Lumbriculus) and testing on marine organisms as Chemical Safety Assessment (CSA) shows risk for marine water and freshwater/marine sediment.

ECHA Secretariat responded to PfAs and did not modify the DD in advance of the meeting. The DD 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 PfAs expressed the view that the proposed long-term toxicity study with the registered substance on *Daphnia magna* would enable for hazard assessment (PNEC derivation and environmental C&L) of the registered substance and therefore the test should be carried out on the registered substance and not on its representative constituents. The Registrant proposed that PBT assessment would be addressed separately from the current testing proposal examination.

In the discussion, following the introduction of the case by SECR, the Registrant reiterated what was expressed in the written comments that the main purpose of the submission of the test proposal is risk assessment and classification and labelling (C&L). This explains why the registrant is proposing to test on the UVCB substance and not on the constituents of the substances. The Water Accomodated Fraction (WAF) approach suggested by the registrant is thus the best way to test the full substance for the purpose of refining PNEC and specifying C&L. The member whose CA submitted PfAs asked for more details on the analytical method to be performed and the registrant explained that they intend to develop the WAF by identifying the loading concentration and the concentration in solution, i.e. the concentration the Daphnia will be exposed to. The registrant was also informed by the same member on the existence of new information giving BCF data on trout which would need to be taken into account in the PBT assessment.

Another member expressed verbally what was already stated in the PfA that since the CSA shows exposure to the sediment and marine compartment, it would be better if the sediment compartment is tested over the water compartment. The registrant explained that even though sediment testing may be a step that would be required, still the *Daphnia magna* test needs to be performed due to C&L reasoning. The result of such a test might lead to a different requirement for the sediment later on.

Regarding the PBT assessment, the registrant explained that if they will look at constituents above 0.1% concentration, due to the high number of constituents, and the in depth review that needs to be done, they would require between 6-9 months for the PBT assessment.

In the end of the discussion, it was concluded that the testing proposal could be accepted. However it was strongly recommended to the registrant to perform the PBT assessment of the substance and it was emphasised that the Registrant needs to consider the concerns raised by the PfAs. Thus the registrant may also need to come back with further testing proposals to clarify the PBT properties of the substance. This is especially needed since the new Annex XIII criteria for PBT substances will enter into force on 19 March 2013.

Session 2 (closed)

MSC found unanimous agreement on ECHA's DD as provided for the meeting and based on the conclusions of the discussion. It was agreed to highlight in the minutes of the meeting the need for the registrant to update the PBT assessment based on the constituents of the UVCB substance.

CCH-060/2012 Bis(2-ethylhexyl) adipate (EC No. 203-090-1)

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. The member as he already did in his PfA suggested not to request a PNDT study in rabbits as the second species mainly because rabbits seem insensitive to developmental toxicity of one of the secondary metabolites 2-ethylhexaoic acid (EHA) of the registered substance. He also provided more detailed arguments for his position in a room document and as an alternative to the rejection of the test in rabbits he proposed to add a reminder to the Registrant about the waiving possibilities based on already available data.

In the discussion, an MSC member highlighted that the substance is on the CoRAP list to be evaluated by her MS for developmental toxicity concerns and in her view the PNDT test on rabbits is needed to address these concerns. ECHA pointed out that the studies on metabolites referred to by the MSCA that proposed the rejection of the test were performed according to old guidelines i.e. with shorter exposure time not covering the whole gestational period. Furthermore, there are no data on rabbits with the registered substance and available data with metabolites which are more than only EHA, are not conclusive.

After the MSC member that proposed the rejection of the test agreed that the available information is not sufficient for rejection and that an already existing paragraph in the SoR sufficiently addresses the waiving possibilities, MSC concluded that only minor editorial changes are needed in DD.

MSC found unanimous agreement on ECHA's DD as amended in the meeting based on the above conclusion.

TPE-185/2012 [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (EC 246-678-3)

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 the MSC member from the MSCA who submitted the only PfA on the DD suggesting inhalation route to be used for the 90-day repeated dose toxicity study instead of the oral route as proposed. The PfA was based on concern for local effects due to the chemical being peroxide, and exposure concerns due to testing with dilutions (40% instead of 100%) and worker processes indicating elevated temperature not considered in the RCOM.

The member presented the PfA by using a Room Document explaining more in detail the reasoning for the PfA followed by further SECR's clarification on the main considerations for proposing oral instead of inhalation route for the study. Further, the member stated that, although some concerns remain, his CA will not insist on their PfA on the DD.

MSC found unanimous agreement on ECHA's DD as provided for the meeting.

e. Items for discussion following commenting by MSCAs (*Closed session)*

MSC agreed on a way forward of how CAs can submit comments and editorials to ECHA.

f. Status report on on-going evaluation work

SECR gave detailed statistics on the status of evaluation work until 31 December 2012 and informed MSC of the recently published 72 final decisions as sent to the registrants (34 CCH and 48 TPE decisions in total). Some statistics regarding the latest MSC-28 round were introduced and the expected workload for 2013 was outlined.

MSC took note of the report. As several members expressed CA-resource related concerns with regard to the expected 285 DDs for the MSC-30 round, the SECR noted of its intention to facilitate to the maximal extend the MSCA work by possible grouping of the similar DDs and levelling the expected peak as far as possible.

Item 7 – Substance evaluation

a) CoRAP:

a. Discussion on the MSC opinion on the draft Community Rolling Action Plan (CoRAP)

SECR introduced the room documents showing the updates to the draft CoRAP that was published on ECHA website in October 2012. SECR went through the room document explaining the changes made. The same changes made were also reflected in the opinion prepared by MSC. Two substances were removed, two substances had the legal basis changed, one substance was postponed for evaluation to a later year whilst two substances had a footnote added to them explaining the future way forward. Some changes were requested from MSCAs as a final editing request. These were also included in the updated draft CoRAP in the room document.

The Rapporteur presented the draft opinion considering also the latest changes made to the draft CoRAP.

In the discussion it was stressed by a member, ECHA and industry alike that registrants of different but similar substances should be encouraged to work together in the same way MSCAs are encouraged to work together. An industry representative explained that in some cases it is possible for registrants to work together if they are in the same consortium. But if they are in different consortia or else are dealing with confidential information, then cooperation is more difficult.

In addition, some members proposed some editorial changes to the opinion which were included in the draft opinion by the Rapporteur.

The Rapporteur presented as well lessons learnt on behalf of the entire working group, during the drafting of this opinion. This was found to be very helpful by ECHA to improve the process for next round.

b. Adoption of the MSC opinion

MSC adopted the supportive opinion on the annual CoRAP update and its annex by consensus, as amended during the meeting. It was concluded that the MSC opinion together with the final update to CoRAP will be published on the ECHA website on 20 March 2013.

Furthermore, members raised more questions on the practicalities following the adoption of the opinion and the publication of the annual CoRAP update, like signing of the contracts and receipt of the aggregated dossiers.

b) *Substance evaluation*

SECR introduced in a presentation the lessons learnt from the consistency screening exercise of MSCAs' initial draft decisions on substance evaluation that was just finished few days before the MSC meeting. The members and StOs alike, showed great appreciation for sharing of this information. This is a voluntary exercise without any

legal obligation for ECHA, and most of the Substance Evaluation (SEV) DDs were sent for consistency screening just before Christmas, i.e. right at the deadline. Out of the 36 substances for 2012 SEV assessment, 32 requested consistency screening. In the consistency screening comments ECHA highlighted that DD needs to link clearly the information request and justification for the request with the concern.

Several other issues were raised by members, such as the need for easy communication on technical submission issues, dealing with dossier updates during the SEV process and the role of the SEV process in setting DNELs, assessment factors and correct RMMs.

During the discussion SECR further clarified that regarding the safety assessment the evaluating MSCA cannot request in the SEV DD a certain assessment factor to be used by the registrant. Evaluating MSCA can however ask the registrant to justify the choice of an assessment factor. If a specific assessment factor is deemed to be very important by the MSCA for the management of the risk, then it would be possible to propose under another legislative process to establish for example a European wide binding exposure limit or a DNEL.

Regarding the data gaps which can be addressed in a compliance check and the relationship of the identified data gaps with substance evaluation, it was explained that the data gaps can be indicated as reasons to request the information under SEV DD. Particular attention is, however, needed in the phrasing of the request in the SEV DD, i.e. that the request for information is linked to the concern and not to the standard information requirements. However, it was agreed that the relationship between dossier evaluation and substance evaluation needs to be further investigated so as to avoid having to ask the registrant for tests under dossier evaluation and substance evaluation. SECR pointed out that several of these more strategic issues will be further discussed during the intended SEV workshop in May 2013.

A member asked for ECHA's plans on the sending of the SEV DDs to the registrants without undue delay and if certain outstanding issues in the DD can still be discussed with ECHA before sending to registrant. SECR explained that in principle the SEV DD has to be ready by the submission deadline and ECHA should only act as a post box. Only editorial changes could be done at this stage but no fundamental changes would any more be possible. It was also explained that without undue delay would mean that the SEV DD would be sent to the registrants for their comments within four weeks' time.

Regarding tiered testing, a member explained that this might be needed for the very complicated cases like PBT and endocrine disrupting substances, since the result of the first test might trigger further testing. SECR explained that whilst ECHA has tried to advice in the consistency screening to avoid such testing yet in some cases such as indicated by the member (i.e. PBT and endocrine disrupting substances) it may be the only pragmatic and scientific approach. This however, needs further discussion.

SECR promised to send personal contact details of experts in the submission pipeline to assist the MSCAs with the submission of their SEV DD and SEV report. SECR reminded that the CAs are welcome to ask for further clarifications based on the ECHA feedback by contacting the substance manager indicated for each substance.

Regarding the SEV report SECR explained that there is no peer review planned especially at this stage since at this point of the process the SEV report is considered as a background document to the DD and there would be no time to peer review and finalise the SEV report before submission of the SEV DDs. The DD has to be a self-standing document which should explain the reasons for requesting of further information.

If however, at this point of time, the registrant asks the MSCA for the SEV report, it is up to the MSCA to decide, but special attention has to be given not to distribute confidential information. On the other hand, when the SEV is concluded and the SEV report would need to be finalised and published, then ECHA might consider a form of consistency screening to ensure consistency and proper handling of confidential

information. The final SEV decision will also be published, in the same way as the dossier evaluation decisions are currently published.

To this a StO asked SECR to reconsider the approach on SEV report since they strongly believe that the SEV report would be useful to let the registrants understand the reasons for further information requests and therefore the report should be part of the package that will be sent to the registrant in the first 30 day consultation period. This StO explained that specification of an undue delay is not the most important issue for the registrants but he proposed to make clear to the registrants the timelines by when they would be receiving the SEV DDs. He made a suggestion to provide the draft decisions in batches.

SECR explained that the timeline for registrants is quite clear since the SEV DDs need to be prepared by 28 February 2013 and for almost all 36 substances, registrants should expect a DD very soon. SECR would communicate via the ECHA website further information to the registrants on when to expect the DDs on specific substances.

Item 8 – Authorisation process

a. SVHC identification process and ECHA's recommendation of priority substances for Annex XIV

SECR gave a brief report on the MSC-27 follow-up with regard to the inclusion of the recently identified 54 SVHCs and the publication of the updated Candidate List on 19 December 2012 followed by the submission to the Commission of ECHA's 4th recommendation for inclusion of priority substances in Annex XIV on 17th January 2013. MSC was further informed about the recently submitted 10 Annex XV proposals for identification as SVHCs of which six substances have been proposed as SVHCs due to their PBT/vPvB properties and three based on Article 57 f (equivalent level of concern) - some of these together with a CMR concern. Members were also informed of the process timelines for the 01/2013 SVHC round.

MSC was informed of the intended applications for authorisation as well as that the first application submission date has passed without any applications sent to ECHA.

A STO observer presented some industry observations related to the preparation of authorisation applications. Specific workshops and briefings were organised jointly by ECHA and industry associations to increase awareness of the requirements. Based on discussion in different fora it seems likely that in many cases the downstream users will apply for authorisation of their uses instead of manufacturers or importers. This is contrary to what was originally assumed and it will potentially make the number of applications higher than expected. Furthermore, some suggestions for improvement of different stages of the authorisation process were brought for further Secretariat's consideration. The MSC Chair thanked the industry observer for the interesting experience shared, although not directly relevant to the authorisation stages with MSC involvement.

b. Prioritisation of Candidate List substances for inclusion in Annex XIV

1) Proposals of MSC regarding prioritisation approach

2) Plan for the next recommendation for inclusion of substances in Annex XIV and outline for review of the prioritisation approach

The Secretariat introduced the plans how ECHA intends to proceed in the preparation of the 5th recommendation of substances for inclusion in Annex XIV. Timing-wise the plan is to follow similar timelines as previously, with the aim to start the public consultation of the draft recommendation after mid-June this year. As regards the assessment of substances which are currently on the Candidate List for their potential priority, SECR explained the way it plans to work. Assessment work will concentrate on the substances that have been added on the Candidate List in 2012 and for which there is a sufficient dataset available to work on (i.e. Part II developed in Annex XV report and full registrations available). Previously assessed but not prioritised substances would only

be re-assessed if they have a similar priority as the last substance of the new prioritised substances. The latest registration data would be taken into account for such re-assessment. It was emphasised by SECR that for this round the assessment of priority of substances follows the current prioritisation approach that has been in use since 2010.

Questions of clarification were raised in the discussion that followed, mainly about the approach to be used for the substances that were assessed previously. In its response SECR explained that in any reassessment it is not merely whether an update of a dossier has been provided but one will also need to evaluate if the update relates to the triggers that had led to the non-prioritisation. Also due to capacity reasons, full assessment upfront was not considered as a best approach for this round.

Following that, MSC was presented ECHA's planning on how the current prioritisation process is to be updated. SECR explained that the need for some revision derives from the fact that the information basis has evolved since 2010 as registrations are the primary source of information. Besides that, the experience gained in applying the current approach has revealed that the level of detail available for the substances is not always suitable or sufficient for prioritisation purposes. The scheme at present seems not fit to the data available on uses and exposures in the registration dossiers or to information submitted in the public consultations.

In the discussion MSC welcomed the review work. Some suggestions for improvement had been submitted in writing by members, and those and some more were introduced and discussed.

Several members called for review on the definition of wide dispersive use and how it is applied. Some interventions called for a more simple and robust approach. One member raised a question if other means of getting further information had been investigated, in particular as regards data from downstream users. This was supported as many uncertainties are linked to that type of information. Few members stressed that a longer timeframe would be useful to allow MSC and MSCA's to discuss even before the public consultation step. Other elements like the choice of the risk management option, economic impact of the authorisation on the companies and on the supply chain, usefulness of the public consultation in getting more correct information on uses and exposures as well as practical possibilities to make authorisation manageable (e.g. longer time for the latest application dates) were raised for consideration in the context of the prioritisation process.

One stakeholder observer welcomed some rethinking on the prioritisation. He suggested to have balance on the level of information needed from industry side as any investments in preparing necessary datasets should then also be something that are used by ECHA as well.

SECR reminded about the role and tasks of MSC as specified in REACH recalling that the work is limited to scientific and technical argumentation and excludes policy considerations.

SECR explained that the aim of the review is also to increase clarity and predictability of the process for industry, other stakeholders and MSCAs. SECR reminded MSC about the purpose of prioritisation in the authorisation process and that the prioritisation criteria of Article 58(3) are the basis for the review work as well as about the scope of ECHA's work in general at each step of the authorisation process, including its Committees. It was emphasised that no risk assessment or socio-economic analysis is carried out for the prioritisation step.

It was pointed out that the final objective, according to Article 59(1) and Recital 77, is to eventually (finally) include all substances from the candidate list to the authorisation list. Through the prioritisation exercise it is considered which substances will go to the authorisation list before others. In these considerations the number of substances to be prioritised in one round has to be taken into account bearing mind the workload for the applicants, Agency and the authorities.

It was stressed by SECR that analysis of different risk management options (RMOs), even if very useful before submission of Annex XV SVHC dossiers, is not part of the prioritisation step. The MSC Chair reminded that MSC is clearly not the venue to discuss efficiency, suitability and economic implications of the possible risk management instruments. One member presented in MSC a proposal for further discussion on the usefulness of different RMOs as part of the Annex XIV prioritisation process.

In the concluding remarks it was noted that policy considerations should ideally happen early on in the process and they should also be in line with the Commission SVHC Road map to 2020. Further discussions on how to carry out and when to discuss risk management option analysis should be continued in other fora, such as CARACAL

The Chair summarised that SECR will start reviewing the present priority setting approach paper. In any case the priority setting approach must be based on the criteria of Article 58(3). The aim is to have a simplified and robust approach which is based on data available in registration dossiers. The approach should ensure predictability and transparency. The first draft for a revised document is intended for discussion at MSC-30 in June 2013.

Item 9 – Update to MSC Rules of procedure

SECR introduced the proposed changes to the MSC RoPs. The RoPs were reviewed to be able to allow case-owners be present in the discussions on substance evaluation draft decisions in the same way as in the dossier evaluation process (Article 6(8) and 6(13)). At the same time clarification was introduced that abstention from a vote in the MSC decision making does not challenge the unanimity of the MSC (Articles 19(5), 19(7) and 20(3)). When modifying the RoPs in this respect the rules applied by the Council of Ministers were followed. Some other adjustments were also introduced.

MSC endorsed the proposed modifications to the RoPs. SECR will provide the modified RoPs for approval at the next Management Board meeting in March.

The Chair thanked for endorsement of the modified RoPs. She concluded that SECR does not encourage deliberate abstentions at the vote of MSC although after modification of RoPs abstentions would be explicitly recognised. The MSC members have been appointed to make decisions and SECR is confident that normally the members will take the responsibility to vote as until now. SECR will, however, follow functioning of the revised RoPs and will take measures to correct the situation if it turns out to be necessary.

Item 10 – Any other business

- **Suggestions from members**

SECR gave an update on the technical discussion session on UDS and TGR assays. It was explained that the consultation period for comments on the conclusions of this technical discussion closed on the week before MSC-28 however, the conclusions are still not yet finalised. Once finalised, these would be published on the ECHA website and provided for MSC. MSC would then need to consider the regulatory implications of these conclusions. Following this technical discussion, SECR explained that the current approach for dossier evaluation is that when there is no data, the default test to request in the frame of compliance check is the TGR. However if the registrant submitted a UDS result to fulfil the endpoint, normally no further testing with TGR would be required. With regards to testing proposal examinations, if UDS is proposed by the registrant, it can be challenged based on substance-specific reasons and TGR requested instead. Several members noted that at this stage, the scientific consensus of the workshop is not yet available and thus, the scientifically most acceptable approach on TGR/UDS in the context of dossier evaluation cannot yet be established. In the end, the science serves the policy goals for risk assessment and classification and labelling, using the best available science to minimise risks.

Since ECHA would like to communicate the conclusions once finalised also in a guidance update, the different options available for such guidance update were explained to the Committee. The most preferred route however, is to do a normal consultation process executed at high speed where PEG, MSC/RAC and CARACAL are consulted. The consultation would be restricted to specific parts of the guidance only and thus the process could be speeded up. The guidance update would be possible to achieve in six months if there is consensus both on the science and policy.

Item 11 – Adoption of conclusions and action points

MSC adopted the conclusions and action points of MSC-28 at the meeting (see Section IV).

Signed
Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
BIWER, Arno (LU)
COSGRAVE, Majella (IE)
CRUZ, Ana Lúcia (PT)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
HUMAR-JURIC, Tatjana (SI)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina(CZ)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
LONDESBOROUGH, Susan (FI)
MARTIN, Esther (ES)
MIHALCEA-UDREA, Mariana (RO)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TRAAS, Theo (NL)
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)
BASTIJANCIC-KOKIC, Biserka (HR)
DE KNECHT, Joop (OECD)
DROHMANN, Dieter (ORO)
MUSU, Tony (ETUC)
POOLE, Alan (ECETOC)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
BALOGH, Attila
BROERE, William
CARLON, Claudio
DE COEN, Wim
DE WOLF, Watze
FEEHAN, Margaret
HAUTAMÄKI, Anne
KARHU, Elina
KORJUS, Pia
LE CURIEUX, Frank
MONTERO RAMIREZ, Manuel
MÜLLER, Birgit
NAUR, Liina
NOUWEN, Johan
REGIL, Pablo
RUOSS, Jürgen
RÖNTY, Kaisu
SOBANSKA, Marta
SUNDQUIST, Anna-Liisa
VAHTERISTO, Liisa
VASILEVA, Katya
ZANDER, Joakim

Proxies

- PISTOLESE, Pietro (IT) also acting as proxy of CAMILLERI, Tristan (MT)
- RUSNAK, Peter (SK) also acting as proxy of ANDRIJEWSKI, Michal (PL)
- KOUTSODIMOU, Aglaia (EL) also acting as proxy of LULEVA, Parvoleta (BG)

Experts and advisers to MSC members

ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
DOBRAK-VAN BRELO, Agnieszka (BE) (expert to VANDERSTEEN, Kelly)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
INDANS, Ian (UK) (expert to DOUGHERTY, Gary)
JUFFERNHOLTZ, Tanja (DE) (expert to FINDENEGG, Helene)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LUNDBERGH, Ivar (SE) (expert to FLODSTRÖM, Sten)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)

PIPIRAITE-VALISKIENE, Donata (LT) (expert to DUNAUSKIENE, Lina)
WIJMENGA, Jan (NL) (expert to TRAAS, Theo)

By WEBEX-phone connection:
BECKER Claudia (DE), DROST Wiebke (DE) and RUEHL Dana (DE) during agenda items 6b and 6d; SMITH Helen (UK) during agenda item 6c; LAGRIFFOUL Arnaud (FR) during agenda items 7 and 8; GARCÍA-JOHN Enrique, BERTATO Valentina, LUVARÀ Giuseppina, BORRAS HERRERO Anna, ROZWADOWSKI Jacek and GIRAL-ROEBLING Anne from EC during agenda items 7 and 8.

Case owners:
Representatives of the Registrant were attending under agenda item 6c for TPE-190/2012.

Apologies:
ANDRIJEWSKI, Michal (PL)
CAMILLERI, Tristan (MT)
LULEVA, Parvoleta (BG)
TALASNIEMI, Petteri (FI)

III. Final Agenda

ECHA/MSC-28/2012/A/28 FINAL

Agenda

28th meeting of the Member State Committee

5-7 February 2013
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

5 February: **starts at 14:00**
7 February**: ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/028/2013

For adoption

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

Item 4 – Administrative issues

- Satisfaction survey – oral report

For information

Item 5 – Adoption of the draft minutes of the MSC-27

MSC/M/27/2012

For adoption

Item 6 – Dossier evaluation

Closed session for 6d&e

Indicative time plan for 6c is Day 1, for 6d Day 2 to 3

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

ECHA/MSC-28/2013/001

For information

b. General topics

- Current Chronic aquatic toxicity testing approach for Testing Proposals

For information and discussion

c. 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 6d:

ECHA/MSC-28/2013/002

Testing proposals

- TPE-176/2012 Vegeflux soy (EC No. 483-980-6)

ECHA/MSC-28/2013/003-4

- TPE-182/2012 Shale oils, heavy (List number 930-690-7)

ECHA/MSC-28/2013/005-6

- TPE-183/2012 Shale oils, light (List number 923-592-0)

ECHA/MSC-28/2013/007-8

- **TPE-184/2012** Distillates (shale oil), middle fraction (EC No. 269-646-0)

ECHA/MSC-28/2013/009-10

- TPE-190/2012 Terphenyl, hydrogenated (EC No 262-967-7)

ECHA/MSC-28/2013/011-12

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 the following cases returned from written procedure for agreement seeking in the meeting[1]

Compliance checks

- CCH-060/2012 Bis(2-ethylhexyl) adipate (EC No. 203-090-1)

ECHA/MSC/D/2013/004-005

For agreement

Testing proposals

- TPE- 185/2012 [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (EC 246-678-3)

ECHA/MSC/D/2013/015-016

For agreement

e. Items for discussion following commenting by MSCAs *(Closed session)*

Items from current cases if not addressed during 6c

For discussion

f. Status report on ongoing evaluation work

For information

Item 7 – Substance evaluation

c) CoRAP:

c. Discussion on the MSC opinion on the draft Community Rolling Action Plan (CoRAP)

d. Adoption of the MSC opinion

ECHA/MSC-28/2013/015

For discussion and adoption

[1] Note to members: The documents listed below are available in the substance specific folders in CIRCABC, as were made available for the written procedure, and are not available in the MSC-28 folders.

d) *Substance evaluation*

- Lessons learnt from consistency screening of substance evaluation draft decisions

For information and discussion

Item 8 – Authorisation process

a. SVHC identification process and ECHA's recommendation of priority substances for Annex XIV – Short status report by the secretariat

For information

b. Prioritisation of Candidate List substances for inclusion in Annex XIV

Discussion on

1) Proposals of MSC regarding prioritisation approach

ECHA/MSC-28/2013/016

2) Plan for the next recommendation for inclusion of substances in Annex XIV and outline for review of the prioritisation approach

For information and discussion

Item 9 – Update to MSC Rules of procedure

- Draft update to MSC Rules of procedure

ECHA/MSC-28/2013/013

For endorsement

Item 10 – Any other business

- Suggestions from members : follow up of the expert workshop on TGR versus UDS in genotoxicity testing

For information

Item 11– Adoption of conclusions and action points

- Table with conclusions and action points from MSC-28

For adoption

IV. Main Conclusions and Action Points (adopted at the MSC-28 meeting)

Main conclusions and action points
MSC-28, 5-7 February 2013
(adopted at the MSC-28 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 - Administrative issues • **Satisfaction survey**	
MSC took note of the oral report given by the Secretariat.	MSC-S to upload the report from the 2012 Satisfaction Survey on MSC CIRCABC when finalised.
Item 5 - Adoption of the draft minutes of the MSC-27	
MSC adopted the draft minutes with modifications proposed by members in writing before the meeting and few slight modifications made in the meeting.	MSC-S to upload final version of the minutes on MSC CIRCABC by 12 February 2013.
Item 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/cover letters on cases agreed in written procedure, as indicated in document ECHA/MSC-28/2013/001. • MSC-S to provide COM for further decision making with documents (DDs, RCOMs, extract of minutes, outcome of the vote, justifications for NO votes) of cases on which MSC did not reach agreement, as indicated in document ECHA/MSC-28/2013/001.
6b. General topics • **Current Chronic aquatic toxicity testing approach for Testing Proposals**	
MSC agreed that in testing proposal DDs where based on acute toxicity tests no inter-species difference in sensitivity between Daphnia and fish due to the low solubility of the substance can be established, ECHA's current standard approach shall be changed: in future similar cases including TPE-176 to be agreed upon at the current meeting DDs shall not specifically refer to assessment factor (AF) 50 but shall leave the choice of relevant AF up to the discretion of the registrant.	• ECHA to apply as an interim solution the agreed approach in testing proposal DDs accordingly. • ECHA to consider the scenario in question for the next update of the relevant guidance

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	document. • MSC-S to set up a folder under MSC CIRCABC for items and thought starters that should be raised in the context of guidance updates.
6c. Introduction to and preliminary discussion on draft decisions on testing proposals after MS-CA reactions (Session 1, open) **6d. 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: • CCH-060/2012 Bis(2-ethylhexyl) adipate (EC No. 203-090-1) • TPE-176/2012 Vegeflux soy (EC No. 483-980-6) • TPE-182/2012 Shale oils, heavy (List No. 930-690-7 • TPE-183/2012 Shale oils, light (List No. 923-592-0) • TPE-184/2012 Distillates (shale oil), middle fraction (EC No.269-646-0) • TPE-185/2012 [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide (EC No. 246-678-3) • TPE-190/2012 Terphenyl, hydrogenated (EC No. 262-967-7)	MSC-S to upload on MSC CIRCABC the final ECHA decisions/cover letters of the agreed cases.
Item 7 – Substance evaluation **7a. CoRAP**	
2). Adoption of the MSC opinion MSC adopted by consensus the draft opinion and its Annex on the annual draft CoRAP update as modified in the meeting.	SECR to upload the MSC CoRAP opinion including its Annex on MSC CIRCABC. This will then be published on the ECHA website together with the annual CoRAP update on 20 March 2013.
7b. Substance evaluation **Lessons learnt from consistency screening of substance evaluation draft decisions**	
MSC took note of the learnings and SECR report.	• MSCAs to be in contact with the substance managers, as necessary, to clarify ECHA's feedback and with person(s) assisting in technical submission when help is needed. • MSCAs to send by 28 February 2013 the outcomes (IUCLID-dossier, DD, SEV report, timesheet) of substance evaluation to ECHA via the web form.
Item 8 – Authorisation process **8b. Prioritisation of Candidate List substances for inclusion in Annex XIV** **2) Plan for the next recommendation for inclusion of substances in Annex XIV and outline**	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
for review of the prioritisation approach	
MSC took note of the plan for the next recommendation and the way how substances for assessment for this round are selected. MSC welcomed the plan to review the prioritisation approach and made some further suggestions on what could be considered during that process.	• SECR to upload to the MSC CIRCABC after the meeting the list of substances envisaged for the assessment for possible prioritisation in the 5th ECHA draft recommendation. • ECHA to present the prioritisation results of the selected substances for 1st discussion in MSC in April. • ECHA to present its proposal for the approach update to MSC in June 2013.
Item 9 – Update to MSC Rules of procedure	
MSC endorsed the updated version of the MSC Rules of procedure, as provided and slightly modified in the meeting.	SECR to forward the endorsed version of the MSC RoPs to the ECHA MB for their approval after the meeting.
Item 10 – Any other business • **Progress report on UDS-TGR, in vivo tests for somatic cell gene mutation endpoint**	
	SECR to present to MSC the report from the technical session when finalised.
Item 11 – Adoption of conclusions and action points	
MSC adopted the conclusions and action points of MSC-28.	MSC-S to upload the conclusions and action points on MSC CIRCABC by 11 February 2013.

V. 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
CCH 059/2012	(E)-4-(2,6,6-trimethyl-1-cyclohexen-1-yl)-3-buten-2-one (IUC4 DSN 574)	201-224-3
TPE 175/2012	Pentaerythritol, reaction product with fatty acids, C8 to 18 (even numbered) and/or branched and/or unsaturated	484-420-3
TPE 177/2012	Dicyclopentyldimethoxysilane	404-370-8
TPE 178B/2012	Benzyl 3-isobutyryloxy-1-isopropyl-2,2-dimethylpropyl phthalate	240-920-1
TPE 180/2012	Polysulfides, di-tert-dodecyl	270-335-7
TPE 189B/2012	Triethoxy(2,4,4-trimethylpentyl)silane	252-558-1

Cases to be referred to COM:

MSC ID number	Substance name used in draft decision	EC No
TPE 178A/2012	Benzyl 3-isobutyryloxy-1-isopropyl-2,2-dimethylpropyl phthalate	240-920-1
TPE 189A/2012	Triethoxy(2,4,4-trimethylpentyl)silane	252-558-1
TPE 191/2012	2,5-Furandione, dihydro-, mono-C15-20-alkenyl derivs.	272-221-2

Cases whose written procedure was terminated:

MSC ID number	Substance name used in draft decision	EC No
CCH 060/2012	Bis(2-ethylhexyl) adipate	203-090-1
TPE 185/2012	[1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[tert-butyl] peroxide	246-678-3