MSC/M/022/2012
ADOPTED AT MSC-23

Final Minutes
of the 22nd Meeting of the Member State Committee (MSC-22)
6-9 February 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 22nd 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 and two of the members. The final Agenda is attached to these minutes.

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

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

Item 4 - Administrative issues

- **Satisfaction survey 2011**

SECR provided preliminary feedback to MSC from the annual satisfaction survey held in December 2011. The average MSC response rate was 67 % and the overall level of satisfaction seemed to be similar to the one in 2010. More precise information will be provided to MSC on the issue later on.

- **Dates for MSC meeting**

SECR introduced the revised MSC meeting calendar for 2012 uploaded to MSC CIRCABC highlighting that the December meeting dates were changed from 3-5 December to 10-14 December 2012.

Item 5 – Adoption of the minutes of MSC-21

SECR presented to MSC the draft MSC-21 minutes (document MSC/M/21/2011). Written comments were received from five 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 with a minor editorial comment made at the meeting. The MSC Secretariat will upload the minutes on MSC CIRCABC and on the ECHA website (public minutes).

Item 6 – Dossier evaluation

The Committee was informed that the full documentation on the dossier evaluation cases sent to the Commission for further decision-making (for which MSC failed to reach unanimous agreement) will be uploaded on MSC CIRCABC for members' information.

a. General topics:

1. *In vitro* and *in vivo* genotoxicity tests in dossier evaluation (closed session)

- **Presentation on ECHA's current approach**
- **Introduction of comments provided on ECHA's presentation in MSC-20**

SECR gave a presentation on *in vitro* and *in vivo* genotoxicity testing under the dossier evaluation process. The general principles of mutagenicity and genotoxicity as well as scope of the relevant *in vivo* test methods recommended in the REACH Guidance documents were explained. SECR informed MSC of its approach to the REACH integrated testing strategy for genotoxicity.

In the following discussion, MSC members took note of ECHA's view on many aspects of the basic scope of application of different *in vitro* and *in vivo* genotoxicity tests. It was however concluded that further scientific discussion is needed on the pros and cons of different *in vivo* tests (in particular Unscheduled

DNA Synthesis Test (UDS), Transgenic Rodent Assay (TGR) and Comet assay all referred to as relevant *in vivo* tests in the Guidance) and which of these tests (liver UDS as opposed to the COMET or TGR test) in testing proposal examinations (TPE) cases with data gaps and in compliance check cases (CCH) should be requested as default in the light of the final adoption of the guideline for TGR by the OECD council.

Some members stressed that TGR is generally providing more reliable results (as it detects mutations and is not an indicator test such as the UDS), and it can cover more target organs than UDS which is suitable only for substances with metabolic activation in the liver. ECHA noted that the UDS assay can only be appropriate for substances that reach the liver.

Regarding the selection of the most appropriate test method during TPEs, MSC members took note of ECHA's view that because UDS is considered as an acceptable test method according to the ECHA guidance, substance specific justifications have to be provided if another test method, like TGR is requested to be used. TGR is a recently adopted test method by the OECD (OECD 488) but not yet included in the EU Test Methods Regulation. The majority of MSC members supported ECHA's view that the proposals for amendments (PfAs) of CAs for the use of TGR instead of other methods proposed by the Registrant have to include substance specific justification.

Regarding the preferred test guideline for CCHs, majority of MSC members also supported ECHA's view that if data based on UDS (or other guideline-compliant test) are available in the dossier normally they would not be challenged. However, if there is a data gap in the dossier, a TGR assay may be requested by default, unless other test guidelines would produce better results for the substance in question.

Some MSC participants expressed disagreement with some elements of the current ECHA approach in particular in relation to testing proposals that substance specific justification should be provided for rejection of UDS proposed by the registrant. In their view a scientific justification should be provided for which test to prefer also in TPE cases. Furthermore, they expressed the view that the default choice by MSC and ECHA in accordance with the view also taken by the EFSA Scientific panel on genotoxicity testing should be the TGR or COMET assay. They explained their view by reference to that both the TGR and COMET assays are possible to recognise by ECHA as being appropriate for use under REACH. Furthermore, the scientific rationale for the preference for the TGR and COMET assays was that these tests contrary to the UDS test are not organ (liver) specific, but provide opportunity to select organs/tissues for analysis including as warranted target organs/tissues relative to the substance in question, e.g. organs/tissues near the site of initial site of contact between reactive substances and the organism, selection of particular organs/tissues if organ/tissue specific biotransformation may take place, tissue from fast or slow growing tissues and/or inclusion of germ cells (testes) in addition to somatic cells.
One MSC participant had furthermore made a room document outlining his views on this matter available.
Furthermore, MSC came to a conclusion that there is a need of exchanging views based on the latest scientific development in this area. SECR informed the members that a workshop on these issues will be organised in September 2012 to further develop the current genotoxicity testing approach. The outcome of the workshop should be used as an input to a guidance update.

2. Terrestrial and chronic aquatic ecotoxicology - current approach (closed session)

SECR presented the general principles of ECHA's current environmental testing approach for terrestrial toxicity, long-term aquatic toxicity and further degradation testing, as well as the possible waiving options.

The presentation introduced ECHA's approach regarding the information requirements of Annex IX and X for ecotoxicological information. In accordance with this approach, column 1 represents the standard information requirements and column 2 the adaptation possibilities to the standard information requirements based on CSA. The presentation further explained the detailed information requirements and possible adaptations for long-term aquatic toxicity, terrestrial toxicity and further degradation testing reflecting also the available guidance.

In accordance with this approach, in case of testing proposals (TPs) ECHA would not investigate the CSA to be able to confirm that the Registrant has considered the need for testing based on CSA. ECHA would accept the TP as proposed by the Registrant as it would be for the Registrant to bring up the adaptation arguments. In case of compliance checks when a data gap is identified ECHA should check the CSA and verify whether the adaptation possibilities have been applied correctly based on the CSA.

ECHA also pointed out in the presentation that the table in the guidance R.7.11 -2 should be clarified for terrestrial information requirements by using figures of tables R.7.11-2/ R.7.11-3.

MSC appreciated that clarity is sought how to apply the relevant standard information requirements as listed in Annex IX/X. In the following discussion the approach proposed by ECHA was generally supported. However, one MSC member expressed concerns to accept the long term aquatic toxicity testing in fish proposed by the Registrant without reviewing the chemical safety assessment (CSA) for the need of the test and without considering the sequence of tests (*Daphnia* or fish).

MSC recognised the presented approach could be tested as a working hypothesis in the context of the cases to be discussed at MSC. One member as indicated above maintained the concern in particular regarding long term aquatic tests. It was agreed that further work between the environmental experts of MSCAs and those of ECHA is needed to specify the acceptable adaptation arguments within the CSA.

3. Handling of Extended One Generation Reproductive Toxicity Study (EOGRTS) versus two-generation issues in MSC - proposal of some members

A MSC member gave a brief presentation based on a room document prepared by four MSC members (from DE, DK, NL and UK) for the MSC-21 meeting with a proposal on handling of cases where EOGRTS (OECD TG 443) has been proposed to be used in PfAs. He proposed to avoid CCHs on the endpoint set out under 8.7.3 of Annex IX/X and to target the CCH to other endpoints. For TPE, he proposed to conditionally reject two-generation TPs unless legal obligation or proper argumentation is found, so that the Registrant could reconsider the necessity of carrying out such testing. Finally, he suggested the TPs on 8.7.3 of Annex X to be addressed in written procedure (WP) which can then go for comitology in case of disagreement as disagreement is the likely outcome of the MSC process in these cases as long as no changes in the relevant pieces of legislation are made.

SECR pointed out, and several members agreed, that even if a TP is proposed to be rejected for the information requirement on generation reproductive toxicity the cases are different and all aspects (e.g. information data gaps, Registrant's consideration, etc.) should be considered. In such cases of rejection, WP could be applied based on the same principle used in some previous cases, i.e. when a TP for two-generation testing is made for Annex IX, 8.7.3, without legal obligation and proper argumentation in the dossier, the TP will be rejected conditionally. The members can in any case decide whether to ask for termination of the WP and ask for discussion in the MSC meeting instead.

Regarding CCHs ECHA explained that systematic opening of CCHs is not likely in the near future because the TPs have to be examined first. A solution will hopefully be available when CCHs will be more in the focus of ECHA. However, ECHA has decided that the CCH draft decisions already in the decision making process should be finalised and tackled on a case-by-case basis.

COM stated that the work on the issue of second generation vs EOGRT testing for the dossier evaluation is ongoing and some principal conclusions could be expected to be reported back to CARACAL this year.

In conclusion, the Chair summarised that regarding CCHs, a policy line on this issue could not be taken at this moment and MSC should handle the draft decisions on a case-by-case basis. Regarding TPs, where two-generation testing is proposed without legal obligation by reference to standard information requirements and without argumentation in the dossier, the TP made under Annex IX, 8.7.3 may be rejected conditionally as already done before. The 'classical' EOGRTS/two-generation proposals (concerning this standard information requirement only) will be addressed by WP, as suggested. Since most cases have TPs for more than one standard information requirement, MSC agreed to grant SECR a mandate to split the draft decisions before the WP, so that the decisions on TPs for 8.7.3 of Annex IX/X could be separately addressed in WP.

4. Status report on ongoing evaluation work

SECR gave an update on the status of evaluation work till the end of January 2012. MSC was also informed that ECHA organises a Workshop on nanomaterials for MSCAs and MSC members preliminarily scheduled for 30-31 May 2012. The aim of the workshop would be to share experience on nanomaterials' characterisation and undergoing nanomaterial evaluation, as well as to discuss with MSCAs the establishment of a working group (consisting of members nominated by MSCAs). It was clarified that as ECHA is involved in different ongoing activities on nanomaterials, the expected outcome of the workshop would be capacity building in MSCAs and also in ECHA and sharing experience with MSs. SECR also informed MSC of the ongoing preparatory work on a mutagenicity workshop in September 2012 and a read-across workshop later this year.

In response to a query of a stakeholder observer (STO) on their participation in these workshops, SECR pointed out that it would depend on the nature and sensitivity of the discussion topics; however, transparency will be a key element in the preparations of these workshops.

5. Report from Dossier Evaluation Workshop January/February 2012

SECR briefly reported from the Evaluation Workshop held on 31 January - 1 February 2012. The key discussion points and main conclusions as regards the strategy proposed by ECHA for priority setting when selecting dossiers for compliance check were outlined, in particular with regard to the proposed targeted compliance checks for addressing problematic dossiers, efficient handling of significant amount of dossiers, as well as further ways to improve the efficiency in the dossier evaluation process. The importance of having smooth communication between MSCAs and their MSC member for providing feedback on outcome of MSC discussions was highlighted.

SECR reminded the members of the Workshop on substance evaluation scheduled for June 2012 that would bring further clarification and support to MSCAs for their substance evaluation work.

6. Work load of MSC – how to tackle high number of dossier evaluation draft decisions

MSC Chair pointed out that significant increase in the workload of MSC is expected from MSC-23 onwards. There are indications that MSC will potentially

have around 30 dossier evaluation cases on the agenda of the April 2012 meeting if the rate of proposals for amendment (PfAs) remains the same. In this regard, SECR has identified a need to consider possible streamlining of the MSC working practices, as well as other means for tackling the disputable cases (as currently 40 % of cases in the MSCA consultation comes to plenary discussion). Possible way forward could be the establishment of an MSC working group preparing the cases in advance for plenary discussion with obligatory membership of members/experts from those MSCAs that submitted a PfA. The Chair also proposed that Session 1 discussions with case owners' and STO would be restricted to the most complex or controversial cases only.

Members agreed that having so many cases for MSC plenary discussion would not be manageable with the present approach. They made some further suggestions to streamline the workflows at both MSCA and MSC stages, as follows:

- Administrative burden for CAs should be reduced and communication between CAs, ECHA and MSC improved to avoid PfAs as was concluded in the workshop (31 Jan – 1 Feb 2012) on dossier and substance evaluation.
- PfAs should - as far as possible - propose a modification to the text of the draft decision for avoiding drafting the text of the decisions at the plenary sessions.

Limiting the introduction session to the more complex cases was considered as a good suggestion; however, a need for development of criteria for case distinction was identified. It was suggested that a higher number of draft decisions with PfAs should be addressed by WP, and only the not-agreed standard information requirements of the cases from the terminated WP be discussed at MSC plenary meetings. Grouping of similar cases and having specific preparatory discussions as other options for quicker problem-solving would be helpful. Discussion on generic issues first, as done at this meeting, was found helpful for the case-specific discussions. Normally, only the open endpoints as left-overs from a WP should be discussed at the meeting.

An industry STO expressed a concern that the case owner involvement in the dossier evaluation process would become unclear if the WG model for preparation of the plenary meetings would be followed. He suggested their involvement on dossier evaluation cases during the plenary discussion be further utilised to gain efficiency. More active use of the MSC Manual of decision (MoD) was recommended.

MSC acknowledged the need to improve the efficiency of meetings due to increasing workload caused by draft decisions from dossier evaluation and tentatively agreed to set up a working group assisting in preparation of plenary sessions. The working group would consist of the members whose CAs had made PfAs but it would be open also for other MSC members. The group should in advance discuss scientific/legal interpretation issues brought up in PfAs and come up with a proposed text for modification of the draft decisions on the agenda of that MSC meeting. Organisation of MSC meetings altogether has to be reviewed to improve efficiency. Other existing means will be continued to be used more efficiently (e.g. telephone end Webex conferences).

In conclusion, the Chair informed MSC that the options for streamlining the MSC work and handling the increasing workload will be compiled in a document for further consideration at MSC-23.

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

SECR gave a report on the written procedures of seven substances – CCH-043 (Phenylbis(2,4,6-trimethylbenzoyl)phosphine oxide), TPE-029 (Phenylbis(2,4,6-trimethylbenzoyl)phosphine oxide), TPE-030 (Azodicarbonamide), TPE-031 TBPIN, TPE-034 (Bis(2-ethylhexyl) fumarate), TPE-036 (Reaction mass of divinylbenzene and ethylstyrene) and TPE-038 (6,6'-Di-tert-butyl-2,2'-

methylenedi-p-cresol). Written procedure was launched on 10 January 2012. Unanimous agreement was reached for TPE-031 by the closing date 20 January 2012. Responses were received from 25 members with voting rights and the Norwegian member. The written procedure for CCH-043, TPE-029, TPE-030, TPE-34 and TPE-36 was terminated on 20 January 2012 on request of at least one MSC member requested further discussion on each of the five cases at the MSC-22 meeting and agreement seeking at the meeting. For case TPE-038/2011 four votes were indicating disagreements to the draft decision, 21 votes were in favour of it and one MSC member did not vote. Therefore, the case was referred to the Commission 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 MS-CA reactions

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

TPE-032/2011 3,4,5,6,7,8,9,10,11,12,13,14-dodecahydro-2h cyclododeca[b]pyran (EC 251-090-5)

Session 1 (open)

Two representatives of the Registrant participated in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representatives of the Registrant on the relevant practicalities during and after Session 1.

ECHA explained that two PfAs to ECHA's draft decision were submitted by two MSCAs.

Both CAs had proposed ECHA to require the Registrant to perform a TGR assay (OECD TG 488) instead of the *in vivo* micronucleus assay (OECD TG 474, proposed by the Registrant). One CA had also suggested meeting discussion on the tissues of choice to be included in the test requirement for TGR.

ECHA had responded to the PfAs and is of the view that the draft decision as presented to the MSCAs on 4 November 2011 does not need to be modified based on PfAs.

The Registrant in his written comments on the PfAs had clearly disagreed with the PfAs and stuck to his original proposal to perform the *in vivo* micronucleus test as the most appropriate test for clastogenicity in this case, or to even withdraw the testing proposal since substance is a transported isolated intermediate used under strictly controlled conditions and extensively tested as required by REACH Regulation.

SECR had not modified the draft decision based on the PfAs. The draft decision, as presented to MSCAs on 4 November 2011 and updated since that date with procedural steps, had been provided to MSC as a meeting document of the current meeting for finding unanimous agreement.

The representatives of the Registrant explained in the meeting that as the substance is used under strictly controlled conditions and is a transported isolated intermediate, in their view no further vertebrate test is necessary, based on lack of exposure (exposure driven waiving according to Annex XI of REACH) and the low mutagenic potential shown in Ames tests. The Mouse Lymphoma Assay is negative. The Registrant confirmed, to not perform the *in vivo* micronucleus test because of a revised interpretation by the Registrant of the existing mutagenicity data: Mouse Lymphoma Assay negative instead of high toxicity positive and the availability of new negative in vitro data (BlueScreen HC Assay). One MSC member confirmed the statement by presenting their own QSAR analysis that showed an absence of mutagenicity alerts. Therefore, the representatives of the Registrant expressed their intention to update the registration dossier and withdraw their testing proposal for the *in vivo* micronucleus test.

MSC discussed the case based on ECHA's draft decision as provided for the meeting, the proposed amendments of MSCAs and the Registrant's comments to the proposed amendments.

At the start of the discussion, an expert from one of the MSs that submitted a PfA withdrew their PfA and expressed their complete agreement with the ECHA's draft decision to request the *in vivo* Mammalian Erythrocyte Micronucleus test, OECD Guideline 474 test. The MSC member from the other MS that proposed amendment accepted ECHA's reply to the PfA. However, he pointed out that in emergency situations the knowledge whether or not a transported intermediate is an *in vivo* mutagen may be important.

SECR explained replying to questions that as the substance is registered for a transported isolated intermediate at >1000 tpa, Annex VII applies i.e. in case of positive in vitro mutagenicity results, an *in vivo* confirmatory mutagenicity test shall be considered. The Registrant appropriately chose the *in vivo* micronucleus study to test clastogenicity as the main area of concern.

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. he 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. It is the Registrant's responsibility to ensure that these requirements are met. In the current stage of decision making MSC can not take any position on potential updates/waivers. SECR also explained that the role of the Registrant in the current meeting is just to clarify certain issues raised by MSC members based on PfAs but not to raise new discussion points or to provide new information for the case.

Session 2 (closed)

MSC found unanimous agreement on ECHA's draft decision as provided for the current meeting without further amending it, and adopted the formal agreement.

TPE-035/2011 1-Methyl-4-(methylsulfonyl)-2-nitrobenzene (4-mesyl-2-nitrotoluene) (EC 430-550-0)

Session 1 (open)

Two representatives of the Registrant participated in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representatives of the Registrant on the relevant practicalities during and after Session 1.

ECHA explained that two PfAs to ECHA's draft decision were submitted by two CAs proposing ECHA to require the Registrant to perform for *in vivo* genotoxicity a TGR assay (OECD TG 488) instead of the UDS assay (OECD TG 486, proposed by the Registrant). One CA had also suggested meeting discussion on the tissues of choice to be included in the test requirement for TGR.

The Registrant in his written comments on the PfAs had submitted new data that in his view do not warrant anymore a second *in vivo* mutagenicity test (i.e. UDS) but may warrant a confirmatory *in vitro* somatic cell gene mutation assay. However, the Registrant clearly reconfirmed his preference to perform the UDS test instead of the TGR assay if ECHA required the *in vivo* mutagenicity test in the final decision.

SECR had not modified the draft decision based on the PfAs. The draft decision, as presented to MSCAs on 4 November 2011 and updated since that date with procedural steps, had been provided to MSC as a meeting document of the current meeting for finding unanimous agreement.

The representatives of the Registrant mainly repeated in the meeting their written comments on the PfAs saying that based on new negative results of a recently

concluded Ames test conducted, as stated in the written testing proposal, in their view no *in vivo* follow-up test (i.e. UDS or TGR assay) is warranted. In line with their written comments on the PfAs, they pointed out that for the substance in question TGR would not have any benefit over the UDS test. Furthermore, they expressed their preference to conduct first a second confirmatory *in vitro* somatic cell gene mutation assay before going to the *in vivo* test and only if the *in vitro* assay was positive in somatic cells, considering potential germ cell mutagenicity. In addition, the registrant suggested that as no specific argument relating to the intrinsic properties of the substance had been put forward, the more appropriate route for discussing the use of TGR over UDS is via the committee procedure in Article 13(3)/ Article 133(4). If UDS cannot be carried out due to certain intrinsic properties then a further replacement should be considered. Until otherwise agreed, UDS is still the one favoured by the Registrant.

MSC discussed the case based on ECHA's draft decision as provided for the meeting, the proposed amendments of MSCAs and the Registrant's comments to the proposed amendments.

In the discussion, SECR explained 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 agreement seeking in MSC is therefore based on the testing proposal of the Registrant for the UDS test. SECR also explained that the role of the Registrant in the current meeting is just to clarify certain issues raised by MSC members based on PfAs but not to raise new discussion points or to provide new information for the case.

In the discussion, two MSC members expressed preference for the TGR assay with examination of intestinal tissue and testis instead of the UDS test as in their view there are indications that metabolic activation of the substance may happen in the gut and not in the liver (i.e. that there might be genotoxicity in the gut wall as a result of the metabolic activation of the substance in the gut). It was noted by SECR that this information, presented orally, had not been included in the written PfAs previously submitted and supplied to the Registrant. The two MSC members also raised concerns whether the identity of substance the recent negative Ames test was carried out with, is the same as the registered substance for which several earlier positive Ames test results are available and suggested a new separate registration may be warranted,

The Registrant reiterated that the generation of the new Ames data presented in the discussion had formed part of the written testing proposal, and the request for the UDS study was conditional on a positive result. The SECR noted that one MSC member had raised further detailed argumentation in favour of the TGR assay which had not been provided in written comments to the meeting.

Session 2 (closed)

Some MSC members raised the concerns that as there are structurally related substances that are genotoxic carcinogens that are activated in the gut, there would be some residual uncertainty remaining if the UDS test were requested and it turned out to be negative. However, it was also brought up that because of the sole use of the substance as an intermediate in chemical synthesis, in this specific case the UDS test could be accepted.

One MSC member and her expert agreed with the request for UDS based on comparison with 2-nitrotoluene (genotoxic carcinogen with structural similarity to the registered substance), which is also positive in UDS tests and in their view probably has the same main metabolic pathway and target organ (liver). Some MSC members also mentioned that an *in vivo* mutagenicity test may not need to be requested if the Registrant classified the substance as germ cell mutagen

Category 1B based on read across to structurally related substances and applied adequate risk management measures accordingly.

ECHA pointed out that all the positive UDS tests on 2-nitrotoluene were carried out on Fisher 344 rats and that the rat appeared to be more sensitive to the induction of liver tumours than mice. However, for TGR the most popular rodent model is mouse. There was the possibility that a TGR test in the mouse could yield a false negative result as a result of lower sensitivity of the mouse to mutagenesis/ carcinogenesis by agents acting similarly to 2-nitrotoluene. ECHA also highlighted that if the UDS test were requested and was negative on the registered substance, a possible compliance check or substance evaluation could clarify any residual uncertainty.

COM mentioned that weighing all the above concerns, proportionality of the measure of requiring a TGR test could be an issue as its costs are 3-4 times higher than those of a UDS test.

MSC concluded that in this case, the UDS test in rat shall be required in the decision as proposed by ECHA. A reminder to the decision should be added that there will be residual uncertainties if the UDS test will be negative but the sole intermediate use of the substance and the Registrant's classification (reprotox Cat 1B) were considered as sufficiently reducing these concerns. The Registrant shall also be reminded that the Fisher 344 rat strain is probably the most appropriate to conduct the UDS test for this substance.

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

TPE-034/2011 Bis(2-ethylhexyl) fumarate (EC 205-448-2)

Session 1 (open)

Two representatives of the Registrant participated in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

ECHA explained that three PfAs to ECHA's draft decision were submitted by two CAs. One PfA had suggested the removal from section II of the draft decision the optional requirement for testing using OECD TG 422 with extension to 90 days, mainly because the OECD TG 422 is a requirement for Annex VIII while for the registered substance Annex IX applies. The second PfA had argued that the Registrant should give stronger evidence to perform the chronic fish study. It had suggested a step-wise approach for aquatic toxicity testing instead of the immediate requirement for long-term toxicity test on fish: first the algal inhibition and acute fish toxicity tests should be performed and, if the risk assessment based on the results of these studies indicates any risk, also chronic Daphnia and/or FELS test should be conducted. This PfA had also suggested requiring the Registrant to revise the data concerning water solubility and log Kow. The third PfA had suggested removing the requirement for a bioaccumulation test in fish.

The Registrant in his written comments on the PfAs had clearly agreed to perform the dietary bioaccumulation test in fish according to the draft OECD 305 guideline.

SECR had modified the 'second' draft decision based on the PfAs concerning the OECD TG 422 study and partly based on the PfA concerning the long-term test on fish. The draft decision, as presented to MSCAs on 4 November 2011, modified and updated since that date with procedural steps, had been provided to MSC as a meeting document of the current meeting for finding unanimous agreement.

The representatives of the Registrant repeated in the meeting their written comments on the PfAs saying that they agree to perform both long term fish test and dietary test for bioaccumulation. They also stated that as the OECD 305

guideline is currently being revised, their intention is to wait for and perform the test according to the finalised guideline. The representatives of the registrant stated also that when contacting the labs for proposals for the bioaccumulation endpoint, the responses of the labs were hesitant. One lab which was in the ringtest of the draft guideline indicated that executing the draft OECD 305 dietary part is very complicated and impossible to perform exactly according to the guideline. Furthermore, looking at the phys/chem properties of this substance, the aqueous study may be possible so labs asked whether it is possible to go for a flow through test instead. SECR pointed out that the conduction of such a test is a standard information requirement under REACH (Annex IX, 9.3.2).

MSC discussed the case based on ECHA's draft decision as provided for the meeting, the proposed amendments of MSCAs and the Registrant's comments to the proposed amendments for the second and third PfA whereas the first PfA for test using OECD TG 422 was not discussed because ECHA agreed with the PfA.

MSC generally supported ECHA's view to request the bioaccumulation test in fish as a standard information requirement, however with some remaining doubt expressed by one member as indicated also in the PfA. It was highlighted that the guideline (OECD TG 305) and exposure route (dietary) to be followed should be precisely specified in the decision. However, concerns were raised regarding the mismatch between the high log-Kow (7,9) and a not so reliable and relatively high water solubility (1,19 mg/L) values reported by the Registrant.

Concerning the long-term fish test proposed by the Registrant and accepted in the draft decision by ECHA, an expert from the MS that submitted the respective PfA was still concerned whether the test is needed at this stage and proposed a tiered testing strategy.

Session 2 (closed)

Concerning the long-term fish test, the concerned MSC member proposed to give the Registrant the option to perform the long-term study on Daphnia. Other MSC members and also ECHA pointed out that although in line with the integrated testing strategy the Daphnia study could be the test to be requested, the physicochemical properties of the substance make this test technically even more difficult than the fish test would be. Furthermore, as the relevant PfA had not clearly mentioned the request for the Daphnia study, from the legal point of view it would not be justified requesting this study.

ECHA also clarified that the concerns related to the feasibility of the long-term fish test are recognised based on physicochemical properties of the substance. However, ECHA has no possibility to verify systematically in a testing proposal examination whether a measured value correlates with estimated QSAR values (which in this case are much lower for water solubility than the reported measured values).

It was indicated by SECR that in similar future cases ECHA will make the Registrant aware of the options to perform a long-term Daphnia study or the fish test and make a reference to an integrated testing strategy. However, in this current case the Registrant seems to have carefully considered all possible options before proposed the long-term fish test. The concerned MSC member asked ECHA for evidence of this consideration. ECHA replied it is the Registrant's responsibility to prepare testing proposals.

MSC concluded on the above discussions that the request for the long-term fish test shall not be changed in the draft decision but the statement of reasons concerning integrated testing strategy be slightly modified.

MSC found unanimous agreement on ECHA's draft decision as provided for the current meeting and further amended based on the above conclusions, and adopted the formal agreement. The MSC member from the MS that submitted the PfA challenging the need for the long-term fish test announced to submit a

written statement on the case to be attached to the confidential minutes of the meeting (please find as part V of the confidential minutes).

CCH-041/2011 Fe(III)HBED (List No. 700-327-5)

Session 1 (open)

Two representatives of the Registrant participated in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representatives of the Registrant on the relevant practicalities during and after Session 1.

ECHA explained that four PfAs to ECHA's draft decision were submitted by two MSCAs. One PfA had proposed to require the Registrant to perform a TGR assay (OECD TG 488) instead of the *in vivo* micronucleus assay (OECD TG 474). However this was a misunderstanding of the CA since the DD requested the Registrant to provide the data for the *in vitro* cytogenicity or micronucleus study and not *in vivo* cytogenicity or micronucleus study. The CA recognised that it was a misunderstanding and agreed with the DD in this regard. The second PfA had suggested requesting the Registrant to perform the screening test for reproductive/developmental toxicity (OECD 421). The third PfA had proposed requiring a long-term plant study instead of a short-term study. The fourth PfA had proposed not requesting a plant test unless terrestrial risks are shown from the risk assessment.

The Registrant in his written comments on the PfAs had not clearly referred to the PfAs but provided a revised toxicokinetics assessment and a revised read-across report (with the read-across substance Fe-EDDHA) and a letter concerning the possible future access to the letter of access. The Registrant had also stated that they are ready to update the CSR with DNEL and PNEC calculations but they intend to waive studies for activated sludge respiration inhibition, short-term toxicity on plants, pre-natal developmental toxicity, subchronic toxicity and mutagenicity based on the read-across.

SECR had modified the draft decision based on the PfAs concerning the OECD TG 421/422 study and plant testing based on terrestrial risks. The draft decision, as presented to MSCAs on 4 November 2011, modified as listed above and updated since that date with procedural steps, had been provided to MSC as a meeting document of the current meeting for finding unanimous agreement.

The representatives of the Registrant mainly repeated in the meeting their written comments which were only partly on the PfAs and mainly focused on the recent updates to the registration dossier. They explained why the read-across is justified and that they had updated the registration dossier with these data on 28 December 2011/9 January 2012. They also referred to a recently finished study with the conclusion that the registered substance is not a sensitiser and to US FDA that approved a similar substance for medical purposes.

MSC discussed the case based on ECHA's draft decision as provided for the meeting, the proposed amendments of MSCAs and the Registrant's comments to the proposed amendments.

In the discussion, SECR explained that the basis for the final decision is the registration dossier as it was available to ECHA at the start of the MSCA consultation (4 November 2011). Later updates of the dossier and new information given by the Registrant in the current MSC-meeting have not been evaluated and can not be considered for the final decision based on the registration dossier which was available on 4 November 2011. Consequently, the update of the dossier on 28 December 2011/9 January 2012 was not for discussion. However, the read-across report, the update of 28 December 2011/9 January 2012 and any other possible future updates will be evaluated 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 raised by MSC members based on PfAs but not to raise new discussion points or to provide new information for the case.

Concerning the PfAs on the plant test, SECR clarified its response to these PfAs explaining that the test provided by the Registrant to fulfil the information requirement for short term toxicity to plants, Annex IX, 9.4.3, was not in line with the test guidelines of standard toxicity test and the concentrations used were much lower than recommended by these guidelines. However, ECHA referred the Registrant in the draft decision to the ECHA Guidance which gives the Registrant the possibility to use the Equilibrium Partitioning Method (EPM). According to the Guidance, if the EPM does not show any risk one confirmatory long-term study is sufficient to fulfil the endpoint.

One stakeholder observer asked ECHA and MSC to mention in the final decision that the data submitted by the Registrant on 28 December 2011/9 January 2012 were not taken into account in the current decision making.

Session 2 (closed)

In the continued discussion on short-term vs long-term plant test, MSC concluded not to express preference for a specific plant test but to give the Registrant two options according to the ECHA Guidance: the OECD TG 208 test or the ISO 22030 test. MSC also agreed to slightly change the SoR for this information requirement to provide clearer reference to the Guidance and the Registrant's options (see Session 1) according to the Guidance. MSC also concluded that clearer reference shall be made to the studies the Registrant had already submitted and that still might need to submit following the Registrant's considerations based on the Guidance.

Concerning the request in a PfA for a screening study for reproductive/developmental toxicity, MSC concluded that a paragraph on the Registrant's responsibility to determine the appropriate order of studies based on the possible outcomes and adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of REACH should be included. Also, the Registrant shall consult the Guidance concerning the integrated testing strategy for reproductive toxicity testing and note that as the screening study does incorporate post-natal parameters which are not covered by the pre-natal developmental study it is advisable not to bypass the screening study when a prenatal developmental toxicity study is triggered.

MSC also concluded to include a note in the procedural part of the decision that the information provided by the Registrant on 28 December 2011/9 January 2012 could not be taken into account for the current decision.

On proposal of some MSC members general discussion on how to handle the comments of Registrants on PfAs will be organised in one of the coming meetings.

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

CCH-040/2011 Hexyl 2-(1-(diethylaminohydroxyphenyl)methanoyl) (EC 443-860-6)

Session 1 (open)

Two representatives of the Registrant participated in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

SECR introduced the seven PfAs submitted to ECHA's DD by four MSCAs. One PfA had suggested ECHA requesting the Registrant to include in the dossier an existing chronic *Daphnia* study as the key study that had already been submitted and selected as a key study under the NONS scheme leading to a harmonised classification of the substance. The second PfA had suggested that based on the

available tests on fish and *Daphnia* hazard category 3 should apply. Therefore, the Registrant should be requested first, to clarify issues for bioaccumulation study, then to derive a terrestrial PNEC and determine if one or both plant and soil microorganism tests are needed. The third PfA had suggested ECHA to change the order of the request for long-term and short-term testing on terrestrial plants. The fourth PfA had suggested deleting the option for the short term test as the substance is persistent and thus, column 2 requirement is met for long-term tests on plants. The fifth PfA had suggested deleting the request to the Registrant to change the wording in the dossier when referring to the substance from "potentially P and vP" to "P and vP". The sixth PfA had suggested requesting the Registrant to perform specifically the N-mineralisation test concerning tests on soil microorganisms as this is more sensitive than the C-mineralisation test. The seventh PfA had proposed to change the wording of the request for identification of PNEC-soil (i.e. specify that the Registrant may estimate the PNEC soil by use of the equilibrium partitioning method (EPM)).

The Registrant explained as also indicated in the written comments on the PfAs that he disagrees with the PfA on the *Daphnia* key study selection and gives detailed justification why the older study should not be considered as a key study. The Registrant agreed with the PfA that further soil testing in addition to the available acute earthworm test is not needed, however, expressed willingness to perform the plant test and soil microorganism test as requested by ECHA to demonstrate that the substance is not of a concern for the terrestrial environment. The Registrant also agreed with the PfA concerning potential P and vP properties of the substance indicating that the conclusion is based on a screening test thus no firm conclusion on "P" and "vP" can be made. Concerning the further PfAs, the Registrant preferred to perform the OECD TG 208 test on terrestrial plants (seedling emergence and seedling growth test) and both the C- and N-mineralisation test.

SECR had modified the draft decision based on the PfAs concerning P/vP assessment and mineralisation test. The draft decision, as presented to MSCAs on 4 November 2011, modified as listed above and updated since that date with procedural steps, had been provided to MSC as a meeting document of the current meeting for finding unanimous agreement.

MSC supported the view that the decision should request the missing *Daphnia* study to be included in the registration dossier because all available information shall be included in the registration dossier and because the study was part of the notification dossier of the new substance. ECHA explained that this request is legally possible. However, in selecting the key study the Registrant with proper justification could deviate from the study with the lowest NOEC (No Observed Effect Concentration) results. The representative of the Registrant agreed to include the robust study summary in the dossier but repeated that they old study should not be considered as a key study.

Concerning the PfAs on the plant test, SECR explained to these PfAs explaining that a long-term test can not be requested for a substance on this tonnage level (100-1000tpa). A long-term test shall be considered based on the indicated parameters of column 2 of Annex IX, 9.4. These considerations were not shown in the dossier. However, the lack of these clear statements does not prove the Registrant did not consider these parameters.

MSC supported ECHA's way of modifying the draft decision based on the PfAs concerning the need for plant/soil-microorganism test, P/vP assessment, N-mineralisation test and PNEC-soil.

Session 2 (closed)

MSC agreed that the Registrant shall be requested to include the robust study summary for the missing chronic *Daphnia* test in the dossier and the SoR shall be modified accordingly. The Registrant can not be requested at this stage to make

the missing *Daphnia* study as the key study. However, the Registrant shall be reminded that they have to use such study as the key study which has the highest concern or provide full scientific justification why they chose another study. It also has to be noted in the SoR that according to the evaluating CA under the NONS scheme, the missing long-term *Daphnia* gives rise to the highest concern. MSC also agreed to modify the request and SoR for the plant test not specifying a specific guideline but giving the Registrant both option for the OECD TG 208 test and the ISO 22030 test and to slightly modify the name of the requested study for the soil-microrganism test.

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

TPE-029/2011 Phenylbis(2,4,6-trimethylbenzoyl)phosphine oxide (EC 423-340-5)

Session 1 (open)

One representative of the Registrant participated in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

ECHA explained that six PfAs to ECHA's draft decision were submitted by three MSCAs. One PfA had suggested that based on the acute toxicity data for fish, invertebrates and algae for the registered substance, hazard category 3 (instead of 4) should apply. Therefore, only one chronic soil toxicity study (OECD 222 chronic earthworm study as proposed by the Registrant) should be requested to derive a terrestrial PNEC and determine if further soil toxicity testing is needed. Hence, the long-term plant and soil micro-organism study should not be required. Another PfA had suggested requesting the Registrant to perform the long-term toxicity study on plants according to the OECD 208 guideline instead of the ISO 22030 guideline (as proposed by ECHA).The third and fourth PfAs had proposed (1) to consider the OECD 232 guideline for soil toxicity testing as an optional substitute for the OECD 222 and (2) to request N-mineralisation test instead of requiring either C- or N-mineralisation test for toxicity testing on terrestrial microorganisms. The fifth PfA also noted that the ISO 22030 guideline proposed by ECHA for long-term toxicity study on plants might be more sensitive than the study according to the OECD 208 guideline. The sixth PfA had suggested not to reject the one-generation generation reproductive toxicity test but to modify it to an EOGRTS with inclusion of DIT and DNT assays and without triggering the second generation (F2).

The representative of the Registrant in the meeting summarised their arguments of the written comments on the PfAs and pointed out that they do not agree with the requested terrestrial toxicity testing, in particular the proposed plant and microorganism toxicity testing. However, he agreed that one chronic soil toxicity study should be performed and further testing should be considered in case the generated data from this study indicate further concern. The Registrant expressed his hesitancy in performing EOGRTS if the DNT/DIT cohorts are required and his intention to withdraw the testing proposal for the one-generation toxicity test.

SECR had modified the draft decision based on the PfAs concerning assignment of an appropriate hazard category (hazard category 3) owing to the fact that the proposing MSCA has evaluated the substance under the new substances notification scheme (NONs) using the full study reports. Consequently, ECHA had not modified the draft decision based on the other PfAs.

The draft decision, as presented to MSCAs on 4 November 2011, modified as explained above and updated since that date with procedural steps, had been

provided to MSC as a meeting document of the current meeting for finding unanimous agreement. The same draft decision had been addressed for agreement in MSC written procedure before the MSC-23 meeting. As complete agreement could not be reached, the written procedure was terminated upon members' request with the aim of further agreement seeking in the current meeting.

MSC discussed the case based on the modified draft decision as provided for the meeting, the PfAs of MSCAs, the Registrant's comments to the PfAs and the justification provided by the MSC member who requested to terminate the written procedure for this substance.

MSC accepted that the substance is of Hazard Category 3. Consequently, the Registrant should be requested to conduct a chronic earthworm toxicity study (OECD 222). However, it was pointed out that the substance of hazard category 3 would actually according to the guidance justify the request for further terrestrial toxicity testing.

Concerning generation test, MSC supported the rejection of the one-generation study (OECD 415) that was proposed by the Registrant. However, the Registrant should be recommended to submit a new testing proposal for the information requirement 8.7.3 of Annex IX, if the results of 90-day reproductive toxicity study (OECD 408) trigger a generation testing.

Session 2 (closed)

MSC agreed to reject the one-generation test (OECD 415), to include in the draft decision a note on the integrated testing strategy outlined in ECHA guidance and to modify the SoR accordingly.

Concerning terrestrial testing, SECR pointed out that the consideration of the application of proper hazard category has an impact on the potential need of terrestrial and soil organism testing. SECR explained that although the REACH Guidance provides mechanism to avoid conducting studies with terrestrial organism, section R 7.1.2 of the Guidance for hazard category 3 substances can be interpreted to give preference to have all trophic levels tested. MSC agreed to accept the test proposed by the Registrant on toxicity to invertebrates but agreed to request also the test on soil microorganisms and terrestrial plants in line with the standard REACH information requirements outlined in 9.4 of Annex IX, since the long-term toxicity test on invertebrates on its own does not fulfil the information requirements laid down in 9.4.2 and 9.4.3 of Annex IX.

The draft decision was modified on the basis of the above agreement.

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

CCH-043/2011 Phenylbis(2,4,6-trimethylbenzoyl)phosphine oxide (EC 423-340-5)

Session 1 (open)

One representative of the Registrant participated in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

ECHA explained that six PfAs to ECHA draft decision were submitted by five MSCAs. One PfA had suggested instead of repeating the bioaccumulation test, requesting the Registrant first to calculate a secondary poisoning PNEC, and PECs using a worst-case BCF of 2000, and only if these data indicate a risk to request the fish bioaccumulation test (Annex IX, 9.3.2) to be repeated. Another PfA had proposed not to request the repeated fish test as despite some shortcomings, the available test provides sufficiently adequate and reliably documented data for risk assessment. The third PfA had suggested MSC meeting discussion to decide

whether the deviations in the reported study are so severe that the study needs to be repeated. The fourth PfA had proposed to require the Registrant to derive PECs in the CSR for the sediment and soil compartment. The fifth PfA had proposed to request the Registrant to conduct a fish long-term toxicity test as the effects in the acute toxicity fish test are not above the maximum water solubility level and fish seems to be the most sensitive species according to test data available in the dossier. The sixth PfA had suggested to require the Registrant to perform further degradation simulation tests (in accordance with Annex IX, point 9.2) in addition to the available positive screening study for ready biodegradation (OECD 301B).

SECR had modified the draft decision based on the PfAs proposing not to request the fish bioaccumulation study and to request PECs for sediment and soil in CSR but not based on the other PfAs. The draft decision, as presented to MSCAs on 4 November 2011, modified as explained above and updated since that date with procedural steps, had been provided to MSC as a meeting document of the current meeting for finding unanimous agreement. The same draft decision was addressed for MSC agreement in written procedure before the meeting but the written procedure was terminated upon members' request with the aim of further agreement seeking in the current meeting.

The representative of the Registrant mainly repeated the arguments of their written comments on the PfAs. He disagreed to repeat the bioaccumulation study and to conduct the biodegradation study and long-term fish toxicity testing. The Registrant expressed willingness to address the missing exposure information on late life stages into the chemical safety report via an update of their registration dossier.

MSC discussed the case based on the modified ECHA's draft decision as provided for the meeting, the proposed amendments of MSCAs, the Registrant's comments to the proposed amendments and the justification of the members requesting for termination of the written procedure.

MSC discussed the need for the long-term toxicity test to fish (Annex IX, 9.1.6) that was waived by the Registrant. The MSC member from the MS that evaluated the substance under the NONs scheme confirmed that the short-term fish test was of low reliability (Klimisch score 4 instead of 2). On this basis the MSC member from the MS that submitted the PfA concluded that the long-term fish test would not be justified and considered the PfA unnecessary.

MSC concluded that a repeated bioaccumulation test would not be needed.

Session 2 (closed)

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

CCH-042/2011 Triphenyl phosphate (EC 204-112-2)

Session 1 (open)

Two representatives of the Registrant participated in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

ECHA explained that six PfAs to ECHA's draft decision were submitted by five MSCAs. Three PfAs had proposed that instead of the two-generation reproductive toxicity test (OECD 416/EU B.35) an EOGRTS (OECD 443) should be requested. The fourth PfA had argued that the available combined screening study (one-generation study combined with developmental toxicity) is sufficient and adequate to cover the endpoint set out under 8.7.3 of Annex X and therefore proposed no further testing on this endpoint. One PfA in addition had referred to

the likely endocrine disrupting properties of the registered substance that in their view makes the necessity to perform EOGRTS even more appropriate. The fifth PfA had proposed the Registrant to perform sequential testing for the 90-day, the prenatal developmental toxicity study (PNDT) and the testing according to Annex X 8.7.3. The second species PNDT test should be conducted only if the results of these studies indicate a need for this, in accordance with Annex X of REACH and with the intelligent testing strategy (ITS) for developmental toxicity. The same PfA had also suggested considering the request to the Registrant to perform an EOGRTS based on the likely endocrine disrupting properties of the registered substance. The sixth PfA had suggested considering whether the information (robust study summary and other available information) provided by the Registrant in the dossier is sufficient for the purposes for classification and labelling and risk assessment because if it so, the 90-day study in their view should not be requested.

SECR had modified the draft decision based on the PfAs concerning sequential testing and partly modified based on the four PfAs concerning EOGRTS (giving two options: two-generation reproductive toxicity test *or* EOGRTS with the second generation). The draft decision, as presented to MSCAs on 4 November 2011, modified as listed above and updated since that date with procedural steps, had been provided to MSC as a meeting document of the current meeting for finding unanimous agreement.

The representatives of the Registrant mainly repeated their written comments on PfAs. They summarised that concerning sub-chronic toxicity, according to many available studies including a recent OECD 407 study on the substance the most severe effect was reduction of body weight. Based on these data that are reliable, sufficient for DNEL derivation and suggest a very flat toxicity profile, the Registrant does not think that a new sub-chronic study is needed. Concerning the generation study, they referred to a non–guideline compliant one-generation study combined with developmental toxicity (Welsh, 1987), where the exposure was longer than set out in the guideline and the substance did not show any effect on fertility up to 600 mg/kg/day. They also referred to separate sub-chronic DIT (developmental immunotoxicity) and DNT (developmental neurotoxicity) studies, where no other effects than reduction of bodyweight up to 700 mg/kg/d could be shown on adult rats. Concerning developmental toxicity, they also referred to a rat study which at 30 times higher dose than the one where effects in sub-acute studies could be seen showed no developmental effect.

One stakeholder observer agreed with the Registrant's view and expressed her sympathy for not requesting any more animal testing based on the weight-of evidence approach.

The MSC member from the MS that submitted a PfA concerning sequential testing agreed to how ECHA modified the draft decision based on the PfA.

Concerning sub-chronic toxicity, ECHA and some MSC members pointed out that in the studies referred to by the Registrant no other key parameters but only the bodyweight was investigated. The Registrant confirmed that the understanding of MSC members and SECR was correct. This should be seen as a reason to perform a guideline-compliant 90-day study as the remaining uncertainty is too high.

Concerning two-generation study, the MSC expert from the MS that has submitted a PfA proposing to drop the two-generation study from the requirements revised his view based on the deficiencies on fertility effects of the one-generation study combined with developmental toxicity referred to by the Registrant and agreed that an EOGRTS is needed. He pointed out that fertility in the studies referred by the Registrant was assessed only for sperm count. Sperm production and function was not investigated and in rats, normal sperm count does not mean functional fertility (i.e. that sperm production and function are not altered). The three MSC members from the MSs that submitted a PfA requesting

only EOGRTS without the second generation and with DIT/DNT cohorts kept their position. One MSC member expressed her preference for not requesting any studies to fulfil the endpoint of 8.7.3 of Annex X. Concerning DIT/DNT effects, some MSC members highlighted that the DNT/DIT studies referred to by the Registrant were performed on adult rats although the sensitivity of the immune and neural system of developing animals is generally expected to be higher. It should also be noted that the substance is listed on the CoRAP for evaluation for 2014.

The pre-natal developmental study in the second species was not discussed in this part of MSC meeting since no PfAs have been provided by any MSCA.

Later updates of the dossier, new information or comments not relating to PfAs possibly given by the Registrant in the current MSC-meeting have not been evaluated and can not be considered for the final decision.

SECR explained that if MSC can not find unanimous agreement on the generation study (two-generation reproductive toxicity or EOGRTS), the decision could be split and the part where agreement was not possible (the generation study) be referred to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH. Another possibility would be to put the part of the compliance check regarding the generation study on hold and to come back to this data gap in a later compliance check when a legal solution regarding application of EOGRTS is available.

Session 2 (closed)

In the continued discussion, no new concerns were raised. MSC agreed that no generation study would be requested from the Registrant at this point of time and the timeframe for submitting the remaining requested information should be shortened accordingly from 36 to 24 months. MSC also concluded that a short explanation why the deadline was shortened needs to be added to the SoR.

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

SECR mentioned that a note into the cover letter of the final decision will be included explaining the situation why no generation study is requested at this point of time so that the Registrant would be prepared for a future compliance check regarding the data gap on the generation study.

TPE-033/2011 Isooctyl acrylate (EC 249-707-8)

Session 1 (open)

The Registrant had not indicated interest in participating in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held.

ECHA explained that five PfAs to ECHA's draft decision were submitted by five MSCAs. One PfA had suggested requesting the Registrant to clarify the discrepancy between substance ID and CAS/EC numbers in different sections of the registration dossier as well as to clarify which substance is to be tested. The four other PfAs had proposed that instead of the two-generation reproductive toxicity test (OECD 416/EU B.35) an EOGRTS (OECD 443) without the second generation. Three PfAs had explicitly mentioned the need for the DIT/DNT cohorts as well.

The Registrant in his written comments on the PfAs had agreed with the PfAs accepting EOGRTS as the test method and stating that he would perform EOGRTS without the F2 generation and with the DNT/DIT cohorts if the results of the 90-day study would justify such testing.

SECR had modified the draft decision based on all the PfAs (for generation testing, ECHA gave two options: two-generation reproductive toxicity test *or*

EOGRTS with the second generation). The draft decision, as referred to MSC on 19 December 2011 with the modifications as listed above and updated since that date with procedural steps, had been provided to MSC as a meeting document of the current meeting for finding unanimous agreement.

The MSC members from the MSs that submitted the PfA requesting EOGRTS noted that the Registrant accepted to include the DIT/DNT cohorts in the EOGRTS as proposed in PfAs and thus the TP should be accepted. SECR highlighted that there is no consensus in the EU how the EOGRTS should be implemented in practice and in ECHA's view there is no consensus either in the scientific community on advantage of EOGRTS over the two-generation study.

SECR expressed the view that for legal reasons requesting only EOGRTS without the second generation would need substance specific justification in accordance with Annex XI thus providing justification for waiving of the second generation which in ECHA's view is the standard information requirement for Annex X, 8.7.3.

Session 2 (closed)

SECR acknowledged that proportionality (i.e. cost implications of conducting EOGRTS for the Registrant) is most likely not an issue for imposing EOGRTS in this case as the Registrant agreed to it. However, the Registrant has not provided any substance specific justification for use of EOGRTS and waiving of the required second generation, neither is such substance specific justification included in the PfAs. In the view of some MSC members such substance specific justification is not needed because the general justifications in PfAs suffice to justify why EOGRTS (OECD TG 443) should be accepted to replace the current test guideline for two-generation reproductive toxicity (OECD TG 416).

The only option therefore in the view of SECR would be in this case to accept the draft decision as modified offering the Registrant the option either to conduct EOGRTS with F2 or to conduct two-generation study and as submitted to MSC as a meeting document.

MSC concluded that it would not reach agreement on the draft decision because of the issue concerning the generation study and agreed to split the draft decision into two parts: one draft decision dealing solely with the testing proposal for the two-generation reproductive toxicity test/EOGRTS with the second generation and another one addressing the 90-day study. The clarification regarding the substance to be tested was to be included in both parts based on the PfA.

MSC concluded that the deadline in the draft decision on 90-day study for submission of the requested information should be shortened from 30 to 18 months because a generation study was no longer included in that part of the draft decision and that a short explanation why the deadline was shortened was to be added to the SoR.

MSC found unanimous agreement on ECHA's draft decision addressing the 90-day study as provided for the meeting and split and amended based on the above conclusions in the current meeting, and adopted the formal agreement.

The Chair initiated a formal voting on the draft decision dealing solely with the testing proposal for the Annex X 8.7.3 standard information requirement.

At the formal vote, 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. One MSC member wished to send a new justification.

One MSC expert raised for ECHA's future general consideration to clarify in which cases examination of alfa-2u- microglobulin nephropathy is triggered that was requested by ECHA in relation to the 90-day study is triggered.

TPE-037/2011 2,2'-Dimethyl-2,2'-azodipropiononitrile (EC 201-132-3)

Session 1 (open)

One representative of the Registrant participated in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

ECHA explained that five PfAs to ECHA's draft decision were submitted by four MSCAs. Four PfAs had suggested that instead of the two-generation reproductive toxicity test (OECD 416/EU B.35) an EOGRTS (OECD 443) should be requested. The fifth PfA had proposed ECHA clarifying in the draft decision that the simulation test on ultimate degradation in surface water proposed by the Registrant is requested because the CSA indicates the need for this test.

SECR had modified the draft decision based on all five PfAs (for generation testing, ECHA gave two options: two-generation reproductive toxicity test *or* EOGRTS with the second generation). The draft decision, as referred to MSC on 19 December 2011 with the modifications as listed above and updated since that date with procedural steps, had been provided to MSC as a meeting document of the current meeting for finding unanimous agreement.

The representative of the Registrant in the meeting stated – recognising the two options now provided by the modified draft decision and deviating from their written comments which opposed EOGRTS - that in case the final decision will give them the options for both test (OECD 416 and OECD 443), based on the results of the 90-day and developmental toxicity studies they will decide if EOGRTS or a two-generation study is the more appropriate to fulfil the endpoint under 8.7.3 of Annex X. It was also pointed out that the Registrant in the written comments on the PfAs had asked to extend the deadline for submission of data from 36 months to 48 months.

Some MSC members pointed out that EOGRTS would by default include DIT/DNT cohorts and they could be omitted only for specific reasons that should be decided by the Registrant.

MSC concluded that it would not reach agreement on the draft decision because of the issue concerning the generation study and agreed to split the draft decision into two parts: one part dealing solely with the testing proposal for the two-generation reproductive toxicity test and another one addressing the 90-day study, prenatal developmental toxicity study and the simulation testing in surface water.

Concerning simulation testing, SECR proposed that the draft decision as provided by SECR for the current MSC meeting should be modified taking into account that column 1 sets the information requirement and the CSA justifies the test as set out in column 2 of Annex IX 9.2.1.2.

Session 2 (closed)

MSC addressed the two draft decisions as result of splitting the original draft decision into two parts: one draft decision dealing solely with the testing proposal for the two-generation reproductive toxicity test and another one addressing the 90-day study, prenatal developmental toxicity study and the simulation testing in surface water.

MSC agreed that the timeframe in the latter draft decision for submission of the requested information should be shortened from 36 to 24 months and that a short explanation why the deadline was agreed to be added to the SoR. MSC also agreed that in the latter draft decision a paragraph explaining the approach for Annex IX 9.2.1.2 as agreed MSC (i.e. column 1 is a standard information requirement which might be waived based on column 2) should be included.

MSC found unanimous agreement on ECHA's draft decision addressing the 90-day study, prenatal developmental toxicity study and the simulation biodegradation

testing in surface water as amended based on the above conclusions in the current meeting, and adopted the formal agreement.

The Chair initiated a formal voting on the draft decision dealing solely with the testing proposal for the Annex X 8.7.3 standard information requirement.

At the formal vote, the Chair also 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-030/2011 Azodicarbonamide (ADCA) (EC 204-650-8)

Session 1 (open)

One representative of the Registrant participated in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

ECHA explained that one PfA to ECHA's draft decision was submitted by a CA suggesting that the biodegradation test proposed by the Registrant should be accepted and the draft decision should explain that this test is a standard information requirement only if the CSA indicates the need for it.

The representatives of the Registrant mainly repeated in the meeting their written comments on the PfA. They reconfirmed that – in agreement with the PfA - they would like to carry out a further screening test for ready biodegradability of the substance (i.e. the OECD 301A or 301C test) to be able to see whether the simulation test (OECD 309) could be waived on the basis of results of the screening test.

SECR clarified that the simulation biodegradation test is a standard information requirement under Annex IX 9.2.1.2. SECR also pointed out that, for the specific case only, the Registrant can perform the screening test (301A or C) which is required under Annex VII and VIII without any decision by ECHA, and decide afterwards whether waiving of the simulation biodegradation testing is possible based on the results of the screening test. MSC supported this view.

One MSC member also raised in the discussion that ammonia which is classified for environmental effects is very likely to be one of the main degradation products of ADCA. This fact (together with the potential existence of other classified degradation products) can influence the classification of ADCA, make further testing unnecessary and be a reason for CSA including risk assessment.

Session 2 (closed)

Concerning simulation biodegradation test in surface water, MSC concluded that in the SoR of the draft decision a paragraph explaining the approach which was discussed in Session 1. The information requirement would remain as in the original draft decision. However, the SoR would explain that ECHA would not object the biodegradation screening studies suggested by the Registrant but the results of such studies would not constitute the information required for Annex IX 9.2.1.2. These results may, however, be used by the Registrant to adapt the standard information requirement. MSC found unanimous agreement on ECHA's draft decision as provided for the current meeting and further amended based on the above conclusions, and adopted the formal agreement.

TPE-036/2011 Reaction mass of divinylbenzene and ethylstyrene (List No. 910-757-7)

Session 1 (open)

One representative of the Registrant participated in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

ECHA explained that two PfAs to ECHA's draft decision were submitted by two CAs. One PfA had proposed specifying in the draft decision that a simulation biodegradation test in surface water (Annex IX, 9.2.1.2) is a standard information requirement only if the CSA indicates the need for it. The other PfA had considered that RCRs in the dossier are sufficiently close to 1 justifying the request for a simulation biodegradation test. Noting that RCR is not used consistently in the argumentation in CSR, the same PfA had suggested a tiered testing strategy where a degradation test shall be performed first and based on the outcome, long-term aquatic toxicity be considered.

SECR had modified the draft decision based on the PfA concerning simulation testing but not on the other PfA. The draft decision, as presented to MSCAs on 4 November 2011, modified as listed above and updated since that date with procedural steps, had been provided to MSC as a meeting document of the current meeting for finding unanimous agreement.

The representative of the Registrant mainly repeated in the meeting their written comments on the PfA. He reconfirmed their conclusion that they would like to perform the simulation test to better characterise the substance. They did not share the view that the RCR is not used consistently in the CSA. He acknowledged that RCRs for some exposure scenarios used in CSA are close to 1, but referred to lower site specific RCRs that they intend to include in the dossier based on the PfA. They also stated that the RCR used for aquatic environment are clearly lower than 1 and therefore further vertebrate animals (fish) should not be tested. SECR explained rationale for the approach to simulation testing as agreed by MSC and ECHA in the current meeting earlier.

Session 2 (closed)

Concerning the biodegradation simulation test in surface water, MSC concluded that in the SoR of the draft decision a paragraph explaining the approach for Annex IX 9.2.1.2 as agreed by ECHA and MSC (i.e. column 1 is a standard information requirement which might be waived based on column 2) should be included (see also the discussions on TPE-037/2011, TPE-030/2011). MSC also concluded that a second paragraph needs to be added to the SoR, clarifying how the Registrant came to the conclusion the simulation test is needed (based on available test results indicating minimal biodegradation and because with the results of the simulation test they would like to refine their exposure assessment for aquatic environment) and why ECHA accepts the testing proposal.

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

e. Items for discussion following commenting by MSCAs

- **Items from current cases if not addressed during 6c**

Two comments of the Dutch CA received on TPE-037/2011 and TPE-30/2011 on biodegradation simulation testing were covered in the context of the discussion under the respective draft decisions under agenda item 6c/d.

The comment of the one CA on CCH-042/2011 requested a generic discussion on the added value of conducting the developmental toxicity study in a second species and the interpretation of the wording in Annexes IX and X in this regard.

It was noted that the legal text and the Guidance on this point can support different interpretations. The need to perform a study with second species should be carefully considered taking into account possible implications for classification purposes, the tonnage level of the substance, possible waiving options and animal welfare issues. MSC concluded that concerning the issue when the second species is needed, both Annexes IX and X have to be read and considered carefully. If there are relevant concerns with a substance at Annex IX level, the Registrant needs to do the test with the second species. If there are no concerns,

there is no need to proceed with the second species at Annex IX level, however, in ECHA's interpretation, at Annex X level the Registrant has to perform the test on the second species unless an Annex XI or a column 2 adaptation specified under Annex IX, 8.7.2 is relevant.

- **Items for cases currently under CA consultation**

There were no issues raised by the members for further clarification on the cases currently under CA consultation.

Item 7 – Substance evaluation

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

The Rapporteur introduced the opinion and the Annex to the opinion by highlighting the changes that were made in the Annex following MSC-21. The (Co-)Rapporteur and working group, removed most of the remarks, included the cooperating MS and rephrased the conclusion for every substance so as to better reflect their work. The (Co-) Rapporteur and the working group proposed to support the draft CoRAP as presented by ECHA. However, based on new information from a MS proposing one of the substances, it was proposed to support the conclusion of the evaluating MS that substance evaluation is not considered necessary anymore.

Following the discussion the (Co-)Rapporteur considered the comments brought up and improved the text of the opinion and its Annex.

After a discussion on how to balance confidentiality and transparency, it was agreed that the opinion would not be published in its entirety but the columns in the table annexed to the opinion indicated as *Summary of the justification* and *Remarks* would not be published. SECR agreed to clarify in the publication of CoRAP that the concerns listed in the CoRAP are just initial concerns. Other types of concern might arise during the evaluation process. For the next update to CoRAP further harmonisation and improvement of the content of the justification documents is expected and in the context of the next MSC opinion it would probably be possible to publish more detailed information on justification for inclusion of substances in the CoRAP.

The (Co-)Rapporteur and the working group presented some recommendations on how to improve the justificatons and the documentation for future CoRAP updates. MSC supported these recommendations. In this context a clarification was requested on the practical implications of a nomination of a substance to be evaluated by a member state under Article 45(5). It was explained that when a member state expresses a specific urgency to include a substance in CoRAP not as part of the full package, the MSC would also need to express an opinion on the inclusion of such substance on its own. This would also imply that there would be a different starting date to that substance from the rest of the substances in the CoRAP.

b. Adoption of the MSC opinion

MSC adopted its opinion on ECHA's draft CoRAP by consensus. MSC supported the draft CoRAP and appreciated that all the substances included, shall be evaluated by the Member State Competent Authorities in the next three years. However, MSC also acknowledged that for one substance, based on new information from the Member State originally proposing the substance, substance evaluation is not considered necessary anymore.

Item 8 – Authorisation process

a. Recommendation of priority substances for Annex XIV

- **Written procedure report on adoption of MSC opinion on ECHA's draft recommendation of priority substances for Annex XIV**

Following the MSC-21 discussion, the draft MSC opinion on ECHA's 3rd draft recommendation of priority substances for Annex XIV was further modified by the Rapporteur in line with the results of those discussions. The revised draft opinion (that includes as annexes the minority opinions clearly indicated during the meeting and provided later in writing by the concerned members) was proposed for MSC adoption by urgent written procedure launched on 12 December 2011. By the closing date of 19 December 2011, responses were received from 22 members with voting right and from the Norwegian member. All responses were in favour of adoption of the MSC revised draft opinion.

Thus, the MSC opinion on ECHA's 3rd draft recommendation of priority substances for Annex XIV was adopted on 19 December 2011.

- **Feedback discussion on the previous round**

The Rapporteur for the MSC opinion on the 3rd draft ECHA recommendation for Annex XIV provided feedback from the process of preparation of the MSC opinion. He stressed some constrains due to the high amount of stakeholder comments and the huge time pressure during the MSC-21 meeting and the adoption period. He clearly indicated the need for early members' reactions and good cooperation and coordination between MSCA and MSC members on the proposed prioritisation of substances for Annex XIV as well as on the comments provided in the public consultation. As further observations he mentioned very late MSCA participation in the process (even after STO input) instead of proper reaction during the consultation process; uncertainty in concerned industry comments on the implementation of the whole authorisation process; duplication of work for the Rapporteur and the supporting working group and high time pressure due to very late availability of ECHA RCOMs in the process. The Rapporteur also highlighted the need to increase the time for revision of final draft opinion after receiving the ECHA RCOMs. He also pointed out that if a proper job is not done at the MSC in the context of the opinion the issues will be opened at the Commission REACH Committee when the vote on the proposal for Annex XIV will take place. In conclusion, he suggested these issues to be further discussed at the ECHA Workshop scheduled for May 2012.

In support of these observations, a member underlined the need of increasing the time in process for MSC to be able to finalise its opinion and adopt an opinion, in case of large input in the public consultation. The member proposed that the MSC opinion could then only be adopted in the February MSC meeting instead of the December meeting of the previous year.

Another member noted that the applied priority settings and definitions may need to be revised after the previous year experience. However, SECR explained that the aim of the generic approach on priority settings is to ensure coherence and equal treatment of all cases and not to refer to specific ones.

It was also mentioned that good guidance is important to facilitate STO's understanding of the authorisation process.

One industry STO observer agreed that there are difficulties for the downstream users in supply chain to understand the potential economic and other consequences of the authorisation process (in particular if they are SMEs in the end of the supply chain). The importance of having early industry contributions in the process, at SVHC stage, was also highlighted, as this would provide good basis for the substance prioritisation later on.

SECR reminded that information describing the authorisation process and roles of different actors therein is already available on ECHA website. The information on uses and exposure of substances collected via the registration should also be considered in the prioritisation process. However, the ways for encouraging early industry comments during public consultation would be further explored.

The Chair concluded that the member's proposal on the extension of timeframe for the 4th recommendation process, as regards the step on the MSC opinion finalisation will be further considered internally by SECR as such a change would affect ECHA's planning on this process.

- **Presentation on aspects to consider in setting latest application dates (LAD)**

SECR gave a presentation on the aspects considered when setting LADs in the context of Annex XIV recommendations. It was underlined that the approach for setting LADs should be simple, implementable, consistent and transparent. MSC was reminded on the development and implementation of the approach for setting LADs during the proceedings of 1st, 2nd and 3rd ECHA recommendations and requested to provide feedback on the approach applied currently at MSC-22 or later on in writing by 24 February 2012.

An industry STO expressed his appreciation on the good interactions in the LAD setting process under the 3rd recommendation round, in particular as regards the concerns of downstream users in supply chains and companies from non-EU countries producing articles containing substances on Annex XIV.

One member expressed general support to the presented approach, however, he stressed the need for flexibility to certain extent due to the specificity of different cases. He also stressed the uncertainty on the credibility of substitution plans provided by industry.

- **Tentative timeline for the 4th recommendation process**

SECR introduced MSC with the tentative time plan for the development of the 4th ECHA recommendation for inclusion of substances in Annex XIV. It was noted that the MSC feedback provided on the timeframe for the MSC opinion on the 3rd draft Recommendation would be further considered and this may lead to changes in the presented tentative planning for the 4th recommendation process.

b. SVHC process

- **Analysis of removing or modifying entries in the Candidate list**

SECR informed MSC of the ongoing work on analysing the impact of removing or modifying entries in the Candidate List, in particular with regard to the four RCF (Refractory Ceramic Fibers) entries. The key considerations are: need for clarity in the current entries in the Candidate List, the technical aspects of the documentation provided and the procedural aspects. Once the analyses are carried out with careful consideration of different aspects, MSC will be informed of the outcome.

As regards the "old" and "new" entries of RCFs on the Candidate List, it has to be examined whether the substance identities for the "new" RCF entries fully cover the substance identities of the "old" entries, what kind of documentation would be needed for making this conclusion and what kind of process would be appropriate to modify the Candidate List if needed. Thus, SECR will make a proposal on the issue for MSC discussion in the following MSC meeting in April 2012.

- **Feedback discussion – lessons learnt from the previous round of proposals**

The Chair gave a brief overview of the lessons learnt from the previous SVHC round pointing out the very good experience gained with the first proposal under Article 57 (f) on 4-tert-octylphenol. This allowed setting up a good meeting model on approaching such proposals by considering whether the substance has endocrine disrupting properties and whether the substances is of equivalent level of concern to other substances with CMR or PBT properties. Referring to this case, other highlights were related to the good quality of the original Annex XV dossier, good working collaboration of MSC with the experts of the submitting MS and the smooth proceeding of the case during the MSC meeting discussions.

An expert expressed his satisfaction with Article 57 (f) case processing and underlined the importance of the good preparation done at CA level that facilitated the smooth meeting discussions.

With regard to the latest proposals on RCFs, the overall conclusion on the experience gained was that there is a need to improve the communication between the submitting MS and SECR, in particular for cases where comments on substance identification or intrinsic properties are received during the public consultation. These should be very carefully considered by the submitting MS, as this could facilitate MSC discussions later on.

- **New Annex XV proposals submitted**

SECR informed MSC that 13 new SVHC Annex XV proposals have been received recently and presented a short overview on the proposals and the timelines for the current SVHC round. The public consultation on these will be started on 27 February. All substances are CMRs and it is unlikely that these cases need to be addressed by MSC.

Item 9 – Manual of Decisions (MoD)

a) New item for discussion to be included in MoD

SECR introduced a topic proposed for inclusion in the MoD of MSC by a member based on the recent dossier evaluation work in MSC-21, as indicated in document ECHA/MSC-22/2012/043.

MSC discussed the content of the topic and concluded that this topic is very important; however, more experience needs to be gained in the context of different dossier evaluation cases or even grouping methods before including such generic issue as an entry in the MoD.

b) MSC involvement in contributing to MoD drafting

Following the MSC support at MSC-20 to the SECR proposal on establishment of a MSC working group in charge of proposing new topics for the MSC MoD, the MSC Secretariat (MSC-S) provided MSC with the Terms of Reference (ToR) of the proposed working group (WG). The presented draft ToR determines the mandate, composition and the objectives of a working group as well as the duration of its activity, in line with the requirements of the MSC Rules of Procedures.

However, as members expressed clear preference not to have formal setting of such WG, it was agreed that an informal group of people could support SECR in the MoD entry drafting in the margin of MSC plenary meetings. Further, several members and the Commission observers volunteered for participation in the informal MoD working group.

Item 10 – Guidance on annual declarations of interest

- **Question and answer session on the filling in of the new form**

MSC was reminded on the legal basis of the annual declarations and the general principles in the ECHA policy on conflict of interests requiring MSC members to declare any relevant interests to REACH and ECHA. SECR provided the members with further clarification and guidance on how to fill in the new form of the declaration of interest.

Item 11 – Report from other ECHA bodies and activities

SECR gave a brief report on the ongoing and planned guidance activities (recently published updates or corrigendum of several REACH Guidance documents, leaflets and fact sheets, ongoing and planned revisions of guidance document and the envisaged ECHA Committees' consultations on them). It was explicitly mentioned that MSC and Forum would be consulted on the revised Guidance on registration before 10 Feb 2012, as the publication of this guidance is expected to be done before 12 May 2012.

Item 12 – Any other business

a. Participation of case-owners and stakeholder observers during dossier evaluation discussions

- **Feedback from MSC to Management Board (MB) in March 2012**

The SECR introduced the topic shortly, reminding the Committee of the suggestions from the MB and that it/SECR was to report to MB in one year's time from the start of the practise to review the practise and agree on any necessary modifications. SECR reminded the Committee on the following conclusions of the MB which were in line with the discussion and conclusions at MSC-12:

- protection of confidential business information need to be safeguarded while maintaining at the same time a high degree of transparency
- experts shall accompany the case owners only if there is added value
- the procedure should not increase the workload of the Agency and the workability of the procedure should be borne in mind
- RoPs shall distinguish between an initial discussion phase and a decision-making phase.

With this introduction the Chair invited for any feedback on stakeholder and case-owner participation in dossier evaluation discussions from MSC, including STOs, to be included in the report to MB for its March meeting.

Representatives of STOs present in the meeting unanimously spoke in favour of the usefulness of being present in the discussions of the MSC concerning dossier evaluation cases. MSC discussions are used by industry representatives to provide feedback to the companies on the application of REACH information requirements and principles applied to adaptation possibilities. This they said is also much used by registrants when updating or submitting their registration dossiers. However, to be able to better understand the cases and to contribute to the discussion the MSC STOs would clearly prefer to receive some documents on the cases, e.g. the slides used in the presentation of the cases. This would be contrary to the present practice which is much based on protection of sensitivities regarding potential confidentiality issues and as such the prerequisite of the MB conclusion. In general STOs considered case-owner participation in the discussion very useful as unclear issues can be clarified in the discussion and transparency increased regarding the MSC procedure.

MSC members considered case-owner participation normally useful but time consuming in such cases where MSC itself would not need introduction to a case. No negative experience was expressed regarding STO participation. While discussing the topic further in the closed session it was noted that in some situations inviting the case owner may not be appropriate. Such situations may arise e.g. if only minor editorial issues are for adoption at a meeting but not actually the main contents of the draft decision, following unsuccessful agreement seeking in written procedure, or if for example a group of draft decisions (cases) will require only one and the same discussion following a similar proposal for amendment and based on that all draft decisions of that group can be concluded without further considerations.

As a conclusion the Chair invited for any further written input to the SECR from the members and STOs to be provided by 17 February. SECR will then, based on its own analysis and the feedback received, provide a report and any suggestions to MB for its consideration.

b. Closed and open sessions – view of MSC

The Chair initiated the discussion on closed and open sessions recognising that STOs are not satisfied with the high number of closed sessions. Several reasons for holding closed sessions in the past were mentioned, such as 1) discussion of

strategic issues or legal interpretations, 2) based on MSC Rules of Procedure any member may ask for a closed session from the Chair, e.g. due to sensitivities of specific compliance related issue or national policies and 3) when taking the formal vote or for some other discussions when a disagreement is likely.

In the following discussion the STOs indicated that the need for holding closed sessions is acceptable, however, the reasoning used for excluding STOs from some discussions, on e.g. legal interpretations, may not be so valid in their view, and could even turn against the intentions. One participant from STOs reminded that also STOs sign the confidentiality declaration, and as such SECR should review if more documents could be provided to them without breaking any confidentiality rules.

As a conclusion the Chair suggested that as the MSC Rules of procedure are quite general on open and closed session, SECR could write down some reasons as why some sessions should be held in closed session and it would then be clearer to refer to them when necessary.

c. Suggestions from members

Few items were suggested by two members as information items but due to lack of time they were postponed until the April MSC meeting.

Item 13 – Adoption of conclusions and action points

The conclusions and action points of MSC-22 were proposed for adoption by written procedure after the meeting (see Annex IV).

Signed

Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
ANDRIJEWSKI, Michal (PL)
BIWER, Arno (LU)[1]
do CARMO PALMA, Maria (PT)
COCKSHOTT, Amanda (UK) (alternate member) [2]
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
DUNAUSKIENE, Lina (LT) [1]
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
HUMAR-JURIC, Tatjana (SI)
KORENROMP, Rene (NL)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina (CZ)
LUDBORZS, Arnis (LV)
LULEVA, Parvoleta Angelova (BG)
MARTÍN, Esther (ES)
MIHALCEA-UDREA, Mariana (RO)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI) (alternate member)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
Representatives of the Commission
KOBE,Andrej (DG ENV)
GARCÍA-JOHN, Enrique (DG ENTR)
Observers
ANNYS, Erwin (CEFIC)
DMYTRASZ, Bohdan (CONCAWE)
FRANCHIOLI, Luigi (UEAPME)
LIGHTART, Jerker (HEAL)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (EUROMETAUX)

ECHA staff
AJAO, Charmaine
BALOGH, Attila
BELL, David
BROERE, William
CARLON, Claudio
CESNATIS, Romanas
DE COEN, Wim
DELOFF-BIAŁEK, Anna
DE WOLF, Watze
FABREGA CLIMENT, Julia
FEDTKE, Norbert
HUUSKONEN, Hannele
JACQUET, Cyril
KARHU, Elina
KARKOLA, Sampo
KOJO, Anneli
KORJUS, Pia
LE CURIEUX, Frank
LEFEVRE, Rémi
LEPPER, Peter
MALM, Jukka
MEGAW, Peter
NAUR, Liina
NOUWEN, Johan
PREVEDOUROS, Konstantinos
RIALA, Riitta
RODRIGUEZ IGLESIAS, Pilar
RÖCKE, Timo
RÖNTY, Kaisu
RUOSS, Jürgen
SUMREIN, Abdel
SUNDQUIST, Anna-Liisa
VAHTERISTO, Liisa
VASILEVA, Katya
VERSONNEN, Bram
VESENTINI, Damiano
ZBIHLEJ, Tomáš

[1] Not present at the vote on the split draft decision dealing with generation study on case TPE-033/2011 and TPE-037/2011

[2] Not present at the agreement seeking on case TPE-034/2011

Proxies

- KOUTSODIMOU, Aglaia (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)
- MARTIN, Esther (ES) also acting as proxy of LULEVA Parvoleta (BG) (for Friday 10th February)
- VANDERSTEEN Kelly (BE) also acting as proxy of BIWER Arno (LU) (Monday, 6th February)
- BIWER Arno (LU) also acting as proxy of KORENROMP René (NL) (from 9th February 4 p.m. onwards)
- VESKIMÄE, Enda (EE) also acting as proxy of LUDBORZS, Arnis (LV) (Friday 10th

February from 10 a.m. onwards)
- STESSEL Helmut (AT) also acting as proxy of DUNAUSKIENE Lina (LT) (Monday, 6th February)
- STESSEL Helmut (AT) also acting as proxy of MICHALCEA UDREA Mariana (RO) (for Friday 10th February)
- RUSNAK, Peter (SK) does not give a proxy to anyone.

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 ANDRIJEWSKI, Michal)
DOYLE, Ian (UK) (adviser to COCKSHOTT Amanda)
INDANS, Ian (UK) (expert to COCKSHOTT Amanda)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
LUNDBERGH, Ivar (expert to FLODSTRÖM, Sten)
MARCSEK, Zoltán (HU) (expert to DEIM, Szilvia)
MOELLER, Ruth (LU) (expert to BIWER, Arno)
RAMOS, Cesaltina (PT) (expert to do CARMO PALMA, Maria)
SCHWÄGLER, Mark (DE) (expert to FINDENEGG, Helene)
TRAAS, Theo (NL) (expert to KORENROMP, Rene)

By WEBEX-phone connection:

HAKKERT, Betty (NL) (adviser to KORENROMP, Rene) for the whole meeting.

Case owners:

Representatives of the Registrant were attending under agenda item 6c for:
TPE-032/2011: Dr ZOETE, Francesca and Dr JENKINSON, Peter
TPE-035/2011: Dr DOBE, Christopher and Dr BOOTH, Ewan D
TPE-034/2011: Dr BELEGRATIS, Michael S and Dr LINKER, Fenneke
CCH-041/2011: Dr PULACZEWSKI, Grzegorz and Dr NAWROCKI, Adam
CCH-040/2011: Dr HOERSTER, Andrea and Dr PAWLOWSKI, Sascha
TPE-029/2011: Dr SCHOLTEN, Edzard
CCH-043/2011: Dr SCHOLTEN, Edzard
CCH-042/2011: Dr OHLBACH, Qin Zhu and Dr BEYER, Dieter
TPE-037/2011: Dr GAOUA-CHAPELLE, Wassila
TPE-030/2011: Dr HOWES, David
TPE-036/2011: Dr HUNZIKER, Rene

Apologies:

CAMILLERI, Tristan (MT)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
RUSNAK, Peter (SK)

III. Final Agenda

Final Agenda
22nd meeting of the Member State Committee

6-10 February 2012
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

6 February**: starts at 9:30**
10 February**: ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/022/2012
For adoption

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

Item 4 – Administrative issues

- Results from the satisfaction survey

For information

Item 5 – Adoption of the draft minutes of the MSC-21

MSC/M/21/2011
For adoption

Item 6 – Dossier evaluation
Closed session for 6a1& 6d
Indicative time plan for 6c is Day 1 (2 pm)-Day 2, for 6d Day 3, 4&5

a. General topics:

1. **In vitro and in vivo genotoxicity tests in dossier evaluation *(closed session)***
   - **Presentation on ECHA's current approach**
   - **Introduction of comments provided on ECHA's presentation in MSC-20**

   For information and discussion
2. **Terrestrial and chronic aquatic ecotoxicology current approach**

For information and discussion

3. **Handling of EOGRTS vs two generation issues in MSC - proposal of some members**

For discussion

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

For information

5. **Report from Dossier Evaluation Workshop January/February 2012**

For information

6. **Work load of MSC – how to tackle high number of dossier evaluation draft decisions**

For information and discussion

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

ECHA/MSC-22/2012/022
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)*

ECHA/MSC-22/2012/041

For discussion followed by agreement seeking under 6d:

- **TPE-032/2011 3,4,5,6,7,8,9,10,11,12,13,14-dodecahydro-2h-cyclododeca[b]pyran** (EC 251-090-5)

ECHA/MSC-22/2012/010-011

- **TPE-035/2011 1-Methyl-4-(methylsulfonyl)-2-nitrobenzene** (4-mesyl-2-nitrotoluene) (EC 430-550-0)

- **TPE-034/2011 Bis(2-ethylhexyl) fumarate** (EC 205-448-2)

ECHA/MSC-22/2012/026-027

- **CCH-041/2011 Fe(III)HBED** (List No. 700-327-5)

ECHA/MSC-22/2012/004-005

- **CCH-040/2011 Hexyl 2-(1-(diethylaminohydroxyphenyl)methanoyl**) (EC 443-860-6)

ECHA/MSC-22/2012/001-002

- **TPE-029/2011 Phenylbis(2,4,6-trimethylbenzoyl)phosphine oxide** (EC 423-340-5)

ECHA/MSC-22/2012/038-039

- **CCH-043/2011 Phenylbis(2,4,6-trimethylbenzoyl)phosphine oxide** (EC 423-340-5)

ECHA/MSC-22/2012/029-030

- **CCH-042/2011 Triphenyl phosphate** (EC 204-112-2)

ECHA/MSC-22/2012/007-008

- **TPE-033/2011 Isooctyl acrylate** (EC 249-707-8)

ECHA/MSC-22/2012/013-014

- **TPE-037/2011 2,2'-Dimethyl-2,2'-azodipropiononitrile** (EC 201-132-3)

ECHA/MSC-22/2012/019-020

- **TPE-030/2011 Azodicarbonamide** (EC 204-650-8)

ECHA/MSC-22/2012/035-036

- **TPE-036/2011 Reaction mass of divinylbenzene and ethylstyrene** (List No. 910-757-7)

ECHA/MSC-22/2012/032-033

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)*

- **TPE-032/2011 3,4,5,6,7,8,9,10,11,12,13,14-dodecahydro-2h-cyclododeca[b]pyran** (EC 251-090-5)

ECHA/MSC-22/2012/010-012

- **TPE-035/2011 1-Methyl-4-(methylsulfonyl)-2-nitrobenzene** (4-mesyl-2-nitrotoluene) (EC 430-550-0)

ECHA/MSC-22/2012/016-018

- **TPE-034/2011 Bis(2-ethylhexyl) fumarate** (EC 205-448-2)

ECHA/MSC-22/2012/026-028

- CCH-041/2011 Fe(III)HBED (List No. 700-327-5)

ECHA/MSC-22/2012/004-006

-CCH-040/2011 Hexyl 2-(1-(diethylaminohydroxyphenyl)methanoyl) (EC 443-860-6)

ECHA/MSC-22/2012/001-003

- TPE-029/2011 Phenylbis(2,4,6-trimethylbenzoyl)phosphine oxide (EC 423-340-5)

ECHA/MSC-22/2012/038-040

- CCH-043/2011 Phenylbis(2,4,6-trimethylbenzoyl)phosphine oxide (EC 423-340-5)

ECHA/MSC-22/2012/029-031

- **CCH-042/2011 Triphenyl phosphate** (EC 204-112-2)

ECHA/MSC-22/2012/007-009

- **TPE-033/2011 Isooctyl acrylate** (EC 249-707-8)

ECHA/MSC-22/2012/013-015

- **TPE-037/2011 2,2'-Dimethyl-2,2'-azodipropiononitrile** (EC 201-132-3)

ECHA/MSC-22/2012/019-021

- **TPE-030/2011 Azodicarbonamide** (EC 204-650-8)

ECHA/MSC-22/2012/035-037

- **TPE-036/2011 Reaction mass of divinylbenzene and ethylstyrene** (List No. 910-757-7)

ECHA/MSC-22/2012/032-034

For agreement

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

- Items from current cases if not addressed during 6c
- Items for cases currently under CA-consultation

For discussion

Item 7 – Substance evaluation

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

d. Adoption of the MSC opinion

ECHA/MSC-22/2012/024-025
For discussion and adoption

Item 8 – Authorisation process

a. Recommendations of priority substances for Annex XIV

- Written procedure report on adoption of MSC opinion on ECHA's draft recommendation of priority substances for Annex XIV

ECHA/MSC-22/2012/023
For information

- Feedback discussion on the previous round

For discussion

- Presentation on aspects to consider in setting latest application dates

For discussion

- Tentative timeline for the 4th recommendation process

For information

b. SVHC process

- Analysis of removing or modifying entries in the Candidate list
- Feedback discussion – lessons learnt from the previous round of proposals
- New Annex XV proposals submitted

For discussion

Item 9 – Manual of Decisions (MoD)

a) New item for discussion to be included in MoD

ECHA/MSC-22/2012/043
For discussion

b) MSC involvement in contributing to MoD drafting

ECHA/MSC-22/2012/042
For discussion & decision

Item 10 – Guidance on annual declarations of interest

- Question and answer session on the filling in of the new form

For discussion

Item 11 – Report from other ECHA bodies and activities

For information

Item 12 – Any other business

Partly closed session for 12a&b

d. Participation of case-owners and stakeholder observers during dossier evaluation discussions[1]

  - Feedback from MSC to Management Board in March 2012

(Partly closed session)
For discussion

b. Closed and open sessions – view of MSC[2]

(Partly closed session)
For discussion

c. Suggestions from members

For information

Item 13 – Adoption of conclusions and action points

- Table with conclusions and action points from MSC-22

For adoption

[1] Input from stakeholder obeservers in open session

IV. Main Conclusions and Action Points

MSC-22, 6-9 February, 2012
(adopted at MSC-23 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
5. Adoption of the minutes of MSC-20	
The confidential and non-confidential versions of the minutes were adopted with one change proposed in the meeting.	MSC-S to upload the adopted minutes on MSC CIRCABC and to publish the non-confidential version of the minutes on the ECHA website.
6. Dossier evaluation **6a) General Topics**	
1. In vitro and in vivo genotoxicity tests in dossier evaluation o **Presentation on ECHA's current approach** MSC members noted with the following points raised by the ECHA-S: • on the basic scope of application of different i*n vitro* and *in vivo* genotoxicity tests • that further scientific discussion is needed on pros and cons of different *in vivo* tests (in particular Unscheduled DNA Synthesis Test (UDS), Transgenic Rodent Assay (TGR) and Comet assay); • that the three tests (see above) are mentioned in the guidance and can therefore be imposed on registrants • that regarding Testing proposals: As UDS is stated in the ECHA guidance to be an acceptable test method, and the ECHA guidance is relevant for registrations under evaluation, substance specific justifications have to provided if an other test guideline, like TGR recently adopted by the OECD (OECD 488), is requested to be used instead of the UDS proposed by the registrant. The proposals for amendments (PfAs) of CAs for the use of TGR instead of other methods have to be explored based on such justifications. • that regarding Compliance checks: If data based on valid UDS (or other guideline) are available in the dossier, normally such data would not be considered incompliant. If there is a data gap in the dossier, ECHA secretariat will by default request a TGR assay. However it was recognised that further discussions are warranted in relation to selection of appropriate *in vivo* test for detection of point mutations relative to the particular properties of the registered substance in question and any other case specific relevant information. Some MSC participants expressed disagreement with some elements of the current ECHA approach in particular in relation to indent number four above. There was discussion on the scientific progress made in the area that required further interaction with a broader community of experts. The MSC generally appreciated ECHAs indication of the possibility later this year to hold a workshop / expert meeting in relation to mutagenicity testing strategies and newly developed test methods	ECHA to organise a workshop on how to use the three different genotoxic assays. Target date September 2012. Feedback to the Guidance process from the workshop as necessary.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
2. Terrestrial and chronic aquatic ecotoxicology current approach MSC generally supported the approach by ECHA however some concerns were raised in relation to long term aquatic toxicity testing on fish due to vertebrate testing. **3. Handling of EOGRTS versus two generation issues in MSC - proposal of some members** There was general support to the way forward presented by a group of members to avoid decisions on Annex IX and X testing requirements 8.7.3 in testing proposals by conditionally rejecting testing proposals on 8.7.3 if there is no legal obligation and no argumentation. MSC agreed to give the mandate to MSC-S to split the draft decisions already at the stage of the written procedure, so that the decision on testing proposal on 8.7.3 could be separately addressed in written procedure. Regarding the compliance checks the DDs in the process already will be handled on a case by case basis. Registrants who received a DD with a request to fulfil the 2-generation information requirement will be informed that pending the decision in the REACH Committee this information requirement will not be covered. For the future compliance checks the information requirement will not be covered until the REACH Committee has reached a decision. It is expected that a solution to the issue will be available from the Commission this year but well before 30 November 2012. **5. Report from Dossier Evaluation Workshop January/February 2012** MSC took note of the report of ECHA-SECR. **6. Work load of MSC – how to tackle high number of dossier evaluation draft decisions** MSC acknowledged the need to improve the efficiency of meetings due to increasing workload caused by DDs of dossier evaluation. Support was expressed by MSC to set up a working group assisting in preparation of Plenary sessions. Other existing means will be used more efficiently.	MSC-S to upload on MSC CIRCABC the presentation and invited StOs to ask questions after consideration of the presentation by Friday 17 February 2012. MSC-S to put on paper the options proposed during this meeting for MSC-23 meeting.
6. Dossier evaluation **6b) Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the report of ECHA.	MSC-S to upload on MSC CIRCABC the final ECHA decisions and agreements on case TPE031/2011 that was agreed in written procedure. MSC-S to provide to COM for further decision making a package of the documents on case TPE-038/2011 (DD on

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	generation testing, MSC DA, RCOM, minutes, outcome of the vote, and justification for the position at the vote).
6c) Introduction to and preliminary discussion on draft decisions (DD) on compliance checks after MSCAs' reactions *(Session 1, open)* **6d) Seeking agreement on draft decisions (DD) on compliance checks when amendments were proposed by MSCAs *(Session 2, closed)***	
TPE-032/2011 3,4,5,6,7,8,9,10,11,12,13,14-dodecahydro-2h cyclododeca[b]pyran (EC 251-090-5) **Discussion (6c, Session 1)** MSC discussed the case (transported isolated intermediate) based on ECHA draft decision (DD) as referred to MSC, the proposed amendments (PfAs) of MSCAs and the Registrant's comments on the PfAs. MSC concluded that the testing proposal for an *in vivo* study (micronucleus assay) with the registered substance should be accepted. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on the draft decision as referred to MSC and without further modifications in the current meeting. MSC adopted the formal agreement. **TPE-035/2011 1-Methyl-4-(methylsulfonyl)-2-nitrobenzene** (4-mesyl-2-nitrotoluene) (EC 430-550-0) **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's draft decision (DD) as referred to MSC, the PfAs of MSCAs and the Registrant's comments on the PfAs. Some MSC members expressed preference for TGR (Transgenic Rodent Assay, OECD 488) over UDS test (*in vivo* Unscheduled DNA Synthesis [UDS] assay, OECD 486). **Agreement seeking (6d, Session 2)** MSC concluded that the testing proposal for an in vivo genetic toxicity study (*in vivo* Unscheduled DNA Synthesis [UDS] assay, OECD 486) with the registered substance in this particular case was acceptable. MSC also concluded that in the statement of reasons (SoR) section of the decision document a reminder to the decision should be added that there will be residual uncertainties if the UDS test will be negative. However, the sole use of the substance as an intermediate and the Registrant's written statement that the substance fulfills the criteria for classification (reprotoxic Cat 1B), indicating that strict risk management measures should already be in place, were considered as reducing the concern. The Registrant was also reminded about the preferred species and strain to conduct the UDS test in this case. MSC agreed that the testing proposal for UDS would be accepted in this specific case. MSC reached unanimous agreement on the draft decision as referred to MSC and modified at the current meeting on the basis of the above conclusions. MSC adopted the formal agreement. **TPE-034/2011 Bis(2-ethylhexyl) fumarate** (EC 205-448-2) **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's modified draft decision (DD) as provided to MSC for the current meeting, the PfAs of MSCAs, the Registrant's comments on the PfAs and the justifications provided by MSC who requested to terminate the written procedure for this substance.	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
A concern was expressed as to whether the long-term fish test and bioaccumulation test in fish are justified and proposed a tiered testing strategy instead. During the discussions also some concerns were raised regarding the high log-Kow (7,9) and the claimed and probable not reliable high water solubility (1,19 mg/L) values of the substance and the feasibility of conducting the long-term fish test. MSC members however, generally supported ECHA's view that the testing proposals on long-term aquatic toxicity made by the Registrant should be accepted and that it would be for the Registrant to apply the appropriate adaptations as specified in column 2 for point 9.1 of the REACH Regulation as well as the REACH Guidance. MSC concluded that the bioaccumulation test in fish (OECD 305) with dietary exposure test shall be requested. **Agreement seeking (6d, Session 2)** MSC concluded that the Registrant's proposal for a long-term fish test shall be accepted but the statement of reasons (SoR) referring to integrated testing strategy is slightly modified. Furthermore, due to the ongoing revision of the OECD 305 guideline, the request for the bioaccumulation test shall be specified as in the OECD 305 draft guideline suitable for testing also hydrophobic substances such as the registered substance . MSC reached unanimous agreement on the amended ECHA draft decision modified in the meeting based on the above conclusions. MSC adopted the formal agreement. **CCH-041/2011 Fe(III)HBED** (List No. 700-327-5) **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's draft decision (DD), the PfAs of MSCAs and the Registrant's comments on the PfAs. MSC supported ECHA's view that 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 and new information given by the Registrant in the current MSC-meeting have not been evaluated and can not be considered for the final decision. Concerning the requirement for long- vs short-term testing on plants, MSC also generally supported ECHA's view that the Registrant shall be referred in the draft decision to the ECHA Guidance which gives the Registrant the possibility to use the Equilibrium Partitioning Method (EPM); if the EPM does not show any risk, one confirmatory long-term study would be sufficient to fulfil the standard information requirement. **Agreement seeking (6d, Session 2)** MSC concluded (1) not to specify the guideline of choice for the plant test but to give the Registrant a choice (2) to slightly change the SoR for this endpoint to provide clearer reference to the Guidance and the Registrant's options (see under Session 1) (3) to make clearer reference to studies the Registrant had already submitted and that still might need to be submitted following the Registrant's actions based on the Guidance (4) to include a paragraph on the Registrant's responsibility to determine the appropriate order of studies based on the possible outcomes and adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of REACH, after consulting the Guidance concerning the integrated testing strategy for reproductive toxicity testing and taking into account that the screening study is advisable not to be bypassed when a prenatal developmental toxicity study is triggered (5) to include a note in the procedural part of the decision that the information provided by the	Members to inform MSCAs to be more specific when making their proposal for amendments (PfAs) especially when submitting the justification. New information submitted during the meeting justifying the proposal for amendment would not have given the Registrant the opportunity to comment on it.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Registrant on 28 December 2011 and 9 January 2012 were not taken into account for the current decision. MSC reached unanimous agreement on the amended ECHA draft decision modified in the meeting based on the above conclusions and editorial suggestions proposed. MSC adopted the formal agreement. **CCH-040/2011 Hexyl 2-(1-(diethylaminohydroxyphenyl)methanoyl**) (EC 443-860-6) **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's modified draft decision (DD) as provided to MSC for the current meeting, the PfAs of MSCAs and the registrant's comments on PfAs. MSC broadly supported the view that the decision should request the missing *Daphnia* study (that the harmonised classification of the substance is based on) to be included in the registration dossier. A MSC member preferred to request OECD guideline 208 over ISO standard. MSC generally preferred the N-mineralisation test to detect effects on soil micro-organisms as it is more sensitive than the C-mineralisation test for many chemicals. A MSC member noted that N-mineralisation is not necessarily more sensitive, but that requesting a test on N-mineralisation is sufficient as it takes place subsequent to C-mineralisation. **Agreement seeking (6d, Session 2)** MSC concluded that the Registrant shall be requested to include the robust study summary for the missing chronic *Daphnia* test in the dossier and the SoR shall be modified accordingly. MSC agreed to amended DD to recommend to the Registrant to use the study with the lowst NOEC/EC10 value as a key study highlighting that the missing study had been regarded as the study with highest concern according to the evaluating CA under the NONS scheme, or provide full scientific justification why they chose another study. MSC also concluded to modify the request and SoR for the plant test (not specifying one test guideline of choice but giving the Registrant both options for both test methods and to slightly modify the title of the requested for the soil micro-organism test. MSC reached unanimous agreement on ECHA's draft decision as referred to MSC and modified in the current meeting on the basis of the above conclusions. MSC adopted the formal agreement. **TPE-029/2011 Phenylbis(2,4,6-trimethylbenzoyl)phosphine oxide** (EC 423-340-5) **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's draft decision (DD) as provided to MSC for the current meeting, the PfAs of MSCAs, the registrant's comments on the PfAs and the justifications provided by MSC who requested to terminate the written procedure for this substance. MSC concluded that the substance is regarded as hazard category 3 instead of category 4 as was the original approach by ECHA, thus certain tests originally proposed by ECHA on the basis of the hazard category 4 conclusion were removed from the DD. MSC and Registrant supported rejection of the one generation study (OECD 415) because it does not fulfil the information requirement of Annex IX, 8.7.3 and to support the approach of the DD to request submission of a testing proposal for the information requirement of	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Annex IX, point 8.7.3 only if the results of the 90 day study justify such a testing proposal. With regards to toxicity to invertebrates the Registrant proposed a long-term toxicity test to earthworm (OECD 222) which was supported by MSC. MSC concluded to ask for further tests on effects on micro-organisms and toxicity to plants to fulfil all the requirements outlined in Annex IX 9.4 since the long-term toxicity earthworm reproduction toxicity test on its own without specific justification, does not fulfil the information requirements laid down in Annex IX sections 9.4.2 and 9.4.3. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on the amended draft decision as provided to MSC and modified in the meeting on the basis of the above conclusions. MSC adopted the formal agreement. **CCH-043/2011 Phenylbis(2,4,6-trimethylbenzoyl)phosphine oxide** (EC 423-340-5) **Discussion (6c, Session 1)** MSC discussed the case based on the modified ECHA draft decision (DD) as provided to MSC for the current meeting, the PfAs of MSCAs, the registrant's comments on the PfAs and the justifications provided by the members who requested to terminate the written procedure for this substance. MSC discussed the need for long-term toxicity test to fish (Annex IX, 9.1.6) that was waived by the Registrant in the light of the available short term test on fish the CA responsible for receiving the notification on the substance under the NONs scheme confirmed that the short term fish test was not of high reliability. On this basis the member representing the CA which had made the PfA decided that the PfA was no longer necessary. MSC also concluded that there is no need to request for repeating the bioaccumulation test in fish. MSC concluded that it would be necessary in accordance with one PfA to add requests for Predicted Environmental Concentrations (PEC) for the terrestrial and sediment compartments. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on the modified draft decision as provided to MSC and further modified in the meeting. Also the deadline for the Registrant to submit the information required is shortened to 6 months from 12 and the statement of reasons changed accordingly because no bioaccumulation study was to be requested. MSC adopted the formal agreement. **CCH-042/2011 Triphenyl phosphate** (EC 204-112-2) **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's modified draft decision (DD) as provided to MSC for the current meeting, the PfAs of MSCAs and the Registrant's comments on the PfAs. MSC concluded that, contrary to one PfA which was no longer considered necessary by the member of the relevant CA that made the PfA, the 90 day study, (Annex IX, 8.6.2) was necessary since the existing studies presented in the dossier do not address all the parameters needed. Regarding the two-generation reproductive toxicity in the rat,(Annex X, 8.7.3) MSC had two options to discuss : 1. put on hold the two–generation reproductive toxicity study and so	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
remove it from the current DD, or 2. split the ECHA DD by separating the two-generation reproductive toxicity study from the other test requirements and communicate to the Registrant that despite not addressing the information requirement in the DD that data gap still exists. **Agreement seeking (6d, Session 2)** MSC agreed that there is a data gap regarding the REACH standard information requirements of Annex X 8.7.3, but currently ECHA is not in a position to decide on the exact test to request since ECHA is waiting for the outcome from the Commission comitology procedure on information requirements for Annex IX/X, point 8.7.3 and the test method to be used to fulfil the information requirement. Therefore, MSC concluded that they would remove the request for this test from the DD with clear justification to the Registrant. MSC agreed to reduce the deadline to 24 months from 36 months because the request for the two–generation study had been removed. MSC reached unanimous agreement on the modified ECHA's draft decision as modified in the meeting. MSC adopted the formal agreement. **<u>TPE-033/2011</u> Isooctyl acrylate** (EC 249-707-8) **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's modified draft decision (DD) as provided to MSC for the current meeting, the PfAs of MSCAs and the Registrant's comments on the PfAs. MSC concluded that the DD should be modified based on the PfA asking to specify that the registered substance shall be used in the tests to be performed. Following the testing proposals submitted by the Registrant ECHA requests in the DD an Annex IX, 8.6.2: Sub-chronic toxicity (90 days) by oral route in rodents and gives a choice for Annex X, 8.7.3. between Two-generation reproductive study and EOGRTS with F2 generation. Following the PfA proposing to reject the two-generation reproductive toxicity study and to request EOGRTS (OECD 443) instead, the Registrant agreed to perform the EOGRTS with DNT/DIT cohorts and without F2 generation based on the outcome of the 90 day sub-chronic toxicity test. MSC needed to consider the scientific and legal arguments for the final decision. **Agreement seeking (6d, Session 2)** Since there are no substance specific arguments in the PfAs and in the Registrant's response to the comments to use OECD test guideline 443 (EOGRTS) and not to trigger the F2 generation at the test, ECHA still maintained the position that the F2 generation cannot be omitted from the test to meet the endpoint requirement for Annex X, 8.7.3. This view is however not shared by all MSC members. MSC reached unanimous agreement on the first part of the split draft decision on repeated dose 90-day oral toxicity testing, (TPE-033A/2011) as modified in the meeting. Also the deadline for the Registrant to submit the information required is shortened respectively to 18 months from 30 months because the study required in accordance with Annex X 8.7.3 was not any more included in the DD. MSC adopted the formal agreement on the (split) draft decision on repeated dose 90-day oral toxicity testing. Furthermore, it was concluded that MSC unanimous agreement could not be reached on the other part of the split draft decision on the	SECR to provide to COM for further decision making a package of the documents (DD on generation testing, MSC DA, RCOM, minutes, outcome of the vote, and justification for the position at the vote). One MSC member to send an amended standard justification in writing to the MSC-S on this case for voting against the split decision TPE-033B/2011.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
generation study (two options for the registrant: two-generation study or EOGRTS with the second generation). **<u>TPE-037/2011</u> 2,2'-Dimethyl-2,2'-azodipropiononitrile** (EC 201-132-3) **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's modified draft decision (DD) as provided to MSC for the current meeting, the PfAs of MSCAs and the Registrant's comments on the PfAs. With regards to the simulation test for ultimate degradation in surface water, MSC concluded to follow the approach suggested by ECHA of accepting the test proposal if the Registrant considers it necessary based on the Chemical Safety Assessment (CSA) but also that the draft text in the SoR section should be revised. PfAs were made to request only EOGRTS (OECD 443) without F2 generation and with DIT/DNT cohorts whereas ECHA's DD requested either two-generation reproductive toxicity study (EU B.35) or EOGRTS (OECD 443) with F2 generation. The registrant did not agree to perform EOGRTS. MSC concluded that no agreement on this information requirement was likely. MSC concluded to split the text of the DD separating the decision on EOGRTS or two-generation reproduction toxicity study from the rest of the testing proposals on repeated dose 90-day oral toxicity testing, pre-natal developmental toxicity study and the simulation testing , for decision making. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on the first part of the split draft decision on repeated dose 90-day oral toxicity testing, pre-natal developmental toxicity study and the biodegradation simulation testing (TPE-037A/2011) as modified in the meeting. Also the deadline for the Registrant to submit the information required is shortened respectively to 24 months from 36 because no requirement regarding Annex X, 8.7.3 remained in this DD. MSC adopted the formal agreement on the split draft decision on repeated dose 90-day oral toxicity testing, pre-natal developmental toxicity study and the simulation testing. Furthermore, it was concluded that MSC unanimous agreement could not be reached on the second part of the split draft decision on the generation study (two options for the registrant: two-generation study or EOGRTS with the second generation). **<u>TPE-030/2011</u> Azodicarbonamide** (EC 204-650-8) **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's modified draft decision (DD) as provided to MSC for the current meeting, the PfAs of the MSCA, the Registrant's comments on the PfAs and the justifications provided by MSC who requested to terminate the written procedure for this substance. PfA was received on simulation testing on ultimate degradation in surface water (OECD 309) and on metabolite formation (ammonium). MSC considered the originally proposed OECD 303A by itself is not sufficient to fill the information requirement, thus a OECD 309 should be requested. It remains an option to the Registrant to generate information through screening studies and generate information that potentially can be applied in an argument to adapt the information requirement. MSC recognised that the decision could be updated by	SECR to provide to COM for further decision making a package of the documents (DD on generation testing, MSC DA, RCOM, minutes, outcome of the vote, and justification for the position at the vote).

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
clarifying this in the statement of reasons. **Agreement seeking (6d, Session 2)** MSC agreed that the screening test alone does not fulfil the information requirement of Annex IX section 9.2.1.2 but may provide a possibility to adapt the standard information requirements in accordance with column 2. So the Registrant is requested to cover the standard information requirement by performing OECD 309 and the testing proposal in accordance with OECD303A is rejected. MSC reached unanimous agreement on the amended ECHA's draft decision as modified in the meeting based on the editorial suggestions proposed. MSC adopted the formal agreement. **<u>TPE-036/2011</u> Reaction mass of divinylbenzene and ethylstyrene** (List No. 910-757-7) **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's modified draft decision (DD) as provided to MSC for the current meeting, the PfAs of MSCAs, the Registrant's comments on the PfAs and the justifications provided by MSC who requested to terminate the written procedure for this substance. Registrant proposed simulation testing on ultimate degradation in surface water. MSC concluded to update the statement of reasons for DD based on the proposals made in the written procedure to clarify to the Registrant the REACH standard information requirement and to bring the wording of DD in line with the other similar DDs discussed at MSC-22. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on the amended ECHA's draft decision as modified in the meeting based on the editorial suggestions proposed. MSC adopted the formal agreement.	MSC-S to upload in MSC CIRCABC the final ECHA decisions and agreements on cases TPE-032/2011, TPE-035/2011, TPE-034/2011, CCH-041/2011, CCH-040/2011 TPE-029/2011, CCH-043/2011, CCH-042/2011, TPE-030/2011, TPE-036/2011 For TPE-037/2011 and TPE-033/2011 the final decisions addressing the agreed parts will be uploaded on CIRCABC and parts not agreed will be referred to the Commission.
7. Substance Evaluation **a. Discussion on the MSC opinion on the draft Community Rolling Action Plan (CoRAP)**	
Following the presentation from the Rapporteur on the changes made to the draft opinion and its Annex, MSC proposed some further changes and amendments for improvement of the text. (Co-) Rapporteur and working group would revise the text as preparation for adoption. Regarding the publication of the opinion, MSC agreed that the remarks	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
and the summary of justification columns in the annexed table would not be published because of confidentiality concerns. MSC also agreed to improve the consistency of the phrases in the grounds for concern column for publication so as to avoid confusion by the readers. MSC agreed that for the next round of CoRAP update, the opinion would contain more information on the justification for proposing a substance for evaluation, since there would be more time available to consider the confidential nature of some of the information.	
b. Adoption of the MSC opinion	
MSC adopted the opinion and Annex to the opinion as amended during the meeting.	The opinion will be published on ECHA website on 29 February together with CoRAP.
8. Authorisation process **8a. Recommendations of priority substances for Annex XIV**	
• **Feedback discussion on the previous round** MSC supported the feedback from Rapporteur who highlighted that if there is not enough time for the MSC todiscuss its opinion on the recommendation and for seeking consensus, the consequences would be faced in the REACH Committee and that MSCAs and MSC members should react and comment earlier in the process preferably already in the initial phase when ECHA presents the recommended substances. There is extreme time pressure towards the end of the opinion forming process and that options should be considered to alleviate this pressure. • **Presentation on aspects to consider in setting latest application dates** MSC took note of the presentation. • **Tentative timeline for the 4th recommendation process** MSC took note of the tentative timelines presented	SECR to consider means how to ensure sufficient time to finalise and adopt the MSC opinion. MSC to send written comments on the presentation by 24 February 2012. MSC-S to present in MSC-23 a more detailed timeline for the 4th recommendation process specifying the timelines for the work for the MSC.
8b. SVHC process	
• Analysis of removing or modifying entries in the Candidate list • Feedback discussion – lessons learnt from the previous round of proposals MSC recognised that there was a very good overall experience in relation to the first Article 57(f) proposal. MSC also recognised that better communication is needed between ECHA SECR, MSCA and MSC and that comments made in the public consultation on substance identification and intrinsic properties need to be carefully considered by the dossier submitters as well as by all	SECR will report to MSC in MSC-23 on the analysis on existing RCF entries made and will propose options for the consideration of MSC on how to improve the clarity of the Candidate list in relation to RCF entries.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
parties involved.	
9. Manual of Decisions (MoD)	
a) New item for discussion to be included in MoD MSC showed a general support on the importance of the topic proposed however recognised that more experience still needs to be gathered on this topic before drafting a firm conclusion for MoD. b) MSC involvement in contributing to MoD drafting MSC agreed to have an informal group of people to propose topics for MoD.	MSC to send notifications of interest for membership in the informal group to SECR.
12. Any other business - Participation of case-owners and stakeholder observers during dossier evaluation discussions	
MSC and StOs acknowledged the importance of having open MSC meeting sessions for case owners and StOs since it increases the transparency of the decision making process and helps in the transmission of information to Registrants. MSC and StOs also recognised that due to the increased workload of the MSC, the meeting structure would need to be reconsidered, which could potentially affect the structure of the meetings and possibilities to invite all case-owners to the meetings.	StOs to send their feedback on their experiences following case owner participation in the MSC meetings in writing to SECR by 17 February.
13. Adoption of conclusions and action points	
The draft conclusions and action points from this meeting would be proposed for adoption by written procedure.	MSC-S to upload the MSC-22 conclusions and action points when adopted