MSC/M/023/2012
ADOPTED AT MSC-24

Final Minutes
of the 23rd Meeting of the Member State Committee (MSC-23)
24-27 April 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 23r^{d} 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 including the changes proposed by the MSC Secretariat (SECR). The 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

- **Meeting calendar for 2013**

MSC took note of the tentative meeting dates for 2013.

Item 5 – Adoption of the minutes and conclusions and action points of the MSC-22

- **Draft minutes of the MSC-22**

SECR presented to MSC the draft MSC-22 minutes and conclusions and action points (document MSC/M/22/2012). Written comments on the minutes were received from six MSC members and the SECR responses on them were provided. Representatives of Registrants who had participated in the meeting have been also consulted for their respective parts of the draft minutes. The public and confidential minutes were adopted including the changes suggested by the six members as well as an editorial change made at the meeting. The SECR would upload the minutes on MSC CIRCABC and on the ECHA website (public minutes).
The conclusions and action points were also adopted with the minutes including the comments made by three members as presented by SECR in writing, without further changes in the meeting.
The Chair explained that SECR would change the approach for the recording of conclusions and action points; instead of writing detailed conclusions that are adopted after the meeting in written procedure, it was proposed shortening them and adopt them during the meeting as per the original practice.

Item 6 – Dossier evaluation

a. General topics:

1. 2nd species in developmental toxicity testing

SECR gave a presentation on ECHA's current approach to the requirement for a prenatal developmental toxicity study in a second species (available for MSC members and stakeholders on MSC CIRCABC). Replying to questions ECHA clarified that if no classification harmonised on Community level is available for a substance ECHA has no power to impose on the Registrant other classification than the self classification of the Registrant. Regarding the selection of the first and second species, it was recognised that ECHA guidance could be improved and that the Registrant has the right to select the most appropriate species based on all available relevant information but also should provide sound justification for adaptation of the information requirement (waiving).

2. Selection of route of administration for human health higher tier testing

MSC took note of ECHA's presentation on selection of route of administration focusing on issues related to the 90-day study (available for MSC members and stakeholders on MSC CIRCABC). MSC generally supported ECHA's view that the decision for route of administration should be made on a case-by-case basis after carefully considering several factors such as route specific toxicity, exposure, Registrant's choice, availability of a reliable DNEL.

3. Read-Across Assessment Framework – development/principles of the second tier (Tier II)

SECR presented to MSC a systematic approach on how the Read Across Assessment Framework (RAAF) is planning to deal with read across submitted by Registrants at Tier II evaluation. The approach consisting of four steps - basic scenarios, conditions, scoring and dealing with uncertainty was very well received by the members. Comments raised by members related to 1) toxicokinetic information requirement as the basis for accepting read across but not a standard information requirement in REACH 2) how to deal with negative and positive read across 3) analysis not to rely on just the presence of trends since not all compounds in that trend could be related 4) how to better inform Registrants on how to properly document their read across 5) how to remove the subjectivity in the scoring approach presented between a read across that is rated as unconvincing or equivocal. To this SECR explained that this approach is still under development and that all the feedback from the members would be used to continue to build up this approach. In fact discussion is planned to continue with the Member State Competent Authorities (MSCAs) and stakeholder observers (StOs) in October 2012 in a workshop. However, preliminary responses were given to some aspects, most importantly explaining that several members of RAAF (i.e. ECHA experts) look at the same case individually and then they take jointly a decision and present it to ECHA Management in the attempt of reducing any subjectivity as much as possible.

4. Update by Commission representative on Use of the Extended One-Generation Reproductive Toxicity Study (EOGRTS) under REACH and CLP

The Commission (COM) representative explained that in March 2012 COM updated MSCAs and StOs in CARACAL on the update of the outcome of the expert group dealing with issues regarding implementation of EOGRTS. The full document is available on CIRCABC. In this document COM compiles its legal argumentation, information on practical consequences of implementation of EOGRTS and information on costs of this new method in its different modalities.
Based on estimations provided mainly by industry the costs of EOGRTS including 2nd generation with DIT/DNT cohorts are about 2,5 higher than the costs for the traditional two generation study. The most expensive part of the EOGRT testing seems to be performance of DIT and DNT cohorts. The number of animals used in the EOGRTS is clearly lower than in the two-generation study. In practical terms it is estimated that currently around 25 EOGRT tests can be performed per year by test laboratories. COM representative explained that there is clear intention to modify the annexes of REACH Regulation and to include EOGRTS in the Test Method Regulation. However, first COM proposes to request ECHA to ask the Risk Assessment Committee (RAC) for an opinion on the utility and applicability of TG 443 for classification and labelling as well as for risk assessment purposes.
One member explained that the prices reflect only the current situation and prices could decrease as more experience is gained by the labs and the request for such tests increase. Another member asked for clarity and background on the calculations and references made in the document. COM representative agreed to explore whether such information can be circulated. It was recognised that because of all the different steps that COM needs to take, a clear timeline for the

guidance update is not possible yet. One StO on the other hand showed frustration on the pace this issue is going to which the Chair also concluded that all parties would like to see EOGORTS implemented under REACH as soon as possible.

5. Proposal for organisation of the MSC work for high number of dossier evaluation cases *(Partly closed session)*

- **Feedback from case-owner and stakeholder participation discussion in the Management Board**

SECR introduced document (ECHA/MSC-23/2012/036) proposing ways how to organise MSC work in dossier evaluation cases in written procedures (WP), preparatory meetings before plenary sessions, plenary sessions and MSC documentation.

It was noted that as many cases as possible will be addressed in WPs. Regarding WP it was clarified that if a member wants to discuss a case that SECR chose for agreement seeking in WP, the members need to ask for termination of the WP. When 'NO' is chosen from the voting template, that means that the member does not agree with the DD and consequently the case will be referred to COM decision making. Since the current voting template does not include the option STOP to terminate the WP, it was agreed that this option should be included in the template. Members choosing STOP will need to briefly explain why they wish to discuss the case in the plenary and terminate the WP. It was agreed that cases that are terminated will normally be addressed in Session 2 of the plenary meeting only and normally only issues left open in the written procedure will be subject to discussion. If the member asking for termination wants the case to be addressed in Session 1, thus having the Registrant invited and giving the possibility for StOs to be present, this needs to be clearly stated in the justification. In response to a question from a StO asking for a possibility to get further information on WP cases, the Chair explained that the cases returned from WP are usually simple cases and no significant principal discussion normally takes place in Session 2 of the meeting on these cases.

Regarding preparatory meetings MSC recognised that Webex conferences are efficient and useful therefore it was agreed that these would continue. The preparatory meetings held before the plenary could on the other hand, help in clarifying the proposals for amendment (PfAs) and give more time to ECHA's Scientific Dossier Manager (SDM) to consider updates to the DD if necessary. This is expected to reduce the need for the drafting on the spot in the plenary meetings. It was thus concluded that this would continue and be reviewed after some time when experience has been gained.

Concerning plenary sessions it was agreed that to improve the discussion in plenary sessions and to reduce the need for redrafting at the plenary it would be beneficial if new versions of DDs would be discussed in smaller groups before presenting the drafts at the plenary Session 2 for agreement. SECR had proposed in the meeting document to restrict the speaking time in the plenary, Session 2, to reduce the time for such discussions. SECR considered that discussion at Session 2 would not require so much time any more taking into account the new arrangements with discussions in the preparatory meeting, in Session 1 and in smaller groups for reviewing the redrafted texts before presenting them in Session 2. Some members did not consider the proposal of the Secretariat appropriate and the Chair did not insist on it. However, it was emphasised by the Chair that for keeping the time of the plenary Session 2 reasonable and manageable the interventions need to be kept concise, brief and to the point.

About draft agreements, SECR proposed to stop the drafting of agreements on DD cases, since the outcome of the agreement seeking discussion is part of the procedural steps of DD and part of the MSC minutes as well. MSC agreed to this.

As regards experience of MSC on StO participation in Session 1 of the dossier evaluation cases discussion, SECR positively reported on the participation of StOs to the Management Board (MB). Even though this practice increased the workload of SECR yet SECR agreed to continue with this initiative. The Chair explained that the current Rules of Procedure (RoPs), do not allow any circulation of documentation to StOs. This precautionary approach was taken and accepted by MB since documents on dossier evaluation cases contain information on registration dossiers which normally contain confidential business information (CBI). Since the presentations made at meetings by SECR are cleaned from CBI it was proposed to MB to distribute these presentations to StOs and case-owners. MB left this matter to be discussed and decided by MSC. MSC agreed that the presentations prepared by SDM could be distributed to StOs and case-owners and therefore agreed that RoPs would need to be revised and sent to MB for agreement.

6. Status report on ongoing evaluation work

SECR gave an update on the status of evaluation work until the end of March 2012 including this time the number of cases whose comments received from third parties prompted the Registrants to remove their testing proposals (TPs) on receipt of DD (a total of three cases). MSC was also reminded on the upcoming substance evaluation workshop scheduled for 4-5 June 2012.

Further clarifications were requested on reasons for termination of a TP and withdrawal of TP due to third party comments. It was explained that TPs are commonly terminated either because of tonnage downgrade or else decision has to be withdrawn because testing was already ongoing by Registrant. Regarding withdrawal of TPs due to third party comments, this is due to the fact that data on a specific endpoint provided by the third party was considered adequate by Registrant/s.

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

SECR gave a report on the outcome of two WPs for agreement seeking on 37 substances (see Section V for the names of the dossier evaluation cases). First WP for agreement seeking on DDs for 28 substances was launched on 28 March 2012 and closed on 11 April 2012 and the second WP for agreement seeking on DDs for 12 substances was launched on 2 April and closed on 12 April 2012. For some substances, DDs had to be split thus resulting with two DDs for certain substances. By the closing dates, responses to each of these WPs were received from 25 members with voting rights and from the Norwegian member. Unanimous agreement was reached for 22 DDs. For nine DDs the WP was terminated by the MSC Chair on the basis of MSC member's request and they were referred to MSC-23 for agreement seeking. For 11 DDs four votes were indicating disagreement to the DDs, 19 votes were in favour of them and two MSC members did not vote. Thus, these 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

CCH-003/2012 Dichloro(dimethyl)silane (EC No. 200-901-0)

Session 1 (open)

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

SECR explained that one PfA proposed not to require the 90-day inhalation study with the registered substance because the substance hydrolyses rapidly to dimethylsilanediol and hydrochloric acid (HCl). It suggests, for local effects via inhalation, existing toxicity data from HCl would be sufficient for risk assessment of the registered substance and therefore Indicative Occupational Exposure Limit (IOEL) of HCl could be used to derive DNEL. For systemic effects, this PfA suggests ECHA requiring the 90-day study with the other hydrolysis product dimethylsilanediol. Another PfA expressed a very similar position. However, it suggested that HCl provides sufficient worker protection for both local and systemic effects and a 90-day study should not be required. Nevertheless, this PfA noted that if the 90-day study would be deemed necessary, it should be performed with the hydrolysis product dimethylsilanediol and not with the substance (read-across substance) the Registrant proposed to be used for testing. The third PfA suggested ECHA adding a reminder to the Registrant to consider all relevant available data and the result of the PNDT study on the first species, referring also to information requirement of Annex X, 8.7.3, before deciding whether or not a PNDT study on a second species is warranted.

ECHA modified the DD based on the third PfA and the results of an informal MSC discussion concerning the request for a PNDT study. The DD updated with procedural steps and the modifications on PNDT as indicated above since presented to MSCAs on 20 January 2012 was provided to MSC for finding unanimous agreement at the MSC-23 meeting.

The main issue for discussion was whether the registered substance would be available for the alveoli of the lungs (and systemic effects would be possible) as such or whether it would hydrolyse already fully in the air or in the upper part of the respiratory tract to HCl and dimethylsilanediol. If the hydrolysis takes place fully already in the air, or in the upper part of the respiratory tract then HCl will dominate the effects and no testing for systemic toxicity would be needed. According to SECR view no information was available on substance(s) a person would be exposed to: the registered substance, dimethylsilanediol or HCl, or a mixture of these.

Registrant's comments on the PfAs of the CAs and discussion

The Registrant agreed with the PfAs suggesting that no testing in 90 day study would be needed because of the rapid hydrolysis of the substance to HCl. Furthermore, the Registrant offers the possibility to ECHA and MS to include the 90-day subchronic toxicity data for hydrochloride (HCl) in the dossier to fullfill the legal requirements related to Annex IX from a formal aspect. If, however, testing would be considered necessary, the Registrant would be willing to test a proposed read-across substance with an additional control group exposed to methanol which is one of the metabolites of the read-across substance. The proposal was made because dimethylsilanediol is not volatile (VP around 7 Pa). Preliminary work has clearly indicated that it is not possible to test it via inhalation as requested by ECHA and MSs. The proposed read-across substance is volatile and inhalation testing would be possible. The Registrant also explained that there are technical issues associated with testing dimethylsilanediol e.g. stability issue: it will quickly polymerise in air due to humidity content. MSC did not support the Registrant's approach to test the read-across substance.

As the issue of hydrolysis of the substance in the air or breathing zone would be decisive for what to test or whether a test is needed the Registrant replied to MSC

members' questions that they are ready to investigate the speed of hydrolysis of the parent substance in the air.

MSC considered the Registrant's comments. MSC members concluded that the investigation of the behaviour of the parent substance in the air and in the breathing zone of experimental animals is essential for the decision on whether hydrochloride (HCl) does dominate the inhalation toxicity profile and if not, which substance should be tested.

Session 2 (closed)

MSC came to the conclusion that 90-day study (OECD 413 or EU B.29) with the registered substance shall be required conditionally: the Registrant, in a step-wise approach, shall determine whether 80% of the registered substance hydrolyses before reaching the experimental animals' breathing zone (step 1) and if not, whether the histopathological changes of the animals' respiratory tract are similar to those of HCl (step 2, range-finding study). If not, the Registrant shall conduct the 90-day study. If any of the results of the two steps is positive, the inhalation toxicity profile of the registered substance is considered to be dominated by HCl and the 90-day is not needed.

MSC found unanimous agreement on ECHA's DD as provided for the current meeting and further amended based on the above conclusions, and adopted the formal agreement.

CCH-004/2012 Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)- (EC No. 213-668-5)

Session 1 (open)

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

SECR explained that one PfA proposed not to require the 90-day inhalation study with the registered substance because the substance hydrolyses rapidly to trimethylsilanol and ammonia. According to this PfA, ammonia provides sufficient worker protection for both local and systemic effects and a 90-day study should not be required. The PfA suggested using IOEL of ammonia to derive DNEL for the registered substance. Nevertheless, it noted that if the 90-day study would be deemed necessary, it should be performed with the hydrolysis product trimethylsilanol. It also noted that the main effects of the registered substance observed only in pregnant female rats in an OECD 422 study (included in the registration dossier) might only be due to a higher susceptibility during pregnancy. Another PfA noted that the registered substance rapidly hydrolyses to highly corrosive ammonia (and trimethylsilanol) and therefore, ECHA should include recommendations in the DD to avoid use of exposure concentrations with clear corrosive effects in the respiratory tract. The third PfA suggested ECHA adding a reminder to the Registrant to take into account all relevant available data and the result of the PNDT study on the first species, referring also to information requirement of Annex X, 8.7.3, before deciding whether or not a PNDT study on a second species is warranted.

ECHA modified the DD based on the third PfA and the results of the written procedure before MSC-23 concerning the request for the second species in a PNDT study. The PfA concerning toxic effects of the registered substance observed in pregnant female rats was also taken into account in the modified DD. The DD updated with procedural steps and the modifications as indicated above since presented to MSCAs on 20 January 2012 was provided to MSC for finding unanimous agreement at the MSC-23 meeting.

Registrant's comments on the PfAs of the CAs and discussion

The Registrant agreed with the PfA that a 90 day study would not be necessary with the registered substance because corrosive ammonia due to rapid hydrolysis with water/humidity on mucous membranes of the upper respiratory tract would dominate the effects. However, if a 90 day study were considered to be necessary the Registrant would be willing to conduct it with trimethylsilanol which is the other hydrolysis product of the registered substance. If it seems to be relevant for ECHA and MSs the Registrant offered the possibility to include the 90-day subchronic toxicity data for ammonia in the dossier to fullfill the legal requirements related to Annex IX from a formal aspect.

MSC considered the Registrant's comments. It was noted by some members in the discussion that results included in the registration dossier on 28 day study indicate some systemic toxicity. MSC discussed whether systemic effects seen in the study with the registered substance are caused only by the hydrolysis product ammonia, by trimethylsilanol or by the parent substance itself and consequently, whether OEL of ammonia would provide enough protection for systemic effects. It was concluded that the available 28 day study shows that testing of the registered substance for repeated dose systemic toxicity is technically possible and systemic effects seem to have been caused by the exposure.

Session 2 (closed)

MSC agreed that as there is a data gap for the 90-day study and there is evidence in the registration dossier that exposure to the registered substance itself can cause systemic effects, 90-day testing via inhalation of the registered substance is necessary.

MSC found unanimous agreement on ECHA's DD as provided for the current meeting and further amended based on the above conclusions, and adopted the formal agreement.

TPE-002/2012 2,2-bis(hydroxymethyl)propionic acid (EC No. 225-306-3)

Session 1 (open)

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

SECR explained that two PfAs to ECHA's DD were submitted by two MSCAs proposing ECHA to modify DD on prenatal developmental toxicity (PNDT) testing by adding further advice for the Registrant to be taken into account when considering the PNDT study in the second species referring also to information requirement (IR) of Annex X, 8.7.3. Furthermore, it was proposed that the Registrant be requested to conduct the required 90 day repeated dose toxicity (RDT) study in rats via the inhalation route and not via the oral route.

Registrant's comments on the PfAs of the CAs and discussion

The Registrant in his written comments on the PfA as regards the proposed inhalation route for the 90-day study indicated that the substance is a known local irritant and that the effects in testing by inhalation are predictable. As the substance is of very low systemic toxicity and is classified as STOT SE 3, risk management measures are required where potential inhalation exposure is expected. The Registrant pointed out that that one of the uses (industrial spraying, PROC 7) indicating potential worker exposure by inhalation is found inappropriate and will be removed in the context of the update of the dossier. The Registrant confirmed willingness to test by oral route pointing out the technical difficulties of testing by inhalation which would lead to lower dose levels than in the oral testing of the substance making assessment of systemic toxicity uncertain. The Registrant did not comment on the other PfA. Further, he proposed the deadline for submission of information to be extended from 12 months to 18 months (no PfA on this issue).

MSC considered the Registrant's comments. SECR had modified the DD based on the PfA on PNDT, but no changes were done as regards the route of administration on RDT study.

Following the Registrant's further explanation in their written comments to the PfA on the most appropriate route for the 90-day study and the indication to withdraw the PROC 7 from the registration dossier, a member from the MSCA that made PfA agreed with the Registrant's argumentation that in this circumstances the oral route is the most appropriate route of administration for the 90-day study and accepted the oral route for the study.

Session 2 (closed)

MSC agreed with the Secretariat's proposal to extend the preliminary indicated deadline of 12 months to 24 months for the Registrant to submit the required information, following the current standard practice when sequential testing is required to be carried out. MSC found unanimous agreement on ECHA's DD as provided for the current meeting and further amended with regard to the deadline, and adopted the formal agreement.

TPE-010/2012 (substance name confidential)

Session 1 (closed)

A representative of the Registrant participated in the initial discussion. Due to specific confidentiality concerns as the substance is a NONS, the discussion was held in closed session.

SECR explained that three PfAs to ECHA's DD were submitted by two MSCAs. One MSCA disagrees with DD that PNDT study in a second species is a standard IR in Annex X, 8.7.2 and proposes to modify DD accordingly. Both MSCAs do not agree with DD that neurotoxicity and immunotoxicity cohorts (DIT/DNT) in Extended One Generation Reproductive Toxicity Study (EOGRTS, OECD TG 443) would be left to the discretion of the registrant. As indicated in DD ECHA agrees with the Registrant on substance specific argumentation and accepts the proposed testing strategy following a weight of evidence (WoE) approach based on Annex XI, 1.2 which would, under specific conditions, allow not producing F2 generation.

In response to the first PfA, SECR has modified DD addressing PNDT study based on the outcome of the written procedure on other similar cases before MSC-23. . However, no need was found for DD modification based on PfAs to require the Registrant to include DIT/DNT cohorts in the study.

Registrant's comments on the PfAs of the CAs and discussion

The Registrant in the written comments on PfAs agrees that the second species in PNDT is not a standard IR under REACH. The Registrant does not agree with both CAs that immunotoxicity (DIT) and neurotoxicity (DNT) cohorts should be required as they are not REACH IRs. The Registrant referred to a 28-day study where immunotoxicity had been already addressed. The Registrant states that the neurotoxicity cohort would voluntarily be carried out. The Registrant agrees with ECHA's draft decision as provided for the meeting.

The representative of the Registrant confirmed willingness to carry out EOGRTS in accordance with OECD 443, for covering the standard IRs of Annex X, 8.7.3 of REACH Regulation, instead of OECD 415 as originally proposed, without extension to the second generation by default. However, the second generation would be triggered only by significant effects observed in the F1 generation which do not allow a reliable evaluation of this endpoint. The Registrant would be willing to conduct additional testing for DNT cohort. The Registrant has further clarified that the substance is of low toxicity with a very low exposure profile not indicating any specific concerns; it has no direct consumer use. No real immunotoxicological triggers have been found for running additional studies. Thus

the Registrant disagreed to perform DIT cohort also due to animal welfare reasons.

MSC considered the Registrant's comments. Some members indicated in the discussion that there are different interpretations on whether the DIT/DNT cohorts and other elements of the test guideline are to be considered as integrated parts of OECD TG 443 and whether they are covered by the standard REACH IRs. In their view the Registrant should provide substance specific arguments for omitting one or both of the cohorts. They indicated that for omitting the cohorts it is not sufficient that no indications of immuno or neurotoxic effects were observed in the 28 day RDT study because the sensitivity of the fetus is generally higher than that of juveniles. Some members also indicated that they cannot support the proposed pre-mating periods indicated in the DD because they would not be in line with OECD 443. Two members indicated their concerns on the DD and preference not to decide this case at this moment in time, but to refer it to COM for decision making.

It was concluded that SECR should split DD in two parts addressing separately the IRs of Annex IX, 8.7.2. and of Annex X, 8.7.3 of REACH Regulation, so the part where MSC agreement is not likely (the generation study) be referred to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

Session 2 (closed)

MSC found unanimous agreement on ECHA's draft decision on TPE addressing the IRs of Annex IX, point 8.7.2 (pre-natal developmental toxicity) as provided for the meeting and as split and amended based on the above conclusions, and adopted the formal agreement in this regard.

The Chair initiated a formal voting on the DD dealing solely with the TP for the Annex X 8.7.3 standard IR (two generation reproductive toxicity study). At the formal vote, as MSC did not reach a unanimous agreement on this DD, the Chair invited the disagreeing MSC members to provide written justifications for their disagreement.

CCH-006/2012 Tert-butyl hydroperoxide (EC No. 200-915-7)

Session 1 (open)

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

SECR explained that one PfA disagreed with the requirement of a 90-day study and proposed instead, on the first place, a TGR assay via inhalation, or alternatively, a carcinogenicity study (EU test method B.32) to evaluate the relevance of the hyperplasia/metaplasia observed in the 28-day study. Another PfA proposed to require, in addition to the 90-day study, a carcinogenicity study (EU test method B.32) unless waiving arguments would apply, and suggested including reference to Annex X, 8.9.1 and Annex I, 0.3, 0.5 and 0.7 in the statement of reasons of the DD.

ECHA did not modify the DD based on the PfAs. The DD updated with procedural steps since presented to MSCAs on 20 January 2012 was provided to MSC for finding unanimous agreement at the MSC-23 meeting.

Registrant's comments on the PfAs of the CAs and discussion

The representatives of the Registrant provided written comments on the PfAs and indicated that they do not consider TGR to be suitable for assessment of site of contact mutagenicity in the rodent respiratory tract because of technical difficulties in conducting such study via the inhalation route. They pointed out that they do not agree with the PfA that a carcinogenicity study would be necessary, since the physico-chemical properties of the substance suggested that

the lesions/hyperplasia seen in the 28 day study are due to the corrosive/irritant effects of the substance. They argued that similar lesions would also occur after sub-chronic or chronic inhalation exposure, with the possibility of tumor induction via non-genotoxic processes secondary to chronic irritation of the nasal epithelia. Conclusions of the risk assessment suggest that the substance was unlikely to reach germ cells after oral, dermal and inhalation exposure and the Registrant has self-classified the substance for Germ cell mutagenicity as Category 2. They did not consider it useful to conduct a 90 day study because they considered it would reproduce the corrosive/irritant results of the 28 day study. The representatives of the Registrant denied that the substance, in an unreacted form, was intentionally present in consumer products supplied by their downstream users and thus a wide dispersive use by consumers would not be relevant for their registration. However, they have not advised against these uses in the registration dossier but indicated that an update to the registration dossier in this regard will take place. The representatives of the Registrant offered to discuss classification of the substance as a Carcinogen, Category 2. However, they also stated that toxicokinetic data indicated that any effects would be restricted to sites of first contact and that therefore the substance would not warrant classification as a Carcinogen or Germ cell mutagen Category 1B under the CLP Regulation, and that their opinion regarding classification would be unchanged even if there were site-of-contact carcinogenicity in a single rodent carcinogenicity bioassay.

MSC considered the Registrant's comments to the PfAs. In the discussion, the MSC member representing the MS that submitted the PfA proposing a TGR assay said that he no longer supported the PfA to perform the TGR assay based on the Registrant's and ECHA's comments on the PfA.

MSC supported ECHA's view that the 90-day study shall be requested as the Registrant's arguments to waive this study can not be considered as fulfilling the specific rules for adaptation of the information requirements for the 90-day study under column 2 of Annex IX, 8.6.2 or the general rules for adaptation of Annex XI of the REACH Regulation.

MSC members noted that the EU RAR for the substance mentioned 162 products containing the substance, that there was more recent evidence of the use of the substance in consumer products, but also noted that the Registrant had not mentioned any consumer use of the substance in their dossier, and that the Registrant had denied that there is consumer exposure to the substance from their downstream users.

MSC considered currently available relevant data (*in vivo* germ cell mutagenicity), that the substance is classified by the Registrant as Germ cell mutagen, category 2, in accordance with Regulation (EC) No 1272/2008, that there is evidence in the registration dossier that the substance can induce hyperplasia in repeated-dose toxicity studies, that the Registrant expressed his position not to classify the substance as category 1A or 1B germ cell mutagen or carcinogen. Based on the registration dossier the substance is used by workers and there is evidence of frequent and long-term human exposure, MSC considered that the conditions for requesting a carcinogenicity study were met. Moreover, MSC considered it proportionate to request a carcinogenicity study, and supported the PfA proposing a carcinogenicity study.

One stakeholder representative supported the Registrant's self-classification as mutagen category 2 for the substance and their intention not to perform the 90-day study.

Session 2 (closed)

MSC concluded to request the 90-day study and the carcinogenicity study via inhalation in addition unless the substance is classified as germ cell mutagen cat 1A or 1B and to set the timeframe to submit these studies within 48 months. MSC also agreed not to determine the order of these two studies (so that the Registrant has the option of performing the carcinogenicity study alone to meet both information requirements) and to remind the Registrant to record in CSR the interim risk management measures he has put in place to manage the risks that are being explored while waiting for the results of testing.

MSC found unanimous agreement on ECHA's DD as provided for the current meeting and further amended based on the above conclusions, and adopted the formal agreement.

CCH-008/2012 Vinyl 2-ethylhexanoate (EC No. 202-297-4)

Session 1 (open)

No representative of the Registrant participated in the initial discussion. The Registrant has not expressed any objection to the presence of StO during these initial discussions, therefore an open session was held.

SECR explained that one of two PfAs suggested requesting a 90-day study based on Annex IX requirements instead of the 28-day study based on Annex VIII requirements as a tonnage upgrade of the registration dossier had been made since the first draft decision had been communicated to the Registrant. The third PfA suggested a recommendation to the Registrant to use NOEL for maternal toxicity from the already available prenatal developmental toxicity study or the NOEL from the requested 90-day study whatever is the lowest.

ECHA did not modify the DD based on the PfAs. The DD updated with procedural steps since presented to MSCAs on 20 January 2012 was provided to MSC for finding unanimous agreement at the MSC-23 meeting.

Registrant's comments on the PfAs of the CAs and discussion

The Registrant in the written comments on PfAs reiterated their support for the read-across argument. The Registrant agreed that a 28 day study is not needed for the substance, and instead stated that a testing proposal for a 90 day study on a read-across substance is planned. The Registrant also promises to consider the second PfA on identifying an appropriate NOEL.

MSC considered the Registrant's comments on the PfAs.

In the discussion, ECHA explained that the tonnage upgrade (from 10-100 tpa to 100-1000 tpa) happened well before the start of the MSCA consultation and that the upgraded dossier contained no proposal for a 90-day study, but an adaptation for the study based on read across, with further arguments in support of the read across argument. The same read-across was proposed also in the original registration dossier for tonnage level 10 – 100 tpa for skin sensitisation, *in vitro* gene mutation and *in vitro* cytogenicity. ECHA did not accept the read-across arguments even after the Registrant's comments on the draft decision and updated of the dossier. The same justification for read-across is used for the endpoint on repeated dose toxicity as for other endpoints. As the registration dossier is deficient for most of the basic data according to Annex VII/VIII, ECHA suggested targeting the draft decision at the Annex VII/VIII information requirements. However, ECHA suggested dropping the requirement for the 28-day study because any decision to request a 90 day study would need to rely on the information requirements of Annex IX, whereas the decision in question was issued when the dossier was registered at Annex VIII, and therefore is limited only to those information requirements. In addition, the decision to request a 90 day study would depend on the outcome of any tests proposed by the Registrant for this endpoint. ECHA suggested including a reminder in the DD that not

addressing the 28/90-day study does not imply that the registration dossier is compliant with the information requirement(s) of Annex VIII, 8.6.1 or Annex IX, 8.6.2 of the REACH Regulation. ECHA also suggested adding additional details in the statement explaining why the read-across for skin sensitisation, *in vitro* gene mutation and *in vitro* cytogenicity could not be accepted.
MSC considered ECHA's suggestions as an appropriate way forward.

Session 2 (closed)

MSC concluded not to require the 90-day study and to add additional details in the statement explaining why the read-across for skin sensitisation, *in vitro* gene mutation and *in vitro* cytogenicity could not be accepted.

MSC found unanimous agreement on ECHA's DD as provided for the current meeting and further amended based on the above conclusions, and adopted the formal agreement.

TPE-023/2012 Silicon (EC No. 231-130-8)

Session 1 (open)

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

SECR explained that one PfA to ECHA's DD was submitted by a MSCA suggesting removing from DD the requirement to include in the study a positive control group exposed to quartz. However, SECR was of the view that DD as presented did not need to be modified.

Registrant's comments on the PfAs of the CAs and discussion

The Registrant in the written comments on the PfA explains the scientific rationale why the positive control group would be needed in the study. They indicate that since the main concern related to silicon is lower respiratory tract effects, BAL analysis are recommended to be included in the planned 90-day test. However, the existing Reutzel et al (1991) study cannot be used for comparison due to the absence of BAL analysis in the study and the further revision of OECD 413 guidance protocol done since the date of the Reutzel study. The Registrant concludes that inclusion of positive control is a common practice in cases where there is a need for validation of the test results, i.e. to ensure that the test can surely identify the toxic effects.

MSC considered the Registrant's comments on the PfAs.

In the meeting the Registrant's representative provided further clarification on the considerations behind their request for use of a positive control group exposed to quartz accompanying the 90-day sub-chronic inhalation toxicity study. She explained the intention to study whether the SiO2 formed on the surface of the silicon could have adverse health effects by inhalation. She confirmed that the Registrant would be willing to include the positive control group in the study to be absolutely sure that the results of the study will be conclusive.

In the following discussion, it was noted that although adverse effects of quartz are already well-known and for that reason the positive control group may not be needed, the Registrant may have reasonable arguments for proposing a positive control data to be generated in this case.

MSC members concluded that only the 90-day sub-chronic toxicity study is required to meet the IRs of REACH Regulation. As the positive control itself is not part of the standard Information Requirements, the inclusion of this additional parameter should not be included in the decision as part of the information required for this substance in the final decision, but the decision to perform such an additional parameter should be left to the Registrant's discretion.

Session 2 (closed)

MSC found unanimous agreement on ECHA's DD as provided for the meeting and amended based on the above conclusion, and adopted the formal agreement in this regard.

TPE-033/2012 Sodium hydroxymethanesulphinate (EC No. 205-739-4)

Session 1 (open)

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

SECR explained that three PfAs were related to pre-natal developmental toxicity (PNDT). One of these PfAs was proposing three options for the Registrant to consider regarding the need to assess further germ cell mutagenicity of the substance. According to all three options the TP for developmental study would not be needed or sufficient time should be allowed first to conduct the relevant studies sequentially to determine whether the substance is Muta Cat 1B. Consequently one PfA proposes to reject the testing proposal for PNDT because the classification with Muta Cat 1B should first be concluded based on substance's germ cell potential. The DD was not modified in this regard.

Following the two other PfAs on the second species in PNDT study, SECR modified the DD as result of the outcome of the written procedure on similar cases before the MSC-23 meeting and provided this modification for agreement seeking at MSC-23.

The fourth PfA was to reject the long-term fish test (Annex IX, 9.1.6, OECD 210) because no scientific rationale was seen for asking for such a study for a chemical of such properties. It is also unclear why the registrant considers the available acute fish test as invalid. Instead the registrant should consider repeating the acute toxicity test on fish. According to PfA the Registrant does not indicate a need for the long-term fish test based on CSA. The PfA proposed to reformulate the draft decision requesting OECD 212 'Fish, short term toxicity in embryo and sac-fry stages' and making the test conditional to the outcome of CSA after recalculation of PNEC. SECR amended DD based on this proposal by reflecting the Guidance on integrated testing strategy for aquatic toxicity to determine the sequence for aquatic tests using the same approach as agreed in the previous meeting (MSC-22). The DD with this modification together with the update of the procedural steps was provided for agreement seeking in MSC-23.

Registrant's comments on the PfAs of the CAs and discussion

The Registrant in the written comments on the PfA regarding options to conclude the germ cell mutagenicity of the substance refers only to one of the options stating that they plan to conduct a toxicokinetic study in the context of the 90 day study which they assume could be used in accordance with column 2 of Annex IX, 8.7. On the other hand they point out that the substance has been part of the US EPA HPV program where no additional testing or investigations for mutagenicity are any longer requested. Neither any CMR effects have been reported based on 100 years' experience of production and handling of substance. On the PfA to reject the test on long term toxicity to fish the Registrant refers to the option to repeat the short term toxicity test on fish if appropriate. The Registrant agrees with the PfA not recognising the second species in PNDT study as a standard information requirement but disagreeing with the other PfA suggesting new formulation on the same issue.

MSC considered the Registrant's comments on the PfAs.

MSC in its discussion showed support for the long-term toxicity testing on fish and to use the same approach as in MSC-22, i.e. to leave the text of DD as was provided for MSC-23. The main argument is that the long toxicity test on fish is a standard information requirement of Annex IX, 9.1.6 which can be waived by the Registrant based on column 2 of of Annex X, 9.1. The draft decision would also

include the reminder on the integrated testing strategy. The Registrant did not actually comment the PfA regarding the test on long term toxicity to fish.

With regards to the PNDT, and considering the vague written comments by the Registrant on the three options given to the first PfA, MSC in its discussion in the meeting recognised that PfAs need to be clearly specified and legally justified so as not to conflict the message given to the Registrant. Some members showed sympathy to the approach presented in this PfA, i.e. to consider further the mutagenicity of the substance before coming to a conclusion to test the substance for PNDT. It was explained that this could be done in accordance with Article 40 (3)(c) where additional tests can be requested when the TP is not in compliance with the information requirements. However, requesting for further tests can result in a long process and would be rather an issue for a compliance check. Due to the tight deadlines of TP MSC agreed not to follow the route proposed by this PfA but concluded that the waiving options regarding CMR classification as category 1A and 1B and the risk management measures implemented should be further explored and discussed in one of the coming MSC meetings.

Session 2 (closed)
MSC found unanimous agreement on ECHA's DD as provided for the meeting and adopted the formal agreement in this regard.

TPE-038B/2012 2-Ethylhexyl Nitrate (EC No. 248-363-6)

Session 1 (open)
A representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in the DD, an open session was held.

SECR explained that DD has been split to TPE-038A and TPE-038B where TPE-038A addresses the information requirement for Annex X, point 8.7.3 (two-generation reproductive toxicity) and TPE-038B addresses the information requirements for Annex IX, 8.6.2 (90 day RDT) and Annex IX and X. 8.7.2 (PNDT in two species). The DD, TPE-038A, has been addressed in WP and resulted in disagreement of MSC. The DD, TPE-038B, was addressed for agreement in the meeting of MSC-23. Two PfAs related to TPE-038B suggest to reject the TP of the Registrant on the second species (rabbit by inhalation) of pre-natal developmental toxicity study and to ask the Registrant to make a new TP as necessary in the context of update of the dossier containing data on the first species (rat by inhalation).

Registrant's comments on the PfAs of the CAs and discussion

The Registrant in the written comments on the PfAs suggests cancelling all the TPs and using instead read across, weight of evidence approach and QSAR method to fill the data gaps. No such PfAs were proposed by the MSCAs which would address the aspects raised by the Registrant in the comments, i.e. the comments are not on the PfAs as required and specified in Article 51.5 of REACH.

MSC considered the Registrant's comments on the PfAs.

The split DD TPE 038B modified on the basis of the two PfAs and updated with procedural steps was provided to MSC as a meeting document of the current meeting for finding unanimous agreement.

The representatives of the Registrant in their intervention, stated their surprise when SECR mentioned that their proposal of cancelling the TP cannot be accepted at this stage of the decision making process. SECR explained that in the current stage MSC cannot take any position on potential updates/waivers. SECR also clarified that the basis for the final decision is the registration dossier as it was available to ECHA at the start of the MSCA consultation. Later updates of the dossier can not be considered for the final decision. The Registrant can update

the dossier at any point in time e.g. the Registrant can also waive a test with adequate justification but these updates/waivers will be examined only when the deadline to fulfil the information requirements set in the final decision expires. SECR also explained that the role of the Registrant in the current meeting is just to clarify certain issues based on PfAs but not to raise new discussion points or to provide new information or proposals for their case. The Registrant agreed during the meeting with the two PfAs that the outcome of the PNDT on rat needs to be seen before proceeding with a second species, i.e the rabbit. The Registrant stated inhalation is a relevant route of worker exposure.

MSC suggested a slight change in DD Section III. Statement of reasons, to show that the 2nd species for PNDT depends on the outcome of the rat developmental toxicity study, as well as on any other available information meaning that the test on 2nd species can be waived on the basis of the result of the rat study and any other available information.

Session 2 (closed)

MSC found unanimous agreement on ECHA's DD as provided for the meeting and amended based on the above conclusion, and adopted the formal agreement in this regard.

TPE-048/2012 Tert-butyl 2-ethylperoxyhexanoate (EC No. 221-110-7)

Session 1 (open)

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

SECR explained that two PfAs suggested rejecting the TP on mutagenicity, with Unscheduled DNA synthesis (UDS) test and instead asking the Registrant to conduct Transgenic Rodent Somatic and Germ Cell Mutation Assay (TGR). The third PfA disagrees with DD to require additional parameters in the sub-chronic toxicity study (90-day) and leave these investigations to the Registrant's discretion. The two other PfAs are related to PNDT study in a second species as a standard information requirement in Annex X, 8.7.2.

SECR modified the DD before MSC-23, as a result of the outcome of the written procedure on similar cases addressing second species in PNDT study, and based on the PfA regarding additional parameters in a 90 day study. The DD was not modified regarding the PfAs on TGR assay.

Registrant's comments on the PfAs of the CAs and discussion

The Registrant in the written comments on the PfAs agrees with the PfAs with regard to the 90 day repeated dose toxicity study and the PNDT study, but disagrees with the PfAs with regards to mutagenicity *in vivo* testing. Registrant prefers the UDS test over the TGR test since it is one of the recommended and suitable methods to address gene mutation *in vivo* as also confirmed by other legal frameworks (biocides or plant protection).

MSC considered the Registrant's comments on the PfAs.

MSC had a scientific discussion on which test i.e UDS or TGR, is the best test to fulfil the information requirement for gene mutation at Annex X 8.4 for this specific substance. There was a consensus, based on the substance's structure, reactivity, irritancy and sensitising properties, that there is a concern that the substance is a short-lived reactive, *in vitro* mutagen which may be mutagenic at the site of contact with the body, and that consequently the UDS test was not acceptable to meet the information requirement. The best test to meet the information requirement in these specific circumstances is the TGR test.

Session 2 (closed)
MSC modified Section II (Testing required) of DD by requesting TGR and mutation frequency to be assessed on tissues of forestomach, intestine, liver, kidney and developing germ cells from the seminiferous tubules and rejecting UDS for the reasons mentioned above. Section III of DD Statement of Reasons was modified accordingly by making a reference to the text of the Guidance document advising to select the appropriate test method for testing on gene mutations for a specific substance. It was pointed out by SECR that also in the future PfAs would be considered appropriate by SECR when they can provide substance specific justification for rejection of the test method proposed by the Registrant (if a relevant test method) and when they can justify the use of an other test method to reach more relevant results for the specific substance. Some MSC representatives were of the opinion that the burden of proof of deviating from a test which generally is optimal from a scientific point of view lies with the Registrant and not with the MSCA or MSC.

MSC found unanimous agreement on ECHA's draft decision as provided for the meeting and amended based on the above conclusion, and adopted the formal agreement in this regard.

TPE-018/2012 2-Octyldodecan-1-ol (EC No. 226-242-9)
Session 2 (closed)
The Chair of MSC explained that agreement seeking on DD on the TP on the standard information requirement of Annex X, 8.7.3 (two-generation reproductive toxicity study) was sought by WP. However, due to identified technical mistake in the documents distribution, the WP for this case was terminated and DD was addressed for agreement at MSC-23 meeting.

The Chair initiated a formal voting on the draft decision dealing with the TP for the Annex X, 8.7.3 standard IR of the REACH Regulation. At the formal vote, four votes were against DD and 21 votes in favour of DD. Two members were not present at the vote. As MSC did not reach a unanimous agreement on this DD, the Chair invited the disagreeing MSC members to provide written justifications for their disagreement unless they accept that SECR will re-use their justification from earlier similar cases.

TPE-025/2012 (1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate BDP (EC No. 425-220-8)
TPE-026/2012 (1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate BDP (new registration) (EC No. 425-220-8)

TPE-027/2012 Benzene, 1,1'-oxybis-, tetrapropylene derivs., sulfonated, sodium salts' (DOWFAX 2A1) (List number 601-601-6)

TPE-049/2012 Sulfonic acids, C14-16 (even numbered)-alkane hydroxy and C14-16 (even numbered)-alkene, sodium salts (EC No. 931-534-0)

Session 2 (closed)
The Chair of MSC introduced the four cases together by explaining that agreement was sought via WP. However the WP was terminated by request of one member because he requested the DD to refer to other relevant long-term test methods with soil invertebrates i.e. OECD 220, OECD 22, OECD 232 and OECD 226. SECR gave a presentation explaining the SECR's view. The member who asked for termination of the WP then accepted to request the test on the species chosen by the Registrant without listing test guidelines for other species for consideration of the Registrant. The four DDs were not modified during the meeting. The member who asked for termination of the WP however requested for these different test methods to be discussed in another MSC meeting.

MSC found unanimous agreement on ECHA's DD as provided for the WP and later on for the meeting and adopted the formal agreement in this regard.

TPE-028B/2012 Hydroxycyclohexyl phenyl ketone (EC No. 213-426-9)

Session 2 (closed)

SECR explained that agreement seeking on this DD, addressing solely the examination of the testing proposals for sub-chronic oral toxicity study (90-day) and PNDT study was sought by WP. However, the WP for this case was terminated by the MSC Chair based on a member's request, due to proposed editorial modifications to be further introduced in DD.

MSC found unanimous agreement on ECHA's DD as provided for the WP and further amended based on the editorial suggestions proposed in the written procedure, and adopted the formal agreement.

TPE 040/2012 Dust, steelmaking (EC No. 266-005-7)

Session 2 (closed)

The DD modified by ECHA based on a PfA and the results of an informal MSC discussion concerning the request for a PNDT study and updated with procedural steps since presented to MSCAs on 20 January 2012 was addressed for agreement seeking in a WP of MSC on 2-12 April 2012. The WP was terminated due to comments of two MSC members concerning handling of recent updates of the registration dossier in the MSC decision making process.

MSC concluded to include in DD a reminder to the Registrant that the "decision does not take into account any updates of the registration dossier submitted by the Registrant after the date of notification of the draft decision to the Competent Authorities of the Member States".

MSC found unanimous agreement on ECHA's DD as provided for the current meeting and further amended based on the above conclusion, and adopted the formal agreement. Two members were not present at the vote.

TPE-056/2012 Pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (EC No. 229-722-6)

Session 2 (closed)

The DD updated with procedural steps since presented to MSCAs on 20 January 2012 was addressed for agreement seeking in a WP of MSC on 2-12 April 2012. The WP was terminated due to a comment of a MSC member concerning an advice to be given to the Registrant for testing difficult substances.

MSC concluded not to include any additional advice in DD as suggested by the PfA above.

MSC found unanimous agreement on ECHA's DD as provided for the current meeting, and adopted the formal agreement.

TPE-57B/2012 Strontium nitrate (EC No. 233-131-9)

Session 2 (closed)

SECR explained that agreement seeking on this DD, addressing solely the examination of the TPs for the developmental toxicity/ teratogenicity (OECD 414) study and long-term toxicity testing on fish (OECD 210, Fish early-life stage toxicity test), was sought by WP. However, the WP for this case was terminated by the MSC Chair based on a member's request, due to proposed editorial modifications to be further introduced in DD.

MSC found unanimous agreement on ECHA's DD as provided for the WP and further amended based on the editorial suggestions proposed in the WP, and adopted the formal agreement.

e. **Items for discussion following commenting by MSCAs -** Items from the MSCA commenting round for MSC-24, including some consistency proposals from DK

SECR gave a presentation on ECHA's ways to ensure consistency of draft decisions in the dossier evaluation process. The presentation also gave responses to specific draft decision related concerns raised by one MSC member. The MSC member raising these concerns recognised ECHA's replies.

Item 7 – Authorisation process

1. SVHC identification process

a) Multiple entries for Refractory Ceramic Fibres on the candidate list – potential corrective measures

The Chair pointed out that at present there is no proposal (Annex XV dossier) which would make it possible to modify the present RCF entries on the Candidate List (CL) or to introduce new entries to the CL. The option available is to explore whether the present four entries could be consolidated based on the facts included in the Support Documents. She explained that MSC has no competence to decide on this issue but as indicated in the meeting of MSC-21 in December 2011 the Secretariat has examined the current four RCF entries on the CL.

The Chair had invited representatives of the sector organisation as experts from the concerned industry to provide information to MSC about the situation on the market with the existence of multiple entries for RCFs in the CL and to share their experience on the issues found problematic from the concerned sectors in this regard. In the following it was explained that, the registrations of RCFs have been made based on the entry of Annex VI of CLP Regulation and using as identifier also the CAS number the industry has chosen to represent these fibres. In the following discussion, MSC noted that the possibility to have a single entry in the CL could be further explored but can be done only on the basis of an Annex XV dossier. SECR clarified that the existing CLH entry for RCFs, that is a UVCB substance, is intentionally kept without any CAS numbers specified, as currently it covers a range of CAS numbers.

The member from the MSCA who had submitted the Annex XV dossiers for RCF explained the reasons for submitting the dossiers following the guidance for identification of UVCB substances and specifying the substance based on risk evaluation. The member stressed that the risk based approach in substance identification was an intentional choice and they did not want to cover the whole entry of Annex VI of CLP Regulation. Furthermore the aim was to cover the old entries by the new ones when submitting the latest Annex XV dossiers and agreed with analysis by SECR presented below.

SECR clarified that in such cases (like RCFs) certain general rules in the ECHA Guidance may not be applicable and if a substance cannot be identified by its final composition, it should be identified by the starting composition of the material.

SECR introduced to the Committee its considerations on the possible ways for consolidating the four entries in the CL and its conclusions that the 'old' entries are completely covered by the 'new' ones. MSC and the COM observers supported ECHA's suggested approach to consolidate the existing multiple RCFs entries in the CL. It was noted that this consolidation is foreseen in the context of the next update of the CL with a decision of the ECHA Executive Director following the similar way of the inclusion of the entries.

b) SVHC time schedule for 2012

SECR introduced MSC with the preliminary observations on the public consultation comments received on the 13 SVHC proposals in the last SVHC round, the identified triggers for MSC involvement and the way considered for addressing them later on. Members also took note of the updated SVHC time schedule for 2012.

2. Recommendation of substances for Annex XIV inclusion

a) Discussion of the draft recommendation/prioritisation results

SECR gave a presentation on the draft results of the prioritisation work carried out by ECHA. The same prioritisation methods were used as in the 3rd recommendation process: a verbal argumentative and a scoring approach combined with regulatory effectiveness considerations. It was explained that the data on the substances on the Candidate List was assessed for the substances included in 2011, and reassessed for those included in the Candidate List before and not yet recommended for Annex XIV. Registration dossiers (including any updates) were surveyed. Besides the registration dossiers, Annex XV dossiers and comments received in the public consultation on identification of SVHCs were used. Having considered the available information and the criteria, ECHA was proposing to prioritise the following 11 substances: Strontium chromate, Potassium hydroxyoctaoxodizincatedichromate (1-), Pentazinc chromate octahydroxide, Dichromium tris(chromate), Bis(2-methoxyethyl) ether (Diglyme), N,N-Dimethylacetamide (DMAC), 1-Methyl-2-pyrrolidone (NMP), 1,2-Dichloroethane, (EDC), 2,2'-dichloro-4,4'-methylenedianiline (MOCA), Formaldehyde, oligomeric reaction products with aniline (technical MDA) and Arsenic Acid.

SECR introduced the draft recommendation and noted that the same approach had been used for defining the draft entries including the latest application dates (LADs) as in previous prioritisation rounds. For the proposed LADs the standard estimated time of 18 months was used as the time needed to prepare authorisation application. Available information on the structure and complexity of the supply chain and similarity of uses of those substances that have already been recommended were used to allocate substances to three groups (LADs 18, 21 and 24 months) to achieve more even workload of ECHA and its Committees to handle authorisation applications. SECR did not include any exemptions or review periods in its proposal.

In the following discussion only some minor comments were made on the substance specific prioritisation justifications during the discussion addressing each substance of the current CL. One stakeholder observer raised an issue regarding justification for LADs arguing that experience gained by companies is not an argument to use shorter LADs because the same companies may be affected and would be busy in preparing several applications at the same time.

Acrylamide is waiting for a ruling in the European Court of Justice on whether a restriction decision should be revoked or not, and ECHA Secretariat indicated that deprioritisations are reversible. A StO asked ECHA to use the SPIN register to find uses not registered for and hence not prioritised, but where MS have indications that the substance is being used. ECHA Secretariat noted that they are using any new information they obtain.

As a conclusion MSC and stakeholders were invited to provide comments in writing by 4 May on the draft recommendation and on the draft prioritisation so that new versions, as necessary, can be introduced in the next meeting. SECR will

upload in CIRCABC the background documents for the substances that are currently proposed to be prioritised by ECHA.

During the discussion some suggestions were made for possible review of the general priority setting approach for future prioritisation rounds, e.g. with regard to the scoring approach. SECR informed MSC that such review of the current prioritisation approach will be considered and suggestions for issues to be reconsidered were welcomed.

b) Time-table of MSC for drafting the opinion on ECHA's draft recommendation on priority substances for Annex XIV

SECR presented a time schedule regarding ECHA's development of the 4th draft recommendation for inclusion of substances in Annex XIV and for MSC to provide its opinion on this draft recommendation. MSC agreed to the time schedule however some members clearly noted that more time for discussion would have been beneficial. According to the current plan the MSC opinion would be adopted in the December meeting of MSC.

In order to proceed with the plan SECR informed MSC that invitation for volunteers for Rapporteurship to draft the MSC opinion and for possible working group members would be launched in advance of the next meeting.

Item 8 – Manual of Decisions (MoD)

- **Any topics identified by members**

There were no topics identified for further discussion. MSC members were requested to send their proposals to SECR via email.

Item 9 – Report from other ECHA bodies and activities

a) Management of MSC documents

- **minutes of MSC plenary meetings**

In the light of the increasing plenary workload, it was suggested MSC to consider changing the type and the structure of the minutes from the Committee's plenary meetings.

Following the discussion on the issue, members agreed that although reflecting the MSC discussions in the meeting minutes is useful, more pragmatic approach should be implemented. MSC agreed that only public version of the minutes from the MSC plenary meetings will be prepared from now on covering the MSC agreements/decisions and the rational that lead to them, but excluding any confidential information and reflections of the specific case discussions before coming to a final conclusion.

- **editorial corrections on final ECHA decisions, on draft decisions already agreed by MSC or on draft decisions without PfAs received**

SECR pointed out on different cases where omissions, procedural or editorial errors were detected in the final legal review before DD is signed, both when DD was referred and agreed by MSC and also when DD was not referred to MSC, as no MSCA PfAs had been submitted on them. Thus, MSC was requested to agree that SECR will make these editorial corrections, under condition that no modifications changing the MSC understanding of the content of DD will be done.

MSC agreed that ECHA can introduce editorial changes to draft decisions based on approaches agreed previously by MSC Members. MSC also agreed that ECHA can make editorial changes on its draft decisions at the stage of their final legal review.

- **responding to the Registrant's comments on MSCA PfAs**

Article 51(5) of REACH notes that MSC shall take into account the comments of the Registrant on the PfAs of MSCAs. Following some members' suggestions to record down that the Registrant's commentshave been considered, the MSC Chair pointed out that due to the narrow timeframe of the MSC dossier evaluation process, it would be difficult in particular in cases where the draft decisions will be addressed in written procedure to record down how the comments of the Registrant have been considered by MSC. The Registrant's comments arrive two weeks after referral of the DDs to MSC, and due to the tight timeframe the written procedure has to be launched within one or two days after receiving the Registrant's comments. Therefore, it was proposed that following the preliminary Secretariat's screening of the Registrant's comments on the PfAs, if they are considered crucial for a DD, such cases are to be addressed for meeting discussion and agreement seeking, and not for written procedure. The Registrant's comments are included in RCOM to be used as a source of information in written procedure and are available for the members to consider before coming to a conclusion whether to vote in favour or against the DD, or whether to request termination of the written procedure and request addressing the case for agreement in the MSC meeting. It was proposed by the Chair that for the cases which are addressed at the meeting the minutes can include a section reflecting the Registrant's comments and how MSC considered them.

MSC agreed that cases where a DD will be addressed for agreement seeking in MSC plenary meeting the minutes will reflect how the comments of the Registrant were taken into account by MSC.

- **rectification of final ECHA decisions in case of appeals**

MSC was introduced with the current practice applied by ECHA with regards to its final decisions. Due to the complexity of the issue, several members indicated a need to re-discuss the issue in some of the following MSC plenary meetings and in CARACAL. MSC supported ECHA's current approach in rectification of ECHA's decisions in appeal processes.

b) Report from the 1st ECHA PBT working group

SECR provided MSC with a brief report from the 1st meeting of the recently established PBT expert group (EG) whose mandate will be to provide scientific support in regard to PBT substances under the different REACH processes. The group follows a screening approach on PBT substances and shares the work among EG members. It was further clarified that MSCA who wishes to nominate members to the PBT EG can still do this by providing the nominations to SECR.

Item 10 – Any other business

Suggestions from members:

- **GLP: Systematic feedback and EU collaboration**

The MSC member suggesting the GLP discussion clarified the reason for his request referring to the dossier evaluation work of ECHA and highlighted the need for ensuring the laboratory compliance with GLP, the high quality of the tests performed and validity of the results provided in the registration dossiers.

SECR explained to MSC its current working practices and mechanisms established under Art. 13(4) of REACH Regulation for ensuring the GLP accordance of the tests performed in particular with regard to the compliance check of the registration dossiers. It was further specified that ECHA participates in the GLP WG which recently concluded on the need for establishing more robust communication among COM, ECHA and MSCAs for sharing information on GLP inspections and test validation, further to the EU monitoring authority list. This

would be useful tool for checking the potential severe problems reported with the tests from any particular laboratories.

- **Exposure assessment in Tier 1**

A member presented an overview of a recently initiated MSCA project on exposure assessment in Tier 1 and invited the other MSCAs to consider potential cooperation with the project team, providing exposure information at their disposal and sharing experience on exposure assessment.

Item 11 – Adoption of conclusions and action points

MSC adopted the conclusions and action points of MSC-23. SECR will upload them to MSC CIRCABC by 30 April 2012.

Signed

Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
BIWER, Arno (LU)
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
HUMAR-JURIC, Tatjana (SI)
KORENROMP, Rene (NL)
KULHANKOVA, Pavlina (CZ)
LUDBORZS, Arnis (LV)
MAJKA, Jerzy (PL) (alternate member)
MARTÍN, Esther (ES)
MARTINS, Ana Lilia (PT) (alternate member)
MIHALCEA-UDREA, Mariana (RO)
PEDERSEN, Finn (DK) (alternate member)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)[5]
SPETSERIS, Nikolaos (EL) (alternate member)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI) (alternate member)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
Representatives of the Commission
GARCÍA-JOHN, Enrique (DG ENTR)
KOBE,Andrej (DG ENV)
Observers
ANNYS, Erwin (CEFIC)
BASTIJANCIC-KOKIC, Biserka (HR)
FRANCHIOLI, Luigi (UEAPME)
LIGHTART, Jerker (HEAL)
NAMEROFF, Tamara (ECETOC)
STAIRS, Kevin (Greenpeace)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (EUROMETAUX)

ECHA staff
AJAO, Charmaine
ANDERSSON, Niklas
BALOGH, Attila
BELL, David
BONNOMET, Vincent
BROERE, William
CARLON, Claudio
DE COEN, Wim
DE RAAT, Karel
DE WOLF, Watze
FEDTKE, Norbert
FEEHAN, Margaret
HALLING, Katrin
HUUSKONEN, Hannele
KARHU, Elina
KOJO, Anneli
LE CURIEUX, Frank
KOULOUMPOS, Vasileios
LEPPER, Peter
MAZZEGA SBOVATA, Silvia
MÜLLER, Birgit
NAUR, Liina
PHILLIPS, Andrew
PREVEDOUROS, Konstantinos
REUTER, Ulrike
RIALA, Riitta
RODRIGUEZ IGLESIAS, Pilar
RÖCKE, Timo
RÖNTY, Kaisu
SUMREIN, Abdel
SUNDQUIST, Anna-Liisa
TARAZONA, José
VAHTERISTO, Liisa
VALENTINI, Marco
VASILEVA, Katya

Proxies

- LUDBORZS Arnis (LV) also acting as proxy of LULEVA Parvoleta (BG)
- SPETSERIS, Nikolaos (EL) also acting as proxy of KYPRIANIDOU-LEONTIDOU,Tasoula,
- PISTOLESE, Pietro (IT) also acting as proxy of CAMILLERI, Tristan (MT)
- MARTIN, Esther (ES) also acting as proxy of DRUGEON Sylvie (FR)
- VANDERSTEEN Kelly (BE) also acting as proxy of BIWER Arno (LU) (Tuesday 24th April)
- BIWER Arno (LU) also acting as proxy of KORENROMP René (NL) (Friday 27th April)
- FINDENEGG Helene (DE) also acting as proxy of FLODSTRÖM Sten (SE) (Friday 27th April)

Experts and advisers to MSC members

ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BALCIUNIENE, Jurgita (LT) (expert to DUNAUSKIENE, Lina)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
GRACZYK, Anna (PL) (expert to MAJKA Jerzy)
INDANS, Ian (UK) (expert to DOUGHERTY Gary)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
LUNDBERGH, Ivar (expert to FLODSTRÖM, Sten)
LØFSTEDT Magnus (DK) (expert to PEDERSEN, Finn)
MOELLER, Ruth (LU) (expert to BIWER, Arno)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
SCHWÄGLER, Mark (DE) (expert to FINDENEGG, Helene)
TRAAS, Theo (NL) (expert to KORENROMP, Rene)

SIMONS, John (ECFIA) (invited expert for Item 7 1.)
WEBSTER, Dawn (ECFIA) (invited expert for Item 7 1.)

By WEBEX-phone connection:
GARCÌA-JOHN, Enrique (items 1-6)
GUHE, Christine (items 1-5, 6a 1. and 2., 6c)
ROZWADOWSKI, Jacek (item 7 1.)

Case owners:
Representatives of the Registrant were attending under agenda item 6c for: CCH-003/2012, CCH-004/2012, TPE-010/2012, CCH-006/2012, TPE-023/2012, TPE-038B/2012.

Apologies:
CAMILLERI, Tristan (MT)
DRUGEON, Sylvie (FR)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
LULEVA, Parvoleta (BG)

III. Final Agenda

Final Agenda
23rd meeting of the Member State Committee

24-27 April 2012
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

24 April**: starts at 9:00**
27 April**: ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/023/2012
For adoption

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

Item 4 – Administrative issues

- Meeting calendar for 2013

ECHA/MSC-23/2012/38
For information

Item 5 – Adoption of the draft minutes and conclusions and action points of the MSC-22

- Draft minutes of the MSC-22

MSC/M/22/2012
For adoption

Item 6 – Dossier evaluation
Closed session for Session 1 on TPE-10/2012 and for 6d
Indicative time plan for 6c is Day 1& 2, for 6d Day 3&4

a. General topics:

2. 2nd species in developmental toxicity testing

For information and discussion

3. Selection of route of administration for human health higher tier testing

For information and discussion

4. **Read-Across Assessment Framework – development/principles of the second tier (Tier II)**

For information and discussion

5. **Update by Commission representative on Use of the Extended One-Generation Reproductive Toxicity Study (EOGRTS) under REACH and CLP**

ECHA/MSC-23/2012/39

For information

6. **Proposal for organisation of the MSC work for high number of dossier evaluation cases *(Partly closed session)***

   - Feedback from case-owner and stakeholder participation discussion in the Management Board

ECHA/MSC-23/2012/036

For discussion and agreement

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

For information

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

ECHA/MSC-23/2012/002

For information

c. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MS-CA reactions *(Session 1, tentatively open session except for TPE-010)*

ECHA/MSC-23/2012/001

For discussion followed by agreement seeking under 6c:

- CCH-003/2012 Dichloro(dimethyl)silane (EC No. 200-901-0)
  ECHA/MSC-23/2012/030-031
- CCH-004/2012 Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)- (EC No. 213-668-5)
  ECHA/MSC-23/2012/003-004
- TPE-002/2012 2,2-bis(hydroxymethyl)propionic acid (EC No. 225-306-3)
  ECHA/MSC-23/2012/015-016
- TPE-010/2012 (*Closed session)*
  ECHA/MSC-23/2012/021-022
- CCH-006/2012 Tert-butyl hydroperoxide (EC No. 200-915-7)
  ECHA/MSC-23/2012/006-007
- CCH-008/2012 Vinyl 2-ethylhexanoate (EC No. 202-297-4)
  ECHA/MSC-23/2012/009-010
- TPE-023/2012 Silicon (EC No. 231-130-8)
  ECHA/MSC-23/2012/018-019
- TPE-033/2012 Sodium hydroxymethanesulphinate (EC No. 205-739-4)
  ECHA/MSC-23/2012/012-013
- TPE-038B/2012 2-Ethylhexyl Nitrate (EC No. 248-363-6)
  ECHA/MSC-23/2012/024-025

- TPE-048/2012 Tert-butyl 2-ethylperoxyhexanoate (EC No. 221-110-7)
ECHA/MSC-23/2012/027-028

For information and discussion

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

- CCH-003/2012 Dichloro(dimethyl)silane (EC No. 200-901-0)
ECHA/MSC-23/2012/030-032
- CCH-004/2012 Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)- (EC No. 213-668-5)
ECHA/MSC-23/2012/003-005
- TPE-002/2012 2,2-bis(hydroxymethyl)propionic acid (EC No. 225-306-3)
ECHA/MSC-23/2012/015-017
- TPE-010/2012
ECHA/MSC-23/2012/021-023
- CCH-006/2012 Tert-butyl hydroperoxide (EC No. 200-915-7)
ECHA/MSC-23/2012/006-008
- CCH-008/2012 Vinyl 2-ethylhexanoate (EC No. 202-297-4)
ECHA/MSC-23/2012/009-011
- TPE-023/2012 Silicon (EC No. 231-130-8)
ECHA/MSC-23/2012/018-020
- TPE-033/2012 Sodium hydroxymethanesulphinate (EC No. 205-739-4)
ECHA/MSC-23/2012/012-014
- TPE-038B/2012 2-Ethylhexyl Nitrate (EC No. 248-363-6)
ECHA/MSC-23/2012/024-026
- TPE-048/2012 Tert-butyl 2-ethylperoxyhexanoate (EC No. 221-110-7)
ECHA/MSC-23/2012/027-029

Cases returned from written procedures for agreement seeking in the meeting:[1]

- TPE-018/2012 2-Octyldodecan-1-ol (EC No. 226-242-9)
ECHA/MSC/D/2012/054-056
- TPE-025/2012 (1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate BDP (EC No. 425-220-8)
ECHA/MSC/D/2012/063-065
- TPE-026/2012 (1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate BDP (new registration) (EC No. 425-220-8)
ECHA/MSC/D/2012/066-068
- TPE-027/2012 Benzene, 1,1'-oxybis-, tetrapropylene derivs., sulfonated, sodium salts' (DOWFAX 2A1) (List number 601-601-6)
ECHA/MSC/D/2012/069-071
- TPE-028B/2012 Hydroxycyclohexyl phenyl ketone (EC No. 213-426-9)
ECHA/MSC/D/2012/124, 125 & 127
- TPE 040/2012 Dust, steelmaking (EC No. 266-005-7)
ECHA/MSC/D/2012/101-103

[1] Note to members: The documents listed for each case here may be found in the substance specific folders in CIRCABC, as were made available for the written procedures, and are not available in the MSC-23 folders.

- TPE-049/2012 Sulfonic acids, C14-16 (even numbered)-alkane hydroxy and C14-16 (even numbered)-alkene, sodium salts (EC No. 931-534-0)

ECHA/MSC/D/2012/0083-085

- TPE-056/2012 Pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (EC No. 229-722-6)

ECHA/MSC/D/2012/089-091

- TPE-57B/2012 Strontium nitrate (EC No. 233-131-9)

ECHA/MSC/D/2012/119, 120 & 122

For agreement

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

Items from the MSCA commenting round for MSC-24, including some consistency proposals from DK

For discussion

Item 7 – Authorisation process

3. SVHC identification process

a) Multiple entries for Refractory Ceramic Fibres on the candidate list – potential corrective measures

For information

b) SVHC time schedule for 2012

ECHA/MSC-23/2012/33
For information

4. Recommendation of substances for Annex XIV inclusion

a) Discussion of the draft recommendation/prioritisation results

ECHA/MSC-23/2012/034 & 035
For discussion

b) Time-table of MSC for drafting the opinion on ECHA's draft recommendation on priority substances for Annex XIV

ECHA/MSC-23/2012/037
For decision

Item 8 – Manual of Decisions (MoD)

- Any topics identified by members

For discussion

Item 9 – Report from other ECHA bodies and activities
Closed session for 9a

a) Management of MSC documents

For information and discussion

b) Report from the 1st ECHA PBT working group

For information

Item 10 – Any other business

Suggestions from members:

- GLP: Systematic feedback and EU collaboration
- Exposure assessment in Tier 1

For information

Item 11 – Adoption of conclusions and action points

- Table with action points and decisions from MSC-23

For adoption

IV. Conclusions and Action Points

Main conclusions and action points
MSC-23, 24-27 April, 2012
(adopted at the MSC-23 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
5. Adoption of the minutes and conclusions and action points of the MSC-22	
MSC adopted the minutes as modified during the meeting. MSC adopted also the conclusions and action points without modificiation.	MSC-S to upload final versions of the minutes on MSC CIRCABC by Monday 30 April 2012.
6. Dossier evaluation **6a) General Topics**	
1. 2nd species in developmental toxicity testing **2. Selection of route of administration for human health higher tier testing** MSC took note of ECHA's presentations. **3. Read-Across Assessment Framework – development/principles of the second tier (Tier II)** MSC took note of the systematic approach for Tier II based on expert judgement. MSC appreciates the progress made in this field especially in the structured approach presented on how to deal with uncertainty and welcomes further discussion. Since this approach is still under construction, discussion is planned to continue with MSCAs and StOs on 4 October 2012. **4. Update by Commission representative on Use of the Extended One-Generation Reproductive Toxicity Study (EOGRTS) under REACH and CLP** MSC took note of the summary of the paper presented to CARACAL on COM's legal position with regard to TG 443 and the REACH information requirements and the proposed next steps for the implementation of EOGRTS. MSC is of the view that EOGRTS needs to be implemented in REACH as soon as possible. **5. Proposal for organisation of the MSC work for high number of dossier evaluation cases *(Partly closed session)*** MSC agreed with the following: a. SECR will continue using written procedures to a maximum extent. b. SECR will continue to organise Webex meetings and preparatory meetings for some time to see if they are helpful for plenary discussions. c. To avoid drafting in the plenary, DDs will be addressed in smaller groups for review and possible drafting before cases are returned to plenary Session 2. d. Interventions during plenary Session 2 to be kept as brief as possible. e. Drafting of agreement documents will be stopped since they are not required by legal text and the information found in the agreement is in the procedural part of the DD and minutes. f. MSC RoPs to be revised in order to start providing case-specific presentations to StOs and case owners. g. Review the above as necessary by end of the year. **6. Status report on ongoing evaluation work** MSC took note of the report.	ECHA to organise a workshop on read across in the first week of October 2012. COM to check whether background information related to test-cost calculations can be distributed to MSC. SECR to add in the response template of the written procedure an option to ask for termination of the written procedure. ECHA announced to organise: - Substance Evaluation

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	Workshop on 4-5 June 2012 - Technical discussion on TGR and UDS on 4 October 2012
6. Dossier evaluation **6b) Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
	MSC-S to upload on MSC CIRCABC the final ECHA decisions and agreements on cases agreed in written procedures, as indicated in document ECHA/MSC-23/2012/002. MSC-S to provide COM for further decision making with documents (DD on generation testing, MSC DA, 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-23/2012/002.
6c) Introduction to and preliminary discussion on draft decisions (DD) on compliance checks after MSCAs' reactions *(Session 1, tentatively open session except for TPE-010)* **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's draft decisions and adopted the respective formal agreements of: **TPE-002/2012** 2,2-bis(hydroxymethyl)propionic acid (EC No. 225-306-3) **TPE-010B/2012** **TPE-023/2012** Silicon (EC No. 231-130-8) **TPE-025/2012** (1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate BDP (EC No. 425-220-8) **TPE-026/2012** (1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate BDP (new registration) (EC No. 425-220-8) **TPE-027/2012** Benzene, 1,1'-oxybis-, tetrapropylene derivs., sulfonated, sodium salts' (DOWFAX 2A1) (List number 601-601-6) **TPE-028B/2012** Hydroxycyclohexyl phenyl ketone (EC No. 213-426-9) **TPE-033/2012** Sodium hydroxymethanesulphinate (EC No. 205-739-4) **TPE-038B/2012** 2-Ethylhexyl Nitrate (EC No. 248-363-6) **TPE 040/2012** Dust, steelmaking (EC No. 266-005-7) **TPE-048/2012** Tert-butyl 2-ethylperoxyhexanoate (EC No. 221-110-7) **TPE-049/2012** Sulfonic acids, C14-16 (even numbered)-alkane hydroxy and C14-16 (even numbered)-alkene, sodium salts (EC No.	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
931-534-0) **TPE-056/2012** Pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (EC No. 229-722-6) **TPE-57B/2012** Strontium nitrate (EC No. 233-131-9) **CCH-003/2012** Dichloro(dimethyl)silane (EC No. 200-901-0) **CCH-004/2012** Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)- (EC No. 213-668-5) **CCH-006/2012** Tert-butyl hydroperoxide (EC No. 200-915-7) **CCH-008/2012** Vinyl 2-ethylhexanoate (EC No. 202-297-4)	
MSC could not reach unanimous agreement on the following draft decisions: **TPE-010A** on the information requirements for Annex X, point 8.7.3 (as the Registrant proposed to carry out EOGRTS with DNT cohort (OECD TG 443), but without the DIT cohort) due to different interpretations on whether the DNT/DIT cohorts and other elements of the test guideline are integrated part of OECD TG 443, or they could not be considered as covered under the standard information requirements of the REACH Regulation. **TPE-018/2012** 2-Octyldodecan-1-ol (EC No. 226-242-9) on the information requirements for Annex X, point 8.7.3 due to different scientific 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, MSC DA, RCOM, minutes, outcome of the vote, justification for the position at the vote) of cases TPE-010A/2012 and TPE-018/2012. MSC members voting against ECHA's draft decisions to provide justification for their vote.
MSC agreed in the light of the discussions on TPE-033/2012, that concerning testing proposal evaluation, a presentation on issues in REACH related to CMR classification category 1 and the implemented risk management measures that would make further testing redundant will be brought to general discussion in the Plenary.	MSC to organise a discussion on this approach in a future MSC meeting.
MSC recognised that: - the proper time for MSCAs to provide advice to Registrants for the Registrant to be able to update the dossier on time for the decision making process, is during the third parties consultation and not during the MSCA consultation. - there is a need for further discussion on which test to use for long term terrestrial plant toxicity as requested in Annex X of REACH, i.e. whether to use ISO or OECD guidelines.	SECR to prepare a presentation for one of the next MSC meetings.
6e) Items for discussion following commenting by MSCAs *(Tentatively closed session)*	
MSC took note of ECHA's presentation on ECHA's ways to ensure consistency of draft decisions in the dossier evaluation process. MSC accepted ECHA's responses to specific draft decision related concerns raised by one MSC member.	
7. Authorisation process **1) SVHC identification process**	
a) Multiple entries for Refractory Ceramic Fibres on the candidate list – potential corrective measures MSC supported ECHA's suggested approach to consolidate the existing multiple RCFs entries in the Candidate List. **b) SVHC time schedule for 2012**	SECR to take the necessary measures in this case, as proposed.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
MSC took note of ECHA's approach to select substances to be referred to MSC for identification as SVHC in a MSC meeting/written procedure. MSC was also informed of the SVHC time schedule for 2012.	SECR to proceed with the SVHC cases as indicated in the document, unless a need for reconsideration of the preliminary planning is found.
2)Recommendation of substances for Annex XIV inclusion	
a) Discussion of the draft recommendation/prioritisation results MSC took note of the work carried out for the 4th draft recommendation for inclusion of priority substances in Annex XIV. SECR will review the general prioritisation approach document over summer 2012.	SECR to consider the comments provided in the discussion. SECR to upload any updated background documents for the substances currently proposed to be prioritised by ECHA. MSC members and MSC stakeholders to review the documentation received and to submit their further comments in writing on ECHA's document concerning prioritisation of substances from the Candidate List by 4 May 2012. ECHA to further refine the document for further discussion in MSC-24 meeting. MSC members and stakeholders to submit their input for the review of the general prioritisation approach document.
b) Time-table of MSC for drafting the opinion on ECHA's draft recommendation on priority substances for Annex XIV MSC agreed upon and adopted the detailed time plan for its work in the process of ECHA's 4th recommendation.	SECR to invite for volunteers for Rapporteurship to draft the MSC opinion and for possible working group members in advance of the next meeting.
8. Manual of Decisions (MoD)	
	MSC members to provide proposals to be included in the MoD of MSC.
9. Report from other ECHA bodies and activities	
a) Management of MSC documents **b) Report from the 1st ECHA PBT working group** MSC took note of the reports.	
10. Any other business	
• **GLP: Systematic feedback and EU collaboration**	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
MSC took note of ECHA's report on how GLP compliance is followed up. • **Exposure assessment in Tier 1**	Concerning exposure assessment, interested experts to provide further data, share their experience and join the relevant exercise started
11. Adoption of conclusions and action points	
MSC adopted the conclusions and action points of MSC-23.	MSC-S to upload the MSC-23 conclusions and action points by 30 April 2012.

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

- **agreed by written procedure:** CCH-005/2012 (Benzaldehyde, 5-dodecyl-2-hydroxy-, oxime, branched); CCH-007/2012 (Tetrahydro-4-methyl-2-(2-methylpropyl)-2H-pyran-4-ol); TPE-001B/2012 (B-TEGME / Tris [2-[2-(2-methoxyethoxy)ethoxy]ethyl] Orthoborate); TPE-006/2012 (2,2,4(or 2,4,4)-trimethylhexane-1,6-diamine); TPE-008/2012 (Reaction mass of 2-tert-butyl-4,6-dimethylphenol and 4-tert-butyl-2,5-dimethylphenol); TPE-021/2012 (Benzoic acid, 2-hydroxy-, mono-C14-18-alkyl derivs., calcium salts (2:1)); TPE-022/2012 (Sodium ethylenesulphonate); TPE-031/2012 (2-ethyl-4-(2,2,3-trimethyl-3-cyclopenten-1-yl)-2-buten-1-ol); TPE-037B/2012 (1-ethylpyrrolidin-2-one); TPE-043/2012 (Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate); TPE-051/2012 (Tris(2,4-ditert-butylphenyl) phosphate); TPE-058/2012 (Strontium carbonate); TPE-059/2012 (Anthraquinone); TPE-007/2012 (Mequinol); TPE-012/2012 (3,5,5-trimethylhexanoic acid); TPE-016/2012 (4,4'-sulphonyldiphenol); TPE-019/2012 (Sodium hexahydroxoantimonate); TPE-020/2012 (Trimethylolpropane Diallyl Ether/2,2-bis(allyloxymethyl)butan-1-ol/2,2- bis[(allyloxy)methyl]butan-1-ol); TPE-024B/2012 (2-Butyne-1,4-diol, polymer with 2- (chloromethyl)oxirane, brominated, dehydrochlorinated); TPE-034/2012 (2010_BEPD); TPE-046/2012 (N-[3-(dimethylamino)propyl]methacrylamide); TPE-050/2012 (Ethanol, 2-mercapto-).

- **referred to COM:** TPE-001A/2012 (B-TEGME / Tris [2-[2-(2-methoxyethoxy)ethoxy]ethyl] Orthoborate); TPE-009/2012 (2-Methylpentane-2,4-diol); TPE-013/2012 (2-chloropropane (IES Isopropylchloride)); TPE-015/2012 (2,6-dimethyloct-7-en-2-ol); TPE-017/2012 (2-Hexyldecan-1-ol); TPE-024A/2012 (2-Butyne-1,4-diol, polymer with 2-(chloromethyl)oxirane, brominated, dehydrochlorinated, methoxylated); TPE-028A/2012 (Hydroxycyclohexyl phenyl ketone); TPE-037A/2012 (1-ethylpyrrolidin-2-one); TPE-038A/2012 (2-Ethylhexyl Nitrate); TPE-057A/2012 (Strontium nitrate); TPE-060/2012 (Tetrahydrothiophene 1,1-dioxide)

- **WP terminated and agreement sought in MSC-23 meeting:** TPE-018/2012 (2-Octyldodecan-1-ol); TPE-025/2012 (BDP); TPE-026/2012 (BDP (new registration)); TPE-027/2012 (DOWFAX 2A1); TPE-028B/2012 947-19-3_hydroxycyclohexyl phenyl ketone; TPE-040/2012 (Dust, steelmaking); TPE-049/2012 (Sulfonic acids, C14-16 (even numbered)-alkane hydroxy and C14-16 (even numbered)-alkene, sodium salts); TPE-056/2012 (Pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4 hydroxyphenyl)propionate); TPE-057B/2012 (Strontium nitrate)