**MSC/M/31/2013**
**ADOPTED AT MSC-32**

# Minutes
## of the 31st Meeting of the Member State Committee (MSC-31)
## 25-27 September 2013

## I. Summary Record of the Proceedings

### Item 1 - Welcome and Apologies

The Chair of the Committee, Ms Anna-Liisa Sundquist, opened the meeting and welcomed the participants to the 31st meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

### Item 2 - Adoption of the Agenda

The Agenda was adopted as modified at the meeting based on the draft agenda as provided for the meeting by SECR and a member's suggestion for inclusion of three sub-items under AOB (final Agenda is attached to these minutes).

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

One member declared a potential conflict of interest in respect to the dossier evaluation case TPE 078/2013 (based on the annual declaration as published on the ECHA website) and was therefore considered not to be in a position to participate in the vote for this case. No conflicts of interests were declared by other members, experts or advisers with any other items on the agenda of MSC-31.

### Item 4 - Administrative issues

SECR informed the Committee of its observation that the travel and accommodation services of ECHA's new provider of travel services have improved and requested the members to provide feedback if problems still exist.

SECR gave a report on the previous and on-going ECHA's guidance consultations and also informed the Committee of two forthcoming guidance consultations of MSC by the end of the year.

### Item 5 – Adoption of the minutes of the MSC-30 meeting

The MSC Chair informed the participants that minutes from MSC-30 were adopted by written procedure and published on MSC CIRCABC and on the ECHA website shortly after their adoption.

### Item 6 – Dossier evaluation

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

SECR gave a report on the outcome of the written procedure (WP) for agreement seeking on five dossier evaluation cases (see Section V for more detailed identification of the cases). WP was launched on 29 August 2013 and closed on 9 September 2013. For three cases, the draft decisions (DD) were split thus resulting in six DDs and overall 13 DDs for the eleven cases. By the closing date, responses to WP were received from 26 members with voting rights and from the Norwegian member. Unanimous agreement was reached on eight DDs. For three DDs on testing proposals involving the standard information requirement for Annex X, 8.7.3 unanimous agreement was not reached by MSC. Thus, these three DDs are to be referred to COM for further decision-making under Article 133 (3) of REACH. For two DDs, WP was terminated by the MSC Chair on the basis of Article 20.6 of the MSC Rules of Procedure as at least one MSC member requested meeting discussion at the MSC-31 meeting.

#### b. General topics

- **Current scientific status and regulatory approach for *in vivo* mutagenicity assays for Testing Proposals**

SECR gave a presentation on *in vivo* mutagenicity assays in the context of the testing proposal examination (TPE) as mentioned in the ECHA guidance in relation to the mutagenicity/gene mutation endpoint and its interlink with the regulatory frame. ECHA guidance recognises three test guidelines for mutagenicity testing *in vivo*: unscheduled

DNA synthesis (UDS) test with mammalian liver cells *in vivo* (OECD TG 486), transgenic rodent somatic and germ cell mutation assays (TGR) (OECD TG 488) and mammalian alkaline Comet assay. Adopted OECD test guidelines are available for UDS and TGR whereas the OECD Guideline for *in vivo* mammalian alkaline Comet assay is not yet formally adopted and its adoption by OECD may happen in summer 2014 if everything goes well. There is not any other internationally accepted test guideline for a Comet assay although there are some recommendations that are publicly available and the test has been quite widely used by the test houses with specific test protocols.

SECR explained the scientific status of the three *in vivo* tests indicating that UDS is able to detect DNA repair in liver cells of mammals (commonly used species rat), TGR gene mutations in any tissues of rodents and Comet assay DNA damage in any tissues of (usually) rodents.

SECR reminded that at MSC-22 meeting, the Committee agreed that in TPEs TGR should normally be requested (and UDS rejected if proposed by registrants) based on the substance-specific reasons, while applicability of the Comet assay was not discussed by MSC due to lacking international test guideline. It was explained by SECR that as no internationally adopted test guideline for Comet assay is available ECHA cannot (cf, Article 13(3), 1st paragraph) therefore require such test to be conducted. However, ECHA can consider in an individual case a Comet test protocol proposed by a registrant be equivalent to data generated by the corresponding method as referred to in REACH Article 13(3) when the conditions listed in Annex XI.1.1.2 are met. Thus ECHA can consider a testing proposal of a registrant who has proposed a Comet assay (which is listed as a recognized test method in the Guidance) for mutagenicity testing *in vivo* when the registrant has specified with the testing proposal a detailed and scientifically sound protocol to be used for the test. SECR suggested that if ECHA in examination of such testing proposal with a protocol comes to a conclusion that it will produce appropriate results ECHA can accept Comet assay to be used. According to SECR this practice would not mean that ECHA would recognise the Comet assay test guideline in general but would be able to consider testing proposals with specified protocols on a case by case basis.

It was agreed in the discussion that for the moment it is not yet known if and how the Comet assay could be used for mutagenicity testing of germ cells and only TGR is currently applicable for germ cell mutagenicity testing.

Some members and experts expressed a wish that a reference to a Comet assay test guideline could be done e.g. in the same way as what EFSA is doing for testing of food additives. It was stated by SECR that the situation in testing of substances in the frame of EFSA (e.g. food additives) is very different because usually much more information is available on toxicity than in the case of chemicals under REACH. Also REACH sets its limitations for general acceptance of test guidelines. On the role of the Comet assay it was concluded that ECHA cannot require a Comet assay to be performed due to lack of internationally/EU adopted test guideline but it can consider a testing proposal for *in vivo* mutagenicity testing with a detailed and scientifically sound protocol for a Comet assay and, after examination, consider accepting such a test on a case by case basis.

Regarding the REACH information requirements on mutagenicity SECR explained that the standard information requirements under 8.4 of Annexes VII and VIII concern *in vitro* mutagenicity tests but based on a positive result of any of the *in vitro* tests *in vivo* mutagenicity studies need to be considered. According to 8.4 of Annex IX, an appropriate *in vivo* somatic cell genotoxicity study shall be proposed by the registrant if there is a positive result in any of the *in vitro* genotoxicity studies in Annex VII or VIII and there are no results available from an *in vivo* study already. Regarding Annex X, 8.4, a second *in vivo* somatic cell study may be necessary, depending on the quality and relevance of all the available data. For both Annexes IX and X the potential for germ cell mutagenicity should be considered on the basis of all available data including toxicokinetic evidence, if there is a positive result from an *in vivo* somatic cell study available. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered.

It was concluded that normally the considerations referred to in all Annexes regarding point 8.4 are to be carried out by the registrant but as the legal text is silent about the

subject for considerations also ECHA could consider that a further *in vivo* mutagenicity study would be necessary. If ECHA required such a study a justification should then be included in the decision. MSC concluded that the registrant should document the considerations in the registration dossier and ECHA/Member States would then have a possibility to review the considerations as a follow-up as well as open an evaluation process as necessary.

Regarding a need for a second *in vivo* mutagenicity test in somatic cells under Annex X MSC concluded that it should be assessed against quality and relevance of all the available data. Also if already a positive result on *in vivo* mutagenicity test in somatic cells is available the potential for germ cell mutagenicity shall be considered normally by the registrant and considerations documented in the registration dossier. Also in these two cases the registrant should document his considerations in the registration dossier and ECHA/Member States would then have a possibility to review the considerations as a follow-up as well as open an evaluation process as necessary.

- **Regulatory approach to testing strategies [Closed session]**

MSC discussed the testing strategies and order of testing in different cases when several higher tier tests are proposed.

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

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

**TPE 079/2013** Alkenes, C7-9, hydroformylation products, distn. residues, heavy cracked fraction (EC No. 308-482-7)

***Session 1 (open)***

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

SECR explained that four PfAs to ECHA's DDs were submitted. Three of them suggest requesting an extended one generation reproductive toxicity study (EOGRTS) for Annex X, 8.7.3 instead of ECHA's proposal to provide the registrant with a choice of two appropriate methods, either to perform the two-generation reproductive toxicity test (EU B.35) or EOGRTS (OECD 443) with the second generation. One PfA suggests keeping the two choices but excluding from the optional request for EOGRTS the extension of cohort 1B (production of F2 generation). SECR did not modify the DD for the meeting based on the PfAs but proposed discussion based on the registrant's comments.

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

The Registrant in the written comments on PfAs expressed the intention to perform, in a tiered approach, a two-generation reproductive toxicity study followed by a pre-natal developmental toxicity (PNDT) study.

SECR introduced the case and explained that in the response to PfAs, the Registrant confirmed the preference to a two-generation reproductive toxicity study according to OECD TG 416 and also presented the sequential testing strategy that was not included in the technical dossier.

The Registrant's representatives confirmed at the meeting their preference regarding the testing sequence - to conduct first the 'two-generation study' with rat and take into account the possible outcome and consider the possibilities for adaptations of the standard information requirements according to the column 2 provisions of the respective Annex. If no adaptation is possible, then the registrant plans to perform the PNDT study with rabbit and utilise the results of these studies in a weight of evidence approach for the second PNDT study with rat. This strategy would thus create potential to avoid testing on two species for PNDT. Some MSC members raised their concerns regarding the potential waiving of the first species for the PNDT study.

***Session 2 (closed)***

Based on the above considerations, MSC concluded not to split the DD because of the Registrant's proposal for the testing sequence and due to the explicit reference in the draft decision that the Registrant was to choose the appropriate testing strategy.

MSC did not reach unanimous agreement on ECHA's DD.

The Chair recognised the results of voting on the DD relating to Testing Proposal (TP) for a two-generation reproductive toxicity study. As MSC did not reach a unanimous agreement on the DD at the vote, the Chair invited the disagreeing MSC members to provide written justifications for their disagreement if the justification were different to those provided for previous similar cases (otherwise SECR would use the justification provided in previous similar cases). ECHA will refer the DD to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH Regulation.

**TPE 073/2013** 2,5-bis-isocyanatomethyl-bicyclo[2.2.1]heptane (Reaction mass of 2,5-bis-isocyanatomethyl-bicyclo[2.2.1]heptane) (EC No. 411-280-2)

***Session 1 (open)***

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

SECR explained that four PfAs were submitted. In relation to mammalian erythrocyte micronucleus test (OECD 474) and Comet assay, three PfAs were provided. In one PfA it is agreed that *in vivo* somatic cell genotoxicity testing is necessary for both gene mutations and clastogenicity and aneugenicity studies. However, it cannot be accepted to request two separate *in vivo* mutagenicity tests in somatic cells. As in this PfA also in two other PfAs it is indicated that a combined Comet assay with *in vivo* micronucleus study should be requested with a modified test protocol in order to reduce the number of test animals, or the testing order with a possibility to avoid the other test should be considered. According to two PfAs it is proposed that if a first (integrated) *in vivo* somatic cell test is positive, germ cell mutagenicity shall be considered in a second *in vivo* test using the TGR assay (OECD 488) as the Comet assay is not adequate for detection of germ cell mutagenicity. In one of the PfAs it is proposed that the germ cell mutagenicity test should be requested in a conditional manner based on the positive outcome of the first *in vivo* assay.

The fourth PfA proposes to reject the *in vivo* Comet assay and instead to request TGR assay on several tissues, including a specific request for sampling germ cells (testes) in case further germ cell mutation studies would be necessary. Extensive justification is provided for this approach in PfA.

SECR did not modify the DD for the meeting but proposed the DD be discussed at the meeting based on PfAs.

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

The Registrant provided comments in writing on PfAs and agrees with the PfA on integrated micronucleus/Comet test protocol accepting, if the integrated micronucleus/Comet assay *in vivo* test turns out to be positive, the need to conduct TGR test to evaluate potential germ cell mutagenicity unless the registrant can demonstrate that the substance does not reach the germ cells. The Registrant raised a concern that a laboratory to do the TGR in the near future cannot be found. Extension of timeline in which the potential test is to be performed is possible, but further delay in testing is in contrast to the potential genotoxic hazard of the substance. It is of general interest to further investigate this characteristic in short notice.

SECR explained that it is difficult to impose the combination of the tests as the Registrant did not provide with detailed protocol on how to integrate the both tests. However, SECR explained that combination of the tests would be possible if the combined study is well documented allowing assessment whether the generated data would meet the conditions of the two separate studies. In this respect, the representative of the Registrant confirmed that it is possible to combine the tests and at the same time respect the requirements to conduct the tests.

The member representing the MS making the proposal to replace the micronucleus/Comet assay with TGR study explained that they wanted to bring up arguments for TGR but that they could also consider the other options brought up by other MSs in their PfAs.

One MSC member explained that *in vivo* Comet assay is not sufficient for mutagenicity category 1B and the result can only be used for mutagenicity category 2. The representative of the Registrant agreed with this statement; however the Registrant further remarked that if the outcome of the both proposed tests is negative, it is scientifically justified to conclude that the substance does not have to be classified and no further testing is necessary since there are no substances known that are not mutagenic to somatic cells, but that are mutagenic to the germ cells. Therefore, only in case of a positive outcome, further testing would be necessary, and the follow-up study should be indeed TGR (OECD TG 488).

***Session 2 (closed)***

Based on the above considerations, MSC agreed unanimously on ECHA's DD addressing the testing proposals for *in vivo* mammalian erythrocyte micronucleus test and *in vivo* Comet assay as amended during the meeting for Section III reflecting the possibility for combining of the tests and that the Registrant should consider depending on the results of the *in vivo* mutagenicity tests in somatic cells the potential for germ cell mutagenicity and document the considerations as part of the end point summary in the registration dossier. If it cannot be clearly concluded on germ cell mutagenicity, the Registrant shall consider additional investigations and may need to submit further testing proposals.

**TPE 078/2013** Reaction mass of (E)-1-chlorobut-2-ene and 3-chlorobut-1-ene (List No. 908-820-9)

***Session 1 (open)***

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

SECR explained that two PfAs to ECHA's DD were submitted. One PfA suggested rejecting the mammalian erythrocyte micronucleus test (OECD 474) with an integrated *in vivo* comet assay and instead request transgenic rodent somatic and germ cell gene mutation assays (TGR, OECD TG 488), including a specific recommendation for sampling of testes tissue for later analysis if one or more of the somatic tissues indicate mutagenicity. According to this PfA micronucleus test would not produce reliable indication that the substance is an *in vivo* gene mutagen.. The second PfA suggested changing the route of exposure for the proposed test from oral route to inhalation on the basis of the physic-chemicals properties of the substance and exposure considerations. In addition to this, both PfAs suggested to include a reminder in the DD indicating that if the proposed *in vivo* test is positive for *in vivo* somatic cell, the Registrant should consider germ cell mutagenicity testing by proposing to add under Section II of DD that in case of a positive result of the conducted test in somatic cells the Registrant should conduct a germ cell mutagenicity test (ref. REACH Annex IX/X, 8.4, column 2) unless the Registrant can clearly demonstrate that the substance does not reach germ cells. The TGR must be performed with oral exposure to enable sufficient exposure of the germ cells.

SECR did not modify the DD for the meeting but proposed discussion based on the PfAs.

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

The Registrant provided comments in writing on the PfAs. Regarding the potential need to conduct TGR assay the Registrant is of the view that Comet assay is scientifically acceptable and appropriate for classification purposes. The Registrant will clarify if testes tissue can be included into the protocol of the proposed *in vivo* Comet Assay, and considers that if this can be done the same conclusions regarding classification could be drawn as with TGR. Otherwise the substance could be classified as a germ cell mutagen (Mut. 1B) following a worst case approach. The Registrant does not plan to perform a further *in vivo* mutagenicity study. Regarding PfA on changing the route of exposure from oral to inhalation the Registrant considers that inhalation route of exposure would not be warranted because the substance is an intermediate handled under strictly controlled and rigorously contained conditions. The additional registration subject to potential customers

not fulfilling the conditions has turned out not to be required. The Registrant notes that the substance is corrosive and has therefore concern about inhalation route of exposure and its consequences regarding reliability of test results.

The representative of the Registrant maintained the arguments provided in writing and explained that according to the view of the Registrant a stand-alone Comet assay is a valid test to fulfil the information requirement for a substance registered at Annex VII level. The Registrant indicated that by proposing an integrated protocol they intended to maximise the amount of information obtained for the number of animals used in the test and to clarify any concern relating to chromosomal aberration.

The member representing the MS making the PfA to replace the micronucleus/Comet assay with TGR study explained that they wanted to bring up arguments for TGR but that they could also consider supporting the proposed combined test, in particular taking into account that the Registrant has acted in a responsible way when proposing for an Annex VII substance *in vivo* mutagenicity test in somatic cells based on positive *in vitro* test.

One MSC member mentioned that depending on the result of the combined protocol this can be followed up by germ cell mutagenicity test. One MSC member reminded that a positive *in vivo* Comet assay is not sufficient for classification of *in vitro* mutagens as mutagen, category 1B and that such a test result can only be used for classification as mutagen category 2. The Registrant repeated that they are not planning to carry out further *in vivo* test and if the result of the testing in somatic cells will be positive the Registrant will classify the substance accordingly.

The member representing the MS making the PfA regarding the route of exposure in the mutagenicity testing pointed out the concern regarding the potential of workers exposure and the physico-chemical properties of the substance leading to assumption that inhalation exposure is likely. The Registrant confirmed that the substance is handled under strictly controlled conditions according to Article 18 of REACH and the worker exposure is not likely and that they still consider the most appropriate route of exposure oral route to be able to get relevant results on the test.

One member raised a concern that the DD does not address the registration of the substance as a transported isolated intermediate (TII) and whether the whole decision would lose its validity if this use would be removed from the registration dossier. SECR confirmed that the decision would remain valid and enforceable even if the registration of the substance on Annex VII level was removed from the registration dossier.

***Session 2 (closed)***

Based on the above MSC considerations, DD addressing the testing proposals for *in vivo* mammalian erythrocyte micronucleus test and an integrated *in vivo* comet assay was modified regarding Section I and Section III of the DD which was amended in order to state the fact that the substance is registered as a non-phase in substance in the tonnage band of 1-10 tpa and also as a TII for 1000 tonnes or more per year. No reminder for the registrant on consideration for germ cell mutagenicity testing was added to the DD due to the substance's low tonnage registration for non TII use. No other changes to DD were introduced.

MSC agreed unanimously on ECHA's DD as modified in the meeting. One MSC member did not participate in the vote due to her declared potential conflict of interest.

**TPE 081/2013** [3-(2,3-epoxypropoxy)propyl]trimethoxysilane (EC No. 219-784-2)

***Session 1 (open)***

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

Three PfAs on ECHA's DD were submitted. According to all three PfAs it was proposed to reject the second in vivo mutagenicity study (cf. Annex X, 8.4, Column 2), i.e. in vivo Comet assay via oral route, as there is sufficient information in the dossier based on positive in *vivo* micronucleus test that the substance to warrant the substance to be classified as Mut. Cat 2 (mutagenic in somatic cells). According to PfAs a second *in vivo* genotoxicity test would not change this conclusion. According to PfAs it is proposed either

to request a TGR test in germ cells or to include a statement in DD which would remind the Registrant about the need to consider further the potential for germ cell mutagenicity when a positive *in vivo* study in somatic cells is available unless it can be clearly demonstrated that the substance does not reach germ cells.

The members representing the MSs that made the PfAs for rejection of the TP repeated their arguments for rejection. The expert to one MSC member indicated that the proposed new test would neither be adequate as the Comet assay via oral route would not produce relevant results because the reactive substance would polymerize in the stomach of animals to form plastic, and result of such test would be questionable. It was suggested that this argument could also support rejection of the testing proposal.

It was noted that the Registrant has not classified the substance based on the positive mutagenicity study (thus appropriate risk management measures would not be in place).

***Session 2 (closed)***

Based on Annex X, 8.4, column 2, 1st paragraph, a second in vivo somatic cell test may be necessary depending on the quality and relevance of all the available data. As a starting point for consideration to reject the testing proposal MSC considered that the available data are based on good quality studies and Klimisch score for the positive micronucleus test is 1. The negative results of other studies are not sufficient to put in doubt the relevance of the positive study. Moreover, the dossier contains positive results of two in vitro sister chromatid exchange tests (SCE), on Chinese hamster ovary cells and on mammalian peripheral lymphocytes. This test does not detect chromosomal aberration per se, but is an indicator test showing DNA damage/recombination. These positive results of the SCE test are however consistent with the positive result of the in vivo micronucleus assay. Also the ECHA Guidance supports the conclusion that a second in vivo mutagenicity study in somatic cells would not be necessary in a case at hand. It was noted that somatic cell genotoxicity has been addressed by the existing study and that the substance has an alert for gene mutation and such in vivo study is not in the dossier. However, it was noted that further *in vivo* testing results on mutagenicity on somatic cells would not provide any relevant additional information for adequate risk management measures. In case of rejection of the testing proposal it was concluded that quality and relevance of all available data need to be reflected in the DD as justification for the rejection.

The Registrant has not classified the substance based on the positive mutagenicity study. Therefore a reminder on classification should be included in DD.

Regarding the need for germ cell mutagenicity testing it was noted that a positive in vivo mutagenicity test is available (cf Annex X, 8.4, column 2, 2nd paragraph). However, it was also noted that the germ cell mutagenicity testing requirement is separate from the conditional requirement for a second in vivo somatic cell test. No testing proposal had been submitted by the registrant in this regard. It was therefore concluded the registrant should consider this requirement. The DD should be modified to include in Section III that the Registrant should document such considerations and submit them with any further data and potential testing proposals to ECHA within a certain (non-binding) timeline and to remind the Registrant that any future evaluation of the substance regarding the information requirement for germ cell mutagenicity may take place.

SECR invited the MSs to make a proposal for harmonised classification for the substance to ensure that appropriate risk management measures would be put in place.

Based on the above considerations, MSC agreed unanimously on rejecting the testing proposal for *in vivo* Comet assay and reflecting in DD the reasons for rejection based on quality and relevance of all available data. Furthermore, the Registrant is requested to consider germ cell mutagenicity testing, to submit such considerations, such as any further data on toxicokinetic and/or testing proposals by six months of the decision in an updated technical dossier. MSC found unanimous agreement on ECHA's DD as amended at the meeting.

**TPE 088B/2013** 2,2'-iminodi(ethylamine) (EC No. 203-865-4)

***Session 1 (open)***

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

SECR explained to the representative of the Registrant that ECHA has split the DD into TPE-088A/2013 and TPE-088B/2013 where TPE-088A/2013 addresses the information requirement for Annex X, 8.7.3 (two generation reproductive toxicity) and TPE-088B/2013 addresses the other information requirements. Only TPE-088B/2013 will be addressed for agreement at the MSC-31 meeting. MSC did not find agreement on part A of the split DD (TPE 088A/2013) in written procedure and therefore that part of DD will be referred to the Commission decision making.

Regarding TPE 088B/2013 five PfAs were submitted. In two PfAs it was proposed to modify DD and to reject the *in vivo* UDS (OECD 486) test and instead to request TGR assay (OECD 488). One of the PfAs proposed a specific request for sampling germ cells (testes) to make analysis of germ cell mutations possible if the results are positive in any of the other tissues. Regarding the earthworm reproduction test (OECD 222) it was proposed in one PfA to give to the Registrant three options for testing on long-term toxicity to terrestrial invertebrates by specifying three optional tested species and test guidelines. Another PfA proposed to include in DD a testing strategy for the terrestrial compartment and together with another PfA proposed to clarify Section III that based on the outcome of earthworm test further toxicity tests on plants could be necessary and testing proposals should be submitted accordingly. A third PfA proposed to request a soil microorganism test (nitrogen transformation test, OECD 216) because according to the terrestrial testing strategy, soil microorganisms may not be covered by the EPM approach.

SECR amended the DD in advance of the meeting concerning the *in vivo* mutagenicity testing proposal i.e. to replace the original proposed *in vivo* UDS test with TGR assay. SECR also amended the DD including a reminder for potential further testing (testing strategy for the terrestrial compartment) and did not amend the DD to give the three options for soil long-term toxicity test nor to include the request for soil micro-organism test.

The members representing the MSs who made PfAs on testing of terrestrial environment were content with the amendments made by SECR on the DD for the meeting and no further discussion was needed on the basis of these PfAs.

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

The Registrant provided comments on the PfAs regarding mutagenicity testing but did not provide any comments on testing for terrestrial environment. The Registrant now believes that there is no need for further testing on mutagenicity based on reassessment of the existing data. The representative of the Registrant repeated the conclusion that after reassessment of the available *in vitro* and *in vivo* mutagenicity data, taking a Weight of Evidence (WoE) approach, the test results are not conclusive. As no positive *in vitro* data exist, there is no justification for further *in vivo* testing. SECR explained to the Registrant the decision making process and stressed that the Registrant has had several opportunities to comment the DD at the earlier steps of the decision making process and that at stage of MSC it is too late to withdraw the testing proposal and to submit an adaptation argument. DD addressed for the Registrant's comments has indicated that any modifications to the registration dossier, e.g. withdrawal of a TP (or comments changing the TP) cannot be taken into account after the MSCA consultation on the DD has started. It was stressed that the registration dossier, which lacks an adaptation argument, does not allow to conclude that testing is unnecessary.

A member expressed doubts regarding soundness of the Registrant's arguments for the negative WoE conclusion on *in vitro* mutagenicity.

SECR explained as well to the representative of the Registrant that the referred WoE could be applied by the Registrant as response to the final decision but at the Registrant's risk. ECHA will evaluate the provided information at the follow-up stage when the deadline for the decision to submit information has expired.

MSC members agreed with the approach regarding the earthworm reproduction test as modified by SECR after the PfAs.

***Session 2 (closed)***

The MSC members shared the view that uncertainty still remains regarding soundness of the Registrant's arguments for the negative WoE conclusion on *in vitro* mutagenicity.

Based on the above considerations, MSC agreed unanimously on rejecting UDS test with mammalian liver cells *in vivo* (OECD 486) and on requesting instead TGR assay (OECD 488) on stomach, liver and bone marrow tissues. The Registrant may consider collecting the male germ cells and storing for potential further analysis of germ cell mutagenicity. MSC found unanimous agreement on ECHA's amended DD as modified at the meeting.

**TPE 075/2013** Reaction mass of Benzeneacetic acid, alpha-oxo-, 1,1'-(oxydi-2,1-ethanediyl) ester and Benzeneacetic acid, alpha-oxo-, 2-(2-hydroxyethoxy)ethyl ester (EC No. 442-300-8)

***Session 1 (open)***

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

Two PfAs to ECHA's DD were submitted. The first PfA proposed to reject TP for a pre-natal developmental toxicity study (PNDT) (OECD 414) which is not a standard information requirement of Annex VIII. According to the PfA no arguments for a PNDT study instead of the screening study (OECD 421) are presented as in accordance with Annex VIII, 8.7.1, column 2, PNDT study can only be proposed in cases where there are serious concerns about the potential for adverse effects on development. According to PfA the Registrant has a data gap for the screening study in the dossier. PNDT study is neither available but only proposed and hence is not a suitable waiving argument for the screening study. The second PfA was similar with the first one and proposed to ask for the screening study instead of PNDT study.

SECR did not modify the DD for the meeting but proposed discussion on the case at the meeting.

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

The Registrant provided written comments on the PfAs and repeated the arguments to conduct a PNDT study because of greater sensitivity and higher statistical power of the study compared with the screening study. They refer to column 2 of Annex VIII, 8.7.1 where it is stated that the screening study does not need to be conducted if a PNDT study is available. They refer to column 2 of Annex VIII, 8.7.1 where it is stated that the screening study does not need to be conducted if a PNDT study is available. On 8 August 2013 the Registrant has updated the dossier upgrading the tonnage band to Annex IX level, where the PNDT study is a standard information requirement. The Registrant believes that the combination of the proposed developmental toxicity study (OECD 414) and the proposed 90-day repeated dose toxicity study (proposal in the updated dossier) with emphasis on the reproductive organs will address reproduction toxicity adequately.

The observer representing industry StO stated that this case should be treated in the same way as if a 90-day study was proposed and 28-day study was missing. His understanding was that in this case 28-day study would not be requested but 90-day study would be considered as available and would be the basis for waiving of the 28-day study. On the same line, the member representing an NGO StO highlighted that the legal text is clear and the PNDT test would give a justification to waive a screening study.

As response a MSC member indicated that screening and PNDT studies are not examining the same parameters/endpoints whereas 28-day and 90-days studies are focusing on the same endpoint. Several MSC members raised their concerns if accepting the testing proposal ECHA is creating a precedent on one hand when accepting a PNDT without a screening study based on intentions of the Registrant to update the dossier for the next tonnage level and on the hand by accepting for the basis of the decision an update to the dossier which took place after starting the CA consultation. SECR responded by stating that the Registrant's intention was well substantiated by an inquiry already at the time of

the evaluation of the TP and that registrants maintain the right to propose testing going beyond the minimum information requirements applicable at their tonnage level, where they see a need for such testing. In any case the present registration at Annex IX level would require PNDT and it would not make sense to reject the TP for PNDT at this point of time as a TP would in any case be needed for PNDT.

***Session 2 (closed)***

Based on the above considerations, MSC agreed unanimously on accepting the testing proposal for pre-natal developmental toxicity test (OECD 414). The DD was slightly amended in order to reflect the fact that the Registrant updated the technical dossier to the tonnage band of 100 to 1000 tpa. MSC found unanimous agreement on ECHA's DD as amended at the meeting.

**CCH 089/2013** Tris(methylphenyl) phosphate (EC No. 215-548-8)

***Session 2 (closed)***

SECR explained that agreement on DD was sought in WP with termination of the written procedure by the Chair of MSC on request of one MSC member suggesting MSC discussion on whether the concern over impurities of ortho- isomers of substance do not warrant a full specification of impurities even below 1%, e.g. in the light of coverage of the scientific literature on concerns over ortho- isomers. The member requested for further clarification on the substance identity (Annex VI, 2.1) and percentage of main impuritites (Annex VI, 2.3.3) which will important for the substance evaluation of this substance on CoRAPand the possible generation of information on substance isomers in this regard.

The issue was further explained and clarified by SECR by stating that it would be possible to develop a request for further information on impurities, even below 1 %. MSC supported SECR practical proposal how to formulate and include the request to the Registrant to provide more information on the percentage of (significant) main impurities (Annex VI, 2.3.3.), in particular information relating to the presence of ortho-isomers of tris(methylphenyl) phosphate in the substance, as well as a description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7). Sections 2 and 3 of DD were modified accordingly.

Based on the above conclusion, MSC found unanimous agreement on ECHA's DD as modified in the meeting.

**TPE 084/2013** Condensation product of N-C12-C18- alkylpropane-1,3-diamine, N-(3- aminopropyl)-N'-C12-C18- alkylpropane-1,3-diamine and formic acid (EC No. 641-088-6)

***Session 2 (closed)***

SECR explained that agreement on DD was sought in WP with termination of the written procedure by the MSC Chair on request of two MSC members suggesting discussion at MSC-31 as a fish bioconcentration study with dietary exposure (OECD 305) may be considered as more appropriate to test bioaccumulation, instead of the proposed lumbriculus bioaccumulation test (OECD 315). SECR pointed out that neither one of the tests, OECD 305 or OECD 315, do produce directly BCF values which could be comparable to the PBT criteria of Annex XIII but in both cases the results of the tests need to discussed in a WoE approach under 3.2 of Annex XIII and the outcome to be compared with the PBT criteria. The issue regarding use of the two tests and assessment of their results has been discussed by the PBT expert group and the PEG preparing guidance for PBT identification. At present there is no final solution to this issue but further considerations will be needed in the future. For the time being each case has to be considered on a case by case basis. Members agreed with the explanation provided and considered that DD as addressed in the written procedure could proceed.

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

**e. Update on appeal cases *(partly open – partly closed session)***

SECR presented to MSC a brief overview of the Board of Appeal's decisions in three cases challenging ECHA's dossier evaluation decisions, as well as the state of play four pending appeals against ECHA dossier evaluation decisions. Further, MSC was informed of the state of play on several SVHC cases before the European Court of Justice.

SECR also presented to MSC the process of rectification of evaluation decisions in Board of Appeal proceedings set out in Article 93(1) of the REACH Regulation.

**f. Status report on on-going evaluation work**

SECR gave detailed statistics and update on the status of evaluation work. The Committee was also informed of the potential workload for the forthcoming MSC meetings. MSC took note of the report.

**Item 7 – Substance evaluation decision making process**

**a. Written procedure report on seeking agreement on one draft decision on substance evaluation**

SECR gave a report on the outcome of the written procedure (WP) for agreement seeking on one substance evaluation draft decision (isoheptane (EC No. 250-610-8) as evaluated by the Latvian CA). WP was launched on 29 August and closed on 9 September 2013. By the closing date, responses to WP were received from 25 members with voting rights and from the Norwegian member. Unanimous agreement was reached on the draft decision.

**b. Processing of draft decisions for substance evaluation - short update by the Secretariat**

SECR provided an update on the number of draft decisions that the evaluating Member States (eMSCAs) are planning to put forward for the next CA consultation rounds. Those eMSCAs that had not yet planned when the decision making process should start, were encouraged to do so, however, considering also that it would not be ideal to have a high number of complex draft decisions in one meeting. SECR presented some lessons learned from the first round of proposals for amendments in the process of substance evaluation to be also shared with experts at the CAs, and tried to clarify the role of ECHA in the PfA process. Further information was provided on the progress made with the outcome documents for the four substances where the evaluation by the eMSCA was concluded without a draft decision. Publication plans for the related conclusion documents and SEv reports is not yet clarified but work is progressing. Finally SECR reminded all eMSCAs working on 2013 CoRAP substances about the timelines for the consistency screening that ECHA is offering, and invited for any feedback on how to improve any of its instructions or tools for the decision making process.

SECR also explained about some practicalities concerning the planned discussion and agreement seeking sessions during the MSC meetings when the substance evaluation draft decisions are on the agenda. The important role of the representative of the eMSCA during the course of the meeting was emphasised and some clarifications about how the case-owner participation is to be organised were provided.

SECR also explained some practicalities concerning the planned discussion and agreement seeking sessions during the MSC meetings when the substance evaluation draft decisions are on the agenda. The important role of the representative of the eMSCA during the course of the meeting was emphasised and some clarifications about how the case-owner participation is to be organised were provided.

## Item 8 – Community Rolling Action Plan (CoRAP) update & MSC opinion development

### a. Update by ECHA on the work on the next annual CoRAP update

SECR gave a brief progress report on the preparation of the CoRAP update for 2014-2016 pointing out that the draft update will be presented to MSC at the next MSC meeting in November 2013. It was further specified that there will be 56 new substances included in the current CoRAP update and split in the following three years for further substance evaluation. MSC members were also reminded of the next referral date (24 October) and of the deadline for any remaining MSCAs' comments (7 October). It was also indicated that by the MSC referral date, some preparatory work should be done by the MSCAs who are expected to update the justification documents for their substances. In accordance with the established working practices, the draft CoRAP update for 2014-2016 will be published on ECHA website after its referral to MSC and MSCAs in November 2013.

### b. Tasks of the Rapporteur in drafting the opinion of the MSC

### c. Appointment of Rapporteur

MSC agreed on the tasks of the rapporteur and the co-rapporteur in drafting the MSC opinion on the draft update of the CoRAP for 2014-2016. The Committee also appointed two of its members as a rapporteur and a co-rapporteur for this opinion preparation.

### d. Establishment of a MSC Working Group to support the Rapporteur

MSC agreed on the mandate of the newly-established working group to support the MSC rapporteur in drafting the MSC opinion on the draft update of the CoRAP for 2014-2016. Further, MSC appointed volunteering MSC members and two members' experts as members of the working group to support the rapporteurs in the opinion development.

## Item 9 – SVHC identification

### a. Brief overview on the SVHC proposals submitted in the 2nd 2013 SVHC round

SECR presented a brief overview on the SVHC proposals submitted in the second round of 2013 and outlined the timelines for this round. It was clarified that all seven SVHC proposals in this round are submitted due to CMR concerns including one that in addition is proposed as being of equivalent level of concern (57 f). All proposals are currently in the public consultation that ends on 17 October 2013.

### b. Revised Annex XV SVHC template and guidance

SECR introduced to MSC the draft update to the Annex XV SVHC guidance and the draft annotated template for an Annex XV report explaining the rationale behind the proposed updates of these documents. Both documents are intended for the authorities. Consultation on the draft revised Annex XV guidance has already been started with MSC.

The revision of the annotated Annex XV template was initiated to take into account e.g. the experience gained in the SVHC process, in particular when identification is to be done under Article 57 (f) of REACH and, the revision of Annex XIII. MSC was informed also that following the on-going MSC consultation, the revised draft documents will be sent to CARACAL-13. SECR is considering organising a workshop to present the final versions of each to the CA experts involved in the Annex XV dossier preparation and to MSC members. The workshop on this topic might be organised back-to-back to the MSC plenary meeting in February 2014. Those who do not feel that such a workshop in February would be necessary should inform MSC-S by 9 October.

Following MSC observer's request for clarification on whether the correct procedure had been followed and expression of the need for transparency, the Committee was informed that due to the procedural nature of the guidance under discussion and the fact that it concerned processes for the MSCAs and ECHA to implement, and time constrains, a "fast-track" procedure had been initiated via a decision of the ECHA Executive Director as foreseen in such cases by the Guidance update procedure. Therefore, as indicated in the ED decision, no PEG consultation had taken place on the update. SECR further noted that the needs to specify in more detail procedures relating to fast-track for guidance specifically for the authorities (and on obsoleting guidance in general) had been identified as issues to be considered in updating or replacing the current guidance update procedure (MB/14/2011 final) in a paper to be presented to the MB for their consideration in their September meeting. Options for improved pre-information of industry stakeholders in cases where the fast-track procedure resulted in missing the PEG stage could be made during elaboration of an updated procedure as a result of the feedback given by industry observers on this specific case.

In conclusion, the MSC chairperson reminded of the on-going consultations on both the guidance document and Annex XV template and invited the members and observers to send their written comments by 9 October 2013.

## Item 10 – Prioritisation of Candidate List substances for inclusion in Annex XIV

### a. Review of the general priority setting approach and next steps

SECR presented a brief summary from the Preparatory Expert Meeting on the revision of the prioritisation approach held prior to this plenary meeting and introduced MSC with the draft conclusions drawn from the discussion on the revised priority setting approach. In the discussion paper provided for the meeting SECR explained the legal basis for the prioritisation, limitations of analysing current and potential future approaches based on the registration data, observed difficulties with the current approach, considerations for updating each of the criterion, weighting of the criteria and testing of various combinations for an updated prioritisation approach.

It was concluded in the preparatory meeting that the principles applied when updating the approach are the following: information needed for prioritisation should generally be available in registrations; transparency and predictability of the prioritisation process should be enhanced, in particular for the stakeholders; consistency across the substances and uses should be ensured; the required level of assessment should be understood according to the role of the prioritisations, i.e. no exposure assessment, no risk assessment and no socio-economic analysis will be part of the prioritisation exercise; resources required have to be proportionate to the purpose of the prioritisation and the workability and efficiency needs to be improved; the approach should take account of Article 57 f substances.

In the preparatory meeting SECR introduced for discussion options (including weighting) for an updated prioritisation approach based on the three legal prioritisation criteria: intrinsic properties, volume and wide dispersive use. Three options were identified for intrinsic properties and wide dispersive use, respectively, and one option for volume. Each of the options was given a certain maximum number of scores. Reliability of the information was taken into account when weighting the information for scoring. Different weights were given to three of the criteria.

It was concluded in the preparatory meeting that verbal description should also be used to explain how and why a certain score was allocated. It was also agreed that the prioritisation approach aims to advice which substances should go first to the authorisation list. This would require a system which would differentiate sufficiently between the substances but the aim would not be to put the substances into a 'right' order. The prioritisation approach should provide a clear message for the registrants on how to complement the dossiers so that the information gives a good basis for prioritisation. However, the registrations should be accurate and up-to-date in any case. The intention is

to apply the new approach to all candidate list substances not yet included in Annex XIV and any newly added substances.

The experts considered contrary to the proposal in the discussion paper that each of the criteria should be given an equal weight. Regarding inherent properties, the PBTs should be favoured, as already indicated in the legal text, and potentially also a higher score could be given to endocrine disruptors.

Two MSC observers expressed concerns if some substances like PBTs are prioritised over the CMRs which would consequently get lower prioritised. They suggested all CMR substances as well as equivalent concern substances to be prioritised as some of them may have several properties of high concern and should get therefore more weight.

SECR confirmed that these substances will not be de-prioritised and once included in the Candidate list, they will be subject to prioritisation; however, limitations have been identified with regard to possible differentiation among CMRs. Furthermore, it was confirmed that from legal point of view, the prioritisation of a substance from the Candidate list, not meeting all three criteria of Article 58 (3), could be done also due to other reasons when proper justification is provided.

Most discussion took place on wide dispersive use (WDU) criterion. Out of the three options for WDU, Option 2 based on the use types "consumer – professional – industrial" seemed currently to be the most predictable and easiest to implement in terms of involving less uncertainties and of workload being more proportionate to role of prioritisation when compared to other options presented. The other two options for WDU involving information on use descriptors (in particular, PROCs and ERCs) could appear to be more scientific; however, practical difficulties have to be acknowledged based on the gained experience in the context of earlier prioritisation exercises, lack of necessary information in the registration dossiers and inconsistent assignment of use descriptors by registrants. It was recognised that for Option 2 possibilities could be explored to have either general or case by case considerations for refinement of the assessment. This might be possible at least in the future when the quality of the registration dossiers is assumed to be improved. The possibilities to use information on tonnages per use should be looked at when such information is available in the registration dossiers. It was concluded that Option 2 would currently be the most predictable and easiest to implement option, but possibilities to further refine it could be explored in future. It was suggested that in future, when use descriptors are more consistently available in registrations an approach that combines information on use type and use descriptors could be developed.

MSC agreed with the conclusions made in the preparatory meeting held prior to the plenary and requested SECR to take them into account when revising the current prioritisation approach document. The MSC Chair informed MSC that the revised draft approach will be scheduled for discussion in MSC-32 in November and for MSC agreement in MSC-33 in December 2013.

**b. Statistical information on the comments received in the public consultation on the draft 5th recommendation for Annex XIV**

SECR presented some statistical information on the comments received in the public consultation on the 5$^{th}$ draft recommendation for inclusion of priority substances for Annex XIV. It was clarified that initially the draft recommendation covered six substances, but that later Bis(pentabromophenyl) ether (decabromodiphenyl ether; DecaBDE) was withdrawn from the consultation and removed from the draft recommendation, due to the proposed inclusion of this substance in the Stockholm convention on persistent organic pollutants and the Commission's request to ECHA to start preparing a restriction proposal for this substance. About 400 comments have been received during the 3-month consultation period from MSCAs, industry, NGOs, trade unions and other interested parties. Members were informed also that more information on the expected restriction proposal is available in the public Registry of Intention on ECHA website.

MSC Chair recognised that the statistics based on the number of the comments does not reflect the importance of the comments. The Chair emphasised that SECR appreciates that in particular many industry organisations send one package of well-structured comments

for a big number of companies. The content of the comments will be carefully analysed by SECR now.

An MSC observer underlined the importance of careful consideration of each individual comment, in particular when a consolidated comment is sent per substance by his organisation on behalf of 60 million workers.

Two MSC observers made suggestions of more technical nature, referring to the size of some recently released documents with a lot of embedded attachments and to the optional inclusion of the comment provided in the public consultation in the automatic response to the commenting party.

SECR agreed to consider the technical feasibility of the suggestions given and to respond to them at a later stage.

**Item 11 - Update of stakeholder observers' participation at MSC**

- **Discussion and update of the MSC decision about the invited organisations**

SECR presented an overview of the accredited stakeholder organisations' (ASO) participation in the MSC work for the past one year and its proposal regarding the new ASOs interested in MSC. Members were also reminded of the main principles regarding ASO participation in work of ECHA's bodies referring to: the ASO registration in the Commission's Transparency Register, the need to follow the principle agreed by the ECHA Committees that the total number of observers should not exceed 50% of the total number of members and the balanced representation (to keep the appropriate balance in the number of observers representing different interests), as well as the opportunity to consider rotation of invited organisations (if more interested parties than seats are available in a body).

In the following discussion, members considered different proposals regarding the involvement of as many as possible of the 47 ASOs interested in the MSC work and expressed a willingness to increase the transparency and openness to their decision-making processes by involving more ASOs in the Committee's work. Particular attention was paid by the members to the rotation proposals of the Environmental & Health Care NGOs (ENV&HH NGOs, as updated for potential involvement of three new NGOs from that sector) and of three new Animal Welfare NGOs.

MSC took the following decisions:

- MSC agreed to keep the quotas for ASOs representing different interests unchanged[1] as followed in the past years,
- MSC agreed to invite all nine MSC-interested Environmental and Health Care NGOs (ChemSec, Client Earth, EEB, Friends of Earth Europe, Greenpeace, HEAL, Health Care without harm Europe, Women in Europe for Common Future and WWF) to follow its work by applying a rotative participation in MSC meetings for the five observer seats allocated for "ENV&HH NGOs" quota,
- MSC agreed to invite all four MSC-interested Animal Welfare NGOs (ECEAE, Eurogroup for Animals, PISC and HIS) to follow its work but providing one observer seat allocated for "Animal Welfare NGOs" quota,
- MSC agreed to invite CEPE as a new industrial ASO replacing FECC as MSC observer in the Industry quota where no further changes regarding other ASO representatives have been done.

MSC also requested SECR to inform the affected ASOs of the Committees' decision, whereas regarding the rotating NGOs clearly indicate that all of them will be granted non-confidential access to MSC documents. They would need to coordinate among themselves when applying the rotation approach who will be participating in each of the MSC meetings

[1] The total number of ASO observers' seats (as MSC has 29 members, i.e. 50% is 14 observer seats) is divided in the following quotas: 7 seats assigned to the Industry quota (incl. General Interest/Sectorial Industry Organisations and one Academic Organisation) and 7 seats assigned to the NGOs quota (incl. trade unions, Environmental and Human health NGOs and Animal Welfare NGOs)

keeping in mind the number of seats available for the group. Regarding the Animal Welfare NGO group no agreement on rotation between all four organisations was available. However, MSC agreed that in any case one seat will be available at the MSC meetings for this interest group and these organisations should agree between themselves who will come to the meeting.

In conclusion, the MSC Chair thanked the members for the fruitful discussion, positive decision and willingness to work in a transparent and open manner with the ASOs.

**Item 12 – Report from other ECHA bodies and activities**

SECR reported to MSC from the last two meetings of the ECHA Management Board (MB) held in June and in September 2013 on the issues concerning the Committees' work. Members were informed that in June, MB was provided with a document on the functioning of the ECHA committees with regard to the increasing workload from different processes with their involvement. Furthermore, the MB was requested to consider the appointment/renewal of RAC&SEAC members. In order to ensure that these members will be enabled to fulfil their Committee-related tasks (that will occupied more than 50 % of their working time), in its June meeting, MB decided to postpone these candidate appointment until their MSCAs confirm their engagement to support these members, as relevant, at the national level. A similar commitment from MSCAs to support MSC members will be requested when renewal of a membership or appointment of a new member is taking place. In the meeting in September, following the receipt of the MSs' commitment regarding their RAC and SEAC members, MB appointed the new candidates for these Committees' membership. The Board also considered and agreed on the SECR's proposal for different measures to be taken for improving the efficiency of the processes with Committees' involvement and for increasing the cooperation among the rapporteurs, MSCAs, other Committees' members and SECR. MB also expressed a willingness to re-visit the decision taken in one year.

MSC was also informed that the issue of expected MSCAs' commitment from the ECHA's Committees' membership will be further discussed at the next MSCA Directors' meeting scheduled for 20 November 2013.

**Item 13 – Any other business**

The MSC Chair reminded that based on a member's request, three suggestions have been received for inclusion in this agenda item. However, the requested update on the outcome of SEv work done in 2012 was covered under agenda item 7 in the context of the substance evaluation presentation. Thus, under AOB only the following two items were included.

- **Information on the development of the proposal for inclusion in Annex XIV**

The COM observer informed MSC of the outcome of the latest REACH Committee's debate regarding the development of a COM proposal for inclusion of priority substances in Annex XIV based on the 4th ECHA's recommendation. It was pointed out that in the previous REACH Committee meeting, no proposal for an update to Annex XIV has been presented but a Room Document regarding latest application dates for some chromium compounds and possible exemptions under Article 58(2) was considered by MSs, in particular with regard to the chromium compounds and DMAC respectively. The COM's draft proposal for inclusion of new substances in Annex XIV, currently under development, will be presented to the REACH Committee most probably in the February 2014 REACH Committee meeting. COM is closely following the development of the NMP restriction process in parallel to its work towards presenting a proposal for an amendment of Annex XIV.

Following the update given, several MSC members and an MSC NGO observer expressed their concerns and disappointment regarding the delay in updating Annex XIV highlighting

the uncertainty-related consequences for the industry and the unpredictability from health perspectives. In conclusion, MSC encouraged COM to prioritise the issue and undertake the necessary steps as soon as possible.

- **Update on the status of EOGRTS**

The COM observer provided also a brief update regarding the plan to implement EOGRTS under REACH specifying that for 1st meeting of REACH Committee in 2014, COM intends to develop a separate small draft ATP to include EOGRTS to the Test Methods Regulation in parallel with the development of an ATP for inclusion of other newly standardised methods in the Test Method Regulation. COM further informed that it is working in parallel in the drafting a measure for the modification of the corresponding REACH annexes, which would also take into account the need to perform a limited number of EOGRTS up to F2, indicating that COM counted on the inputs from ECHA in defining the criteria for the selection of substances to be subjected to testing of the 2nd generation.

**Item 14 – Adoption of conclusions and action points**

The conclusions and action points of the meeting were adopted in the meeting (see Annex IV).

*SIGNED*

Anna-Liisa Sundquist
Chair of the Member State Committee

**II. List of attendees**

| **Members/Alternate members** |
|---|
| ALMEIDA, Inês (PT) |
| ANDRIJEWSKI; Michal (PL) |
| BASTIJANCIC-KOKIC, Biserka (HR) |
| BIWER, Arno (LU) |
| COCKSHOTT, Amanda (UK) |
| COSGRAVE, Majella (IE) |
| DEIM, Szilvia (HU) |
| DRUGEON, Sylvie (FR) |
| DUNAUSKIENE, Lina (LT) |
| FINDENEGG, Helene (DE) |
| FLODSTRÖM, Sten (SE) |
| GAIDUKOVS, Sergejs (LV) |
| HUMAR-JURIC, Tatjana (SI) |
| KOUTSODIMOU, Aglaia (EL) |
| KULHANKOVA, Pavlina (CZ) |
| KYPRIANIDOU LEONTIDOU, Tasoula (CY) |
| LULEVA, Parvoleta (BG) |
| MARTIN, Esther (ES) |
| PISTOLESE, Pietro (IT) |
| REIERSON, Linda (NO) |
| RUSNAK, Peter (SK) |
| STESSEL, Helmut (AT) |
| TALASNIEMI, Petteri (FI) |
| TIRCHILA, Liliana Luminita (RO) |
| TYLE, Henrik (DK) |
| VANDERSTEEN, Kelly (BE) |
| VESKIMÄE, Enda (EE) |
| WIJMENGA, Jan (NL) |
| **Representatives of the Commission** |
| GARCIA-JOHN, Enrique (DG ENTR) |
| KOBE, Andrej (DG ENV) |
| **Observers** |
| ANNYS, Erwin (CEFIC) |
| BUONSANTE, Vito (ClientEarth) |
| DROHMANN, Dieter (ORO) |
| MUSU, Tony (ETUC) |
| SANTOS, Tatiana (EEB) |
| TAYLOR, Katy (ECEAE) |
| WAETERSCHOOT, Hugo (Eurometaux) |

| **ECHA staff** |
|---|
| BELL, David |
| BRAUNSCHWEILER, Hannu |
| BROERE, William |
| CARLON, Claudio |
| DE COEN, Wim |
| DEMATTIO, Silvia |
| DE WOLF, Watze |
| FALCK, Ghita |
| KARHU, Elina |
| KORJUS, Pia |
| KOULOUMPOS, Vasileios |
| LE CURIEUX, Frank |
| MEGAW, Peter |
| MELZER, Kai |
| MONTERO RAMIREZ, Manuel |
| MÜLLER, Birgit |
| NAUR, Liina |
| NICOLAS, Ronan |
| O'FARRELL, Norah |
| RODRIGUEZ IGLESIAS, Pilar |
| ROSSI, Laura |
| RUOSS, Jürgen |
| RÖCKE, Timo |
| RÖNTY, Kaisu |
| SOBANSKA, Marta |
| SUMREIN, Abdel |
| SUNDQUIST, Anna-Liisa |
| VAHTERISTO, Liisa |
| VASILEVA, Katya |
| VESENTINI, Damiano |
| WIK, Anna |

**Proxies**

- PISTOLESE, Pietro (IT) also acting as proxy of CAMILLERI, Tristan (MT)
- TYLE, Henrik (DK) also acting as proxy of WIJMENGA, Jan (NL) on Thursday late afternoon and Friday

**Experts and advisers to MSC members**

ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
FERNANDEZ, Raquel (ES) (expert to MARTIN, Esther)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
INDANS, Ian (UK) (expert to COCKSHOTT, Amanda)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
MALKIEWICZ, Katarzyna (SE) (adviser to FLODSTRÖM, Sten)
MEYS, Catherine (BE) (expert to VANDERSTEEN, Kelly)
MOELLER, Ruth (LU) (expert to BIWER, Arno)

TRAAS, Theo (NL) (expert to WIJMENGA, Jan)
VOLUJEVIC, Beata (LT) (expert to DUNAUSKIENE, Lina)

**By WEBEX-phone connection:**
Betty Hakkert (NL CAs) and Minne Heringa (NL) for agenda item 6b,
Katarina Pirselova (DG ENV) for agenda item 8,
Georg Streck (DG ENTR) for agenda items 6-11,
Valentina Bertato (DG ENTR) for agenda items 9, 10 and 11,
Anna Borras Herrero (DG ENTR) for agenda items 9, 10 and 11,
Mariana Fernandes de Barros (DG ENTR) for agenda items 9, 10 and 11,
Anne Giral-Roebling (DG ENTR) for agenda items 9, 10 and 11,
Giuseppina Luvarà (DG ENTR) for agenda items 9, 10 and 11,
Temenuzhka Popova (DG ENTR) for agenda items 9, 10 and 11
Jacek Rozwadowski (DG ENTR) for agenda items 9, 10 and 11.

**Case owners:**
Representatives of the Registrants were attending under agenda item 6c for TPE 079/2013, TPE 073/2013, TPE 078/2013, TPE 088B/2013 and TPE 075/2013.

**Apologies:**
CAMILLERI, Tristan (MT)
DOUGHERTY, Gary (UK)

**III. Final Agenda**

ECHA/MSC-31/2013/A/31

# Agenda
# 31st meeting of the Member State Committee

25-27 September 2013
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

25 September: **starts at 9:00**
27 September: **ends at 13:00**

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

MSC/A/031/2013
***For adoption***

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

**Item 4 – Administrative issues**

***For information***

**Item 5 – Minutes of the MSC-30**

- Final minutes of MSC-30

***For information***

**Item 6 – Dossier evaluation**
***Closed session for 6d and partly for 6b&e***
***Indicative time plan for 6c is Day 1 and for 6d Day 2-3***

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

ECHA/MSC-31/2013/003
***For information***

**b. General topics**

**- Current scientific status and regulatory approach for *in vivo* mutagenicity assays for Testing Proposals**

***For information and discussion***

**- Regulatory approach to testing strategies *(Closed session)***

***For information and discussion***

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

***For discussion followed by agreement seeking under 6d:***

ECHA/MSC-31/2013/002

**Testing proposals**

- TPE 079/2013 Alkenes, C7-9, hydroformylation products, distn. residues, heavy cracked fraction (EC No. 308-482-7)

  ECHA/MSC-31/2013/020-21
- TPE 078/2013 Reaction mass of 1-chlorobut-2-ene and 3-chlorobut-1-ene (List No. 908-820-9)

  ECHA/MSC-31/2013/008-009
- TPE 073/2013 2,5-bis-isocyanatomethyl-bicyclo[2.2.1]heptane (Reaction mass of 2,5-bis-isocyanatomethyl-bicyclo[2.2.1]heptane) (EC No. 411-280-2)

  ECHA/MSC-31/2013/004-005
- TPE 081/2013 [3-(2,3-epoxypropoxy)propyl]trimethoxysilane (EC No. 219-784-2)

  ECHA/MSC-31/2013/010-011
- TPE 088B/2013 2,2'-iminodi(ethylamine) (EC No. 203-865-4)

  ECHA/MSC-31/2013/012, ECHA/MSC/D/2013/0145
- TPE 075/2013 Reaction mass of Benzeneacetic acid, alpha-oxo-, 1,1'-(oxydi-2,1-ethanediyl) ester and Benzeneacetic acid, alpha-oxo-, 2-(2-hydroxyethoxy)ethyl ester (EC No. 442-300-8)

  ECHA/MSC-31/2013/006-007

***For information and discussion***

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

As listed above under **6c** and cases returned from written procedure

- Compliance check CCH 089/2013 Tris(methylphenyl) phosphate (EC No. 215-548-8)

  ECHA/MSC/D/2013/0130-0131[2]
- Testing proposal TPE 084/2013 Condensation product of N-C12-C18- alkylpropane-1,3-diamine, N-(3- aminopropyl)-N'-C12-C18- alkylpropane-1,3-diamine and formic acid (List No. 641-088-6)

  ECHA/MSC/D/2013/0136-0137[1]

***For agreement***

**e. Update on appeal cases *(Partly closed session)***

***For information***

**f. Status report on on-going evaluation work**

***For information***

[2] Documents available in substance specific folders

**Item 7 – Substance evaluation decision making process**

a. **Written procedure report on seeking agreement on one draft decision on substance evaluation**

ECHA/MSC-31/2013/022

***For information***

b. **Processing of draft decisions for substance evaluation - short update by the Secretariat**

***For information and discussion***

**Item 8 – Community Rolling Action Plan (CoRAP) update & MSC opinion development**

a. **Update by ECHA on the work on the next annual CoRAP update**

***For information and discussion***

b. **Tasks of the Rapporteur in drafting the opinion of the MSC**

ECHA/MSC-31/2013/014

***For discussion & decision***

c. **Appointment of Rapporteur**

***For decision***

d. **Establishment of a MSC Working Group to support the Rapporteur**

ECHA/MSC-31/2013/015

***For decision***

**Item 9 – SVHC identification**

a. **Brief overview on the SVHC proposals submitted in the 2nd 2013 SVHC round**

***For information***

b. **Revised Annex XV SVHC template and guidance**

ECHA/MSC-31/2013/018-019

***For information and discussion***

**Item 10 – Prioritisation of Candidate List substances for inclusion in Annex XIV**

a. **Review of the general priority setting approach and next steps**

ECHA/MSC-31/2013/001&013

***For discussion***

b. **Statistical information on the comments received in the public consultation on the draft 5th recommendation for Annex XIV**

***For information***

**Item 11 – Update of stakeholder observers' participation at MSC**

***Closed session***

- Discussion and update of the MSC decision about the invited organisations

ECHA/MSC-31/2013/016

***For decision***

**Item 12 – Report from other ECHA bodies and activities**

***For information***

**Item 13 – Any other business**

- **Information on the development of the proposal for inclusion in Annex XIV**
- **Update on the status of EOGRTS**

***For information***

**Item 14 – Adoption of conclusions and action points**

- Table with conclusions and action points from MSC-31

***For adoption***

## IV. Main Conclusions and Action Points

**Main conclusions and action points**
**(adopted at MSC-31, 25-27 September 2013)**

| CONCLUSIONS / DECISIONS / MINORITY OPINIONS | ACTIONS REQUESTED |
|---|---|
| **Item 4 - Administrative issues** | |
| MSC was informed of two guidance consultations that will be addressed to MSC this year. | |
| **Item 6 - Dossier evaluation**<br>**6 a. Written procedure report on seeking agreement on draft decisions on dossier evaluation** | |
| MSC took note of the report. | MSC-S to upload on MSC CIRCABC the final ECHA decisions/cover letters on cases agreed in written procedure, as indicated in document ECHA/MSC-31/2013/003.<br><br>For the cases not unanimously agreed MSC-S to provide COM for further decision making with the relevant documents (DD on generation testing, RCOM, minutes, outcome of the vote, justification for the position at the vote). |
| **6 b. General topics**<br>**Current scientific status and regulatory approach for *in vivo* mutagenicity assays for Testing Proposals** | |
| MSC agreed that Comet assay can be accepted when proposed by the Registrant with a specified protocol. MSC agreed that it is necessary that the registrants consider testing for germ cell mutagenicity or the potential of the substance to reach germ cells when positive in vivo test results are available and document the considerations in the registration dossier. | |
| **6 c. Introduction to and preliminary discussion on draft decisions on testing proposals after MS-CA reactions (*Session 1, open*)**<br>**6 d. Seeking agreement on draft decisions on testing proposals and one compliance check when amendments were proposed by MS's (Session 2, closed)** | |
| MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting where appropriate:<br><br>• TPE 078/2013 Reaction mass of 1-chlorobut-2-ene and 3-chlorobut-1-ene (List No. 908-820-9)<br>• TPE 073/2013 2,5-bis-isocyanatomethyl- | MSC-S to upload on MSC CIRCABC the final ECHA decisions/cover letters of the agreed cases. |

| CONCLUSIONS / DECISIONS / MINORITY OPINIONS | ACTIONS REQUESTED |
|---|---|
| bicyclo[2.2.1]heptane (Reaction mass of 2,5-bis-isocyanatomethyl-bicyclo[2.2.1]heptane) (EC No. 411-280-2)<br>• TPE 081/2013 [3-(2,3-epoxypropoxy)propyl]trimethoxysilane (EC No. 219-784-2)<br>• TPE 088B/2013 2,2'-iminodi(ethylamine) (EC No. 203-865-4)<br>• TPE 075/2013 Reaction mass of Benzeneacetic acid, alpha-oxo-, 1,1'-(oxydi-2,1-ethanediyl) ester and Benzeneacetic acid, alpha-oxo-, 2-(2-hydroxyethoxy)ethyl ester (EC No. 442-300-8)<br>• CCH 089/2013 Tris(methylphenyl) phosphate (EC No. 215-548-8)<br>• TPE 084/2013 Condensation product of N-C12-C18-alkylpropane-1,3-diamine, N-(3- aminopropyl)-N'-C12-C18- alkylpropane-1,3-diamine and formic acid (List No. 641-088-6)<br><br>MSC could not reach unanimous agreement on the following draft decisions:<br><br>• TPE 079/2013 Alkenes, C7-9, hydroformylation products, distn. residues, heavy cracked fraction (EC No. 308-482-7) | MSC-S to provide COM for further decision making with the relevant documents (DD on generation testing, RCOM, minutes, outcome of the vote, justification for the position at the vote). |
| **Item 7 – Substance evaluation decision making process**<br>**a. Written procedure report on seeking agreement on one draft decision on substance evaluation** | |
| MSC took note of the report. | MSC-S to upload on MSC CIRCABC the final ECHA decision that was agreed in written procedure, as indicated in document ECHA/MSC-31/2013/022. |
| **7 b. Processing of draft decisions for substance evaluation - short update by the Secretariat** | |
| Feedback is welcomed from the representatives of the CAs and MSC regarding the practicalities in the substance evaluation process. Feedback can be taken into account for the practical instructions on substance evaluation process for MSCAs and MSC. | Based on experience gained, the update to the practical instructions for MSCAs and MSC on substance evaluation process will be uploaded by the Secretariat to Evaluation CIRCABC.<br><br>SECR to upload to CIRCABC the updated Code of conduct for case-owners in MSC meetings. |
| **Item 8 – Community Rolling Action Plan (CoRAP) update & MSC opinion development**<br>**a. Update by ECHA on the work on the next annual CoRAP update** | |
| MSC took note of the update. | SECR to provide the draft CoRAP update for 2014-2016 to MSC by 24 October. |

| CONCLUSIONS / DECISIONS / MINORITY OPINIONS | ACTIONS REQUESTED |
|---|---|
| | Draft CoRAP update to be published on ECHA website early November 2013. |
| **8 b. Tasks of the Rapporteur in drafting the opinion of the MSC**<br>**8 c. Appointment of Rapporteur**<br>**8 d. Establishment of a MSC Working Group to support the Rapporteur** | |
| MSC adopted the mandate and the tasks of the rapporteur, and appointed one member as a Rapporteur and another member as a Co-Rapporteur for drafting the MSC opinion on the draft annual CoRAP update. MSC established a working group to support the Rapporteur and appointed volunteering members to it. | SECR to send the appointment letters to the Rapporteur and the Co-Rapporteur. |
| **Item 9 – SVHC identification** | |
| **9 b. Revised Annex XV SVHC template and guidance** | |
| MSC took note of the background for the updates. | MSC to provide comments on the draft revised Annex XV template and guidance update by 9 October. |
| **Item 10 – Prioritisation of Candidate List substances for inclusion in Annex XIV**<br>**a. Review of the general priority setting approach and next steps** | |
| MSC agreed with the conclusions of the preparatory meeting held prior to the plenary and requested SECR to take them into account when developing the revised priority setting approach paper. | SECR to prepare revised prioritisation approach paper for discussion at the next plenary. |
| **Item 11 – Update of accredited stakeholder observers' (ASOs) participation at MSC**<br>• Discussion and update of the MSC decision about the invited organisations | |
| MSC took the following decisions regarding the ASOs participation in their work:<br>• MSC agreed to keep the quotas for ASOs representing different interests unchanged as followed in the past years,<br>• MSC agreed to invite all nine MSC-interested Environmetal and Health Care NGOs (ChemSec, Client Earth, EEB, Friends of Earth Europe, Greenpeace, HEAL, Health Care without harm Europe, Women in Europe for Common Future and WWF) to follow its work by applying a rotative participation in MSC meetings for the five observer seats allocated for "ENV&HH NGOs" quota,<br>• MSC agreed to invite all four MSC-interested Animal Welfare NGOs (ECEAE, Eurogroup for Animals, PISC and HIS) to follow its work by applying a rotative participation in MSC meetings for one observer seat allocated for "Animal Welfare NGOs" quota.<br>• MSC agreed to invite CEPE as a new industrial stakeholder group replacing FECC as MSC observer. Other representatives of this quota to continue without changes. | SECR to inform the concerned ASOs of the outcome of the MSC decisions and to follow their implementation when organising the Committee's work. |
| **Item 14 – Adoption of conclusions and action points** | |
| MSC adopted the conclusions and action points of MSC-31. | MSC-S to upload the conclusions and action points on MSC CIRCABC by 30 September 2013. |

## V. Dossier evaluation cases addressed for MSC agreement seeking in WP:

**Draft decisions unanimously agreed by MSC in WP:**

| MSC ID number | Substance name used in draft decision | EC No |
|---|---|---|
| CCH 076/2013 | Isophthaloyl dichloride | 202-774-7 |
| CCH 083/2013 | 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether | 200-076-7 |
| CCH 085/2013 | 4,4'-sulphonyldiphenol | 201-250-5 |
| TPE 076/2013 | Calcium carbonate | 207-439-9 |
| TPE 085/2013 | Tetraethylenepentamine, linear, cyclic and branched/90640-66-7 | 292-587-7 |
| TPE 086/2013 | pentaethylenehexaamine/4067-16-7/PEHA [3,6,9,12-tetraazatetradecamethylenediamine] | 223-775-9 |
| TPE 087B/2013 | polyethylenepolyamine/68131-73-7/PEPA-HEPA-NEW | 268-626-9 |
| TPE 089B/2013 | Amines, polyethylenepoly-, triethylenetetramine fraction | 292-588-2 |

**Draft decisions for which no unanimous agreement was reached via WP:**

| MSC ID number | Substance name used in draft decision | EC No |
|---|---|---|
| TPE 087A/2013 | polyethylenepolyamine/68131-73-7/PEPA-HEPA-NEW | 268-626-9 |
| TPE 088A/2013 | 2,2'-iminodi(ethylamine) | 203-865-4 |
| TPE 089A/2013 | Amines, polyethylenepoly-, triethylenetetramine fraction | 292-588-2 |

**Draft decisions that written procedure was terminated for:**

| MSC ID number | Substance name used in draft decision | EC No |
|---|---|---|
| CCH 089/2013 | tris(methylphenyl) phosphate | 215-548-8 |
| TPE 084/2013 | Condensation product of N-C12-C18-alkylpropane-1,3-diamine, N-(3-aminopropyl)-N'-C12-C18-alkylpropane-1,3-diamine and formic acid | 641-088-6 |