MSC/M/37/2014
(Adopted at MSC-38)

Minutes
of the 37th Meeting of the Member State Committee (MSC-37)
16-18 September 2014

I. Summary Record of the Proceedings

Item 1 - Welcome and Apologies

The Chairman of the Committee, Mr Watze de Wolf, opened the meeting and welcomed the participants to the 37th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

Item 2 - Adoption of the Agenda

The Agenda was adopted as provided for the meeting by the MSC Secretariat without further changes (final Agenda is attached to these minutes).

The Chairman informed the MSC of the withdrawal of the case CCH-161/2014 from the dossier evaluation process due to the need to first resolve some substance identity issues, and therefore its subsequent removal from the provisional draft agenda of the MSC-37.

The Chairman also informed the MSC that for this and the future meetings the agenda may indicate documents for information which will not be addressed during the meeting unless requested by the members.

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

No potential conflicts of interests were declared by any members, experts or advisers with any item on the agenda of MSC-37.

Item 4 - Administrative issues

SECR informed the MSC of the changes in the labelling of the MSC documents.

SECR collected feedback from the MSC on the template for presentations on dossier evaluation cases in order to serve the needs of the audience better in the future.

Item 5 –Minutes of the MSC-36 meeting

The Committee was informed that the minutes of MSC-36 were adopted during written procedure and that they have been uploaded on MSC CIRCABC and ECHA website.

Item 6 – Substance evaluation

6.1 Community Rolling Action Plan (CoRAP) & 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 2015-2017 pointing out that the draft update will be presented to MSC at the next MSC meeting in October 2014. It was further specified that there will be 75 new substances included in the current draft CoRAP update, divided over the following three years for further substance evaluation, together with the 68 substances from the previously adopted CoRAP. In accordance with the established working practices, the draft CoRAP update for 2015-2017 will be published on ECHA's website after its referral to MSC and MSCAs in the end of October 2014. However this year on request of industry and stakeholders ECHA will publish in addition to the address of the eMSCA also the initial grounds for concern. MSC members were encouraged to remind their MSCA colleagues to consider ECHA's recommendations on the results of the similarity check, to update the justification documents (JD) when still needed and to include in the JD whether the substance was previously evaluated under a different regulatory framework and reasons why it needs to be re-evaluated under REACH, if it was already evaluated.

b. Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update and for Working Group membership

b1. Draft Terms of Reference and possible appointment of Rapporteur and Co-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 2015-2017. The Committee also appointed two of its members as a rapporteur and a co-rapporteur for this opinion preparation.

b2. Discussion and possible establishment of a MSC Working Group to support the Rapporteur

MSC agreed on the mandate of a working group to support the MSC rapporteur in drafting the MSC opinion on the draft update of the CoRAP for 2015-2017. Further, MSC appointed five volunteering MSC members, one alternate member and one member's expert as the working group members to support the rapporteurs in the opinion development.

6.2 Decision making process

a. Short general update by the secretariat on ongoing substance evaluations

SECR explained that from the 2012 CoRAP substances, three cases are still pending out of a total of 36 substances. SECR showed the increasing number of substances per year, since there is a total of 47 substances for 2013 CoRAP and 51 substances for 2014 CoRAP (i.e. on-going evaluations). SECR reminded that the deadline for any draft decision (DD) following these evaluations is 26 March 2015. However due to the increase in number of entries on the CoRAP per year, SECR pointed out the potential challenges for decision making at MSC, including development of a noticeable backlog of substance evaluation (SEV) cases. Among others SECR provided estimates based on the evaluations and decision making of the 2012 CoRAP substances and encouraged MSC members to book the MSC meetings for their SEV cases as early as possible and to aim whenever possible for agreement in written procedure.

With regards to other substance evaluation activities, SECR informed that the report from the Workshop on substance evaluation 26-28 May 2014 was published on the ECHA website in July. There are now two ECHA working groups, one to explore best practices in drafting a SEV draft decision and the other one how best to summarise the evaluation performed in the public SEV report. In this context, evaluating MSCAs were advised that working it is appreciated if the confidential information is put in an Annex. This would facilitate cleaning of the document for publication purposes once the SEV report format has been agreed upon. It was explained that eMSCAs are expected to prepare a conclusion document also for cases that were terminated. In such cases, registrants are informed on the finalisation of the case by the eMSCA with a termination letter from ECHA. An industry stakeholder representative pointed that industry prefers not to have the SEV report and the conclusion document merged together.

b. Update on appeals *(Closed session)*

SECR presented to MSC a brief overview on a new appeal recently received, making the total number of appeals on substance evaluation of four, and another appeal challenging a dossier evaluation decision. The state of play of ongoing appeals against ECHA decisions was also given. Further, MSC was informed of the state of play on several SVHC cases before the European Court of Justice including the anthracene oil cases (Case C-288/13 to C-290/13 P) which the European court of Justice dismissed as unfounded.

Item 7 – 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 35 dossier evaluation draft decisions (see Section V for more detailed identification of the cases). WP was launched on 21 August 2014 and closed on 1 September 2014. For 11 cases the draft decisions (DD) were split resulting overall to 35 DDs for 24 cases. By the closing date, responses were received from 23 members with voting rights and from the Norwegian member. Unanimous agreement was reached on 23 DDs. 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 discussion at the MSC-37 meeting. For the other 10 DDs MSC did not find unanimous agreement due to divergent opinions on the appropriate test method to fulfil the two-generation reproductive toxicity endpoint and these cases will

be referred to the Commission to be dealt with in accordance with the procedure referred to in Article 133(3) of REACH Regulation. SECR reported the justifications of "no" voting given by the MSC members in written procedure.

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

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

CCH-219A&B/2014 4-hydroxy-4-methylpentan-2-one (DAA) (EC No. 204-626-7)

Session 1 (open)

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

SECR explained that seven PfAs to ECHA's DD were submitted by four MSCAs.

Three PfAs received suggested requesting 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 study (EU B.35) or EOGRTS (OECD 443) with the second generation). They suggested requesting EOGRTS only, and two PfAs suggested including the DNT/DIT cohorts. One PfA suggested to keep the choice of two methods including the DNT/DIT-cohorts but excluding the extension of cohort 1B (production of F2 generation) from the optional request for EOGRTS.

Additionally another PfA was related to the read across approach submitted by the Registrant to fulfil the information requirements of Annex X, 8.7.3, Annex IX, 8.7.2, Annex IX, 8.6.2. In the read-across approach the registered substance (DAA) is the metabolite and the read-across substance (MIBK, 4-methylpentan-2-one) is the parent substance. The PfA did not express disagreement with the conclusion by ECHA not to accept the read-across, however, it was not in agreement with the formulation of four out of the seven arguments ECHA provided to reject the read-across.

One PfA proposed requesting the Registrant to provide documentation for the recommended PPE (gloves: type of material, thickness and breakthrough times) in the CSR, and to revise exposure assessment and risk characterisation for workers and justify why efficiency values used for gloves differ from values recommended in ECETOC TRA.

SECR had modified DD based on the PfAs and split DD into two parts prior to the meeting: CCH-219A/2014 and CCH-219B/2014. Part A addresses the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity study) and part B other information requirements.

The Registrant provided comments on the PfAs, including further information on his justification for read-across. They mentioned that an oral single exposure toxicokinetic study of DAA to rats is currently on-going to allow a better estimation of the correction factor due to differences in systemic exposure to the registered substance following administration of the read-across substance or the registered substance. According to the Registrant, a definite conclusion about the toxicity profiles of the two substances can be made from the available data. Regarding the PfA on chemical safety assessment (CSA) and chemical safety report (CSR) the Registrant showed surprise on such a PfA and considered it outside the scope of the DD, and further commented that appropriate and relevant information has already been provided in the SDS and Section 11 in IUCLID. Hence they considered it redundant to mention them also in the CSR.

The Registrant further commented on the choice of PPE and explained that the need to specify the make of protective gloves is information typically provided in (extended) SDS for the pure substance. However, the choice of gloves could not be based on DAA only but also on the composition of the formulation as used by downstream users. He also noted that ECETOC TRA v3 would be used to estimate exposure for professional workers. In this assessment the assumption that training and intensive supervision on the use of gloves for such workers would lead up to 98% exposure reduction efficiency will not be used anymore, and a correction of 100% substance to 25% substance in a mixture would be made.

Some MSC members posed clarifying questions to the Registrant representatives on the read across, the reprotoxic effects of the registered substance and on the PPE to be used. Regarding the speed and extent of conversion of MIBK to DAA *in vivo* the registrant reiterated his initial view that metabolism of MIBK to DAA is quick and extensive as stated in the original dossier. This was based on an animal study where no lag-time was found after oral administration of MIBK because DAA was measured in the blood of animals at 7.5 min. However, the registrant agreed with ECHA that DAA is more persistent than MIBK, as also stated in the original dossier.

Regarding the ongoing toxicokinetic study it was explained that there was no need for the submission of a testing proposal since toxicokinetic studies are not an information requirement under REACH. However, since the information from such studies could lead to reduction of animal testing, the company in performing such studies is fulfilling their REACH responsibilities in reducing animal testing. Furthermore, it was clarified to the Registrant representatives that following issuance of the decision, the Registrant can still provide arguments to further substantiate their read across rather than going directly to the test. Then it is up to ECHA in the follow-up stage to decide whether the justifications provided are acceptable or not. Regarding the surprise expressed by the Registrant on the PfA related to the CSA and CSR, it was explained that the Member State Competent Authorities when consulted on the DD, they also look at other elements in the registration dossier, on which they can also propose a PfA.

Session 2 (closed)

The MSC discussion focused on how to better formulate the decision to clarify to the Registrant the deficiencies in the read-across adaptations, a.o. not sufficiently covering the slow metabolism of the parent substance (MIBK), the different metabolism of MIBK after oral and inhalation exposure, and higher systemic exposure of the registered substance when given as a parent substance or not providing sufficient documentation and/or justification for some assertions. MSC agreed unanimously on a reformulation of several arguments for rejection of the read-across.

MSC agreed unanimously on ECHA's split of the DD addressing the above studies in part B, as modified by SECR and with a change of the deadline for submission of the data due to the splitting of the DD.

MSC did not reach unanimous agreement on the DD addressing the two-generation reproductive toxicity study (part A). However, MSC agreed to modify the deadline due to the splitting of the DD. 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). SECR will refer the DDs to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

CCH-214A&B/2014 2-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate] (TMPTA) (EC No 239-701-3)

Session 1 (open)

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

SECR explained that nine PfAs to ECHA's DD were submitted by five MSCAs.

Four PfAs received suggested requesting 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 study (EU B.35) or EOGRTS (OECD 443) with the second generation). Three suggested to request EOGRTS only, and two PfAs suggested to include the DNT/DIT cohorts. One PfA suggested to keep the choice of two methods including the DNT/DIT-cohorts but excluding the extension of cohort 1B (production of F2 generation) from the optional request for EOGRTS.

One PfA was received on the DNEL derivation, requesting the Registrant to revise the DNEL derivation for the inhalation route and use the methodology recommended by SECR or full justification for not using the recommended assessment factors. Another PfA highlighted the absence of an appropriate read-across such that the use of the NOAEL

from the read-across substance as a starting point for the DNEL derivation is not acceptable.

Regarding information related to the CSA and CSR, a PfA proposed to request the Registrant to document the recommended personal protective equipment (mask and the type of filter) in the CSR.

Two PfAs were received proposing revision of environmental exposure assessment and risk characterisation. One PfA highlighted that whilst performing this revision the Registrant need to be made aware to potentially revise some waiving arguments that were made e.g. for chronic aquatic toxicity date. Another PfA proposed to request a long-term toxicity testing on fish as the most sensitive species. SECR suggested considering these two PfAs jointly.

SECR had modified DD based on the PfAs and split DD into two parts prior to the meeting: CCH-214A/2014 and CCH-214B/2014. Part A addresses the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity study) and part B other information requirements.

The Registrant provided comments on the PfAs considering the request for the 2-generation study unjustified based on the results from the studies already provided (i.e. OECD 422 screening studies with a structurally related substance and a screening study with the registered substance) and the use in industrial processes where the exposure is limited.

The Registrant considered that dermal long term toxicity studies available show that maximum tolerated dose based on skin effects (substance is an irritant) did not affect sperm parameters or estrous cycle is rats and mice. When animals were exposed orally they tolerated higher dosages without showing any systemic effects (no neurotoxic or immunotoxic effects). Histopathology of sex organs did not reveal substance related effects. However, because they recognise that they have a data gap, if they had to perform a test to cover the reproductive toxicity endpoint, they prefer to perform the two generation reproductive toxicity study rather than EOGRTS because there is more lab capacity and there is historical control available. Registrant representatives also stated that DNEL for inhalation still needed to be updated.

Some MSC members posed clarifying questions to the Registrant representatives with regards to the handling of the substance and whether respiratory protective equipment is needed and whether the Registrant had information on the composition of the mixtures used to be able to decide which respiratory equipment to recommend. It was noted that the Registrant does not indicate any systemic effects of the substance however these are further evaluated in a substance evaluation.

Session 2 (closed)

During the discussion MSC considered that selection of appropriate personal protective equipment (PPE) is a complex issue since there are many factors influencing the types of PPE to be recommended. It not only depends on other substances in the mixture being used, but also on an individual's physique wearing the PPE (e.g. with or without beard) and site specific considerations. Furthermore, DD requests need to be enforceable and MSC also recognised that although Annex II of REACH states that the safety data sheets (SDS) and CSR must not contradict each other, yet they do not need to be identical. It was recognised that the details on the type of PPE to be worn should be present in the (e)SDS, yet case-specific discussions might be needed to agree on the detail required in the CSR and/or IUCLID Section 11. For the specific case it was agreed that when the composition of the mixture/formulation is known to the Registrant, he may further define and include in their registration dossier the type of PPE to be worn. No such requirement was however included in the DD.

MSC agreed unanimously on ECHA's split of the DD addressing the above studies in part B, as modified by SECR and with a change of the deadline for submission of the data due to the splitting of the DD.

MSC did not reach unanimous agreement on the DD addressing the two-generation reproductive toxicity study (part A). However, MSC agreed to modify the deadline due to the splitting of the DD. 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). SECR will refer the DDs to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

CCH-211/2014 Manganese carbonate (EC No. 209-942-9)

Session 1 (open)

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

SECR explained that two PfAs to ECHA's DD were submitted. A PfA suggested the Registrants to be reminded in the DD to consider the relevant information, including a supporting non-guideline developmental toxicity study in mice (Sanchez 1993) and the adaptation possibility in Annex IX, Section 8.7, Column 2 before conducting the requested pre-natal developmental toxicity (PNDT) study (OECD 414).

The other PfA on the same endpoint suggested conducting a PNDT study on a soluble inorganic manganese salt, such as the dichloride, but not with manganese carbonate, as the results of such a study would be useful for a number of inorganic manganese salts and would represent a worst-case scenario based on maximum systemic availability. Further, having in mind ECHA's consideration regarding the small respirable fraction of the granulometry findings and the lack of guidance available to indicate where the cut-off lies, the PfA proposed the study to be conducted via inhalation route instead of the oral one as the inhalation exposure appears to be relevant and the most occupational exposure occurs via this route.

The Registrant provided comments on the PfAs and on the DD, the latter not considered for MSC discussion. In the view of the Registrant the Sanchez paper is very weak with regards to its application for regulatory compliance and its use to comply with the PNDT endpoint. With regards to the second PfA, the Registrant commented that testing using a soluble inorganic manganese salt (worst case) is plausible, but more robust information would be gained from a study conducted with the substance itself or a suitable analogue. Thus, the Registrant agreed with ECHA's DD to carry out a PNDT study via the oral route, as although inhalation is the likely route of exposure based on bioavailability, the oral route also gives information on systemic toxicity. Further, the Registrant requested a choice to be given to him to select an appropriate test material amongst the suite of inorganic manganese substances while taking into consideration the properties of the registered substance, the properties of any analogue substance which may be suitable to read-across, information available on intelligent testing strategies and animal welfare.

Session 2 (closed)

Taking into consideration the Registrants' comments and the SECR's clarification provided, MSC concluded that the information request for PNDT study (test method: EU B.31./OECD 414 in rats or rabbits by the oral route with the registered substance) should be kept unchanged; however, the DD should be modified to urge the Registrant to consider possible adaptation according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation (when considering the OECD 414 information request) and to provide the rationale for accepting or rejecting the MSCAs' proposals for amendment and the Registrant's comments on them.

MSC found unanimous agreement on ECHA's DD as amended for the meeting and modified at the plenary based on MSC deliberations.

CCH-215 A&B /2014 Dimethylamine (EC No. 204-697-4)

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.

SECR explained that nine PfAs were submitted in total to ECHA's DD by four MSCAs.

Four PfAs received suggested requesting 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 study (EU B.35) or EOGRTS (OECD 443) with the second generation). Three suggested to request EOGRTS only, and two PfAs suggested to include the DNT/DIT cohorts. One PfA suggested to keep the choice of two methods including the DNT/DIT-cohorts but excluding the extension of cohort 1B (production of F2 generation) from the optional request for EOGRTS.

Four PfAs on the CSR were received. One PfA suggested that the risk characterization for physicochemical properties should be provided since the substance is classified as Flam. Gas 1, H220, and that the assessment should entail an evaluation of the likelihood that an adverse effect will be caused under the reasonably foreseeable conditions of use in the workplace or by consumers. Another PfA on explosive properties suggested to delete the information on explosion limits under the endpoint "Explosiveness" and on "Risk of explosion in contact with mercury". Two PfAs on PPE suggested to report glove type, thickness and minimum breakthrough times need to be reported in both CSR and IUCLID, and also to justify the use of high glove efficiencies (>95%) taking into account the use of the substance in aqueous solutions.

One PfA on the environmental exposure assessment and risk characterisation suggested to revise the annual tonnage used in the environmental exposure assessment for each site.

SECR had modified DD based on the last PfA only, and split DD into two parts prior to the meeting: CCH-215A/2014 and CCH-215B/2014. Part A was addressing the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity study) and part B other information requirements.

The Registrant did not provide written comments on the PfAs but provided extensive comments on DD, which were not considered for MSC discussion. Some members raised the issue on the additionally provided data on explosivity, but MSC considered it useful and to be retained.

Session 2 (closed)

MSC agreed unanimously on ECHA's split of the DD addressing the above studies in part B, including the request for revision of the annual tonnage used in the environmental exposure assessment for each site and with a change of the deadline for submission of the data due to the splitting of the DD.

MSC did not reach unanimous agreement on the DD addressing the two-generation reproductive toxicity study (part A). However, MSC agreed to modify the deadline due to the splitting of the DD. 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). SECR will refer the DDs to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

CCH-222/2014 Dimethylamine (EC No. 204-697-4)

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.

SECR explained that two PfAs were submitted in total to ECHA's DD by one MSCA.

One PfA on risk characterization for physicochemical properties suggested that the risk characterization for physicochemical properties should be provided since the substance is classified as Flam. Gas 1, H220, and that the assessment should entail an evaluation of the likelihood that an adverse effect will be caused under the reasonably foreseeable conditions of use in the workplace or by consumers. The other PfA on the substance identity, composition of the substance, suggested to delete in IUCLID Section 1.2 the composition of the mixture "dimethylamine, aqueous solution", because the solvent (water) can be separated from the substance without affecting its stability or composition and therefore should not be used for the definition of the substance.

SECR did not amend DD for the meeting based on any PfAs.

The Registrant did not provide written comments on the PfAs.

Session 2 (closed)

Based on the above considerations, MSC found unanimous agreement on ECHA's draft decision as provided for the meeting.

CCH-223/2014 Dimethylamine (EC No. 204-697-4)

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.

SECR explained that three PfAs were submitted in total to ECHA's DD by one MSCA.

One PfA on risk characterization for physicochemical properties suggested that the risk characterization for physicochemical properties should be provided since the substance is classified as Flam. Gas 1, H220, and that the assessment should entail an evaluation of the likelihood that an adverse effect will be caused under the reasonably foreseeable conditions of use in the workplace or by consumers.

Another PfA on the substance identity, analytical information, suggested to provide separate analytical data, as the information provided in this registration dossier was identical to the data of the Joint Submission's lead registrant dossier.

The third PfA on environmental release categories (ERCs) used in the technical dossier and in the CSR suggested to review the description of identified uses to confirm whether or not the technical functions of the substance match the identified uses, and to provide an updated environmental exposure assessment and risk characterization where necessary. It also suggested that the Registrant should provide information regarding amounts and handling of wastes from manufacture and the uses of the substance.

SECR had amended the DD in advance of the meeting based on the PfAs on substance identity, analytical information, and ERCs.

The Registrant did not provide written comments on the PfAs.

Session 2 (closed)

Based on the above considerations, MSC found unanimous agreement on ECHA's DD as amended for the meeting.

CCH-218A&B/2014 1,1-dichloroethylene (EC No. 200-864-0)

Session 2 (closed)

SECR explained that agreement on the split DDs was initially sought in Written Procedure. SECR had modified DD based on the PfAs and split DD into two parts prior to the meeting: CCH-218A/2014 and CCH-218B/2014. Part A addressed the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity study) and part B other information requirements. The written procedure was terminated by the Chairman of MSC on request of one MSC member suggesting a MSC discussion.

Firstly, related to part B, it was commented that if a comet assay would be carried out sampling of gonadal cells tissue should occur at the same time as the somatic tissues and stored for later analysis in case somatic tissues showed genotoxic effects. It was agreed that it was scientifically justified that such analysis might provide a proof that the tested substance and/or its metabolites not only would have reached the gonads but, in addition, also caused genotoxic effects. MSC supported a further modification of the DD in this regard.

Secondly, related to part A, a concern was raised that some cardiac effects could be missed. Due to the proposed study design, affected offspring that die in the first period after birth (e.g. due to cardiac effects) would not be included in the analysis on PND 22 (post-natally at weaning). This would be different from the reported study which

conducted cardiac investigations of offspring on GD 21 (short time before the birth of the foetuses).

MSC agreed unanimously on ECHA's split of the DD addressing the above studies in part B with a change of the deadline for submission of the data due to the splitting of the DD and with editorial modifications mentioned.

MSC did not reach unanimous agreement on the DD addressing the two-generation reproductive toxicity study (part A). However, MSC agreed to modify the deadline due to the splitting of the DD. 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). SECR will refer the DDs to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

CCH-213A&B/2014 2-diethylaminoethanol (EC No. 202-845-2)

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.

Eight PfAs were submitted in total to ECHA's DD.

Four PfAs were submitted three of which 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 study (EU B.35) or EOGRTS (OECD 443) with the second generation). Two of these PfAs suggest to include the DNT/DIT cohorts. One PfA suggested to keep the choice of two methods including the DNT/DIT-cohorts, but excluding the extension of cohort 1B (production of F2 generation) from the request for EOGRTS.

Three PfAs were submitted on CSR and Personal Protective Equipment (PPE) requirements. First PfA suggested the Registrant to consider the relevant information related to the CSA and the CSR with details of the Personal Protective Equipment (PPE) employed and recommended for handling the substance and the duration of use, and to report the information by including it both in section 11 of the technical IUCLID dossier (Guidance on Safe Use) and in the CSR. Second PfA suggests the Registrant to provide revised risk characterisation ratios (RCRs) for human health and to recalculate the risk characterisation ratios. Third PfA suggests the Registrant to provide a revised exposure assessment for those uses where the substance is used in a mixture and to take into account that only concentrations lower 25% yield a reduction of the estimated exposure values.

An additional PfA required detailed specification of PPE and suggested the Registrant to submit information on PPEs (eye/face, skin and respiratory protection) taking into account breakthrough times for gloves and clothing, and type of filter for the specified respiratory protective equipment and to update and submit the technical dossier and the CSR with the relevant information.

The Registrant in his comments on the PfAs disagreed generally with the request to include DIT/DNT modules on a default basis into the OECD 443 study design, and generally agreed with the PfA that the F2 generation/Cohort 1B is not needed on a default basis, but should be triggered by findings.

Some MSC members mentioned that details on skin/face protective equipment information is useful for downstream users who are entitled to be informed on safe use and the safety limitations for using the substance.

SECR had split DD into part A and B where part A addressed the information requirement for two-generation reproductive toxicity (Annex X, 8.7.3) and part B addressed the information requirement for the CSR and on detailed specification of PPE. SECR had also modified the DD based on some of the PfAs and amended section II and section III accordingly in advance of the meeting.

Session 2 (closed)

In relation with part B on the CSR, MSC concluded that the DD should be modified with a request for a revised exposure assessment and risk characterisation for inhalation route addressing exposure estimations for the use of the substance in a mixture in accordance with the guidance for the model used, and a risk characterisation ratios for inhalation route using the DNELs derived according to ECHA's Guidance or an evaluation of the scientific background for setting the national OEL.

As regards the detailed specification of PPE MSC concluded that the Registrant is to be requested to provide documentation for the recommended skin and respiratory protection with regard to the amount and duration of exposure, and to provide documentation for the filter type for the respiratory protection. MSC agreed unanimously on ECHA's split of the DD addressing the above studies in part B, as modified during the meeting, and with a change of the deadline for submission of the data due to the splitting of the DD.

MSC did not reach unanimous agreement on the DD addressing the two-generation reproductive toxicity study (part A). However, MSC agreed to modify the deadline due to the splitting of the DD. 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). SECR will refer the DDs to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

CCH-221/2014 4-methylpentan-2-one (EC No. 203-550-1)

Session 1 (open)

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

Two PfAs were submitted to ECHA's DD.

One PfA suggests that the Registrant shall submit in the CSR the documentation for the recommended PPE and the revised exposure assessment and risk characterisation for workers and for spraying applications in professional uses, requesting that the information should be included both in section 11 of the technical IUCLID dossier and in the CSR.

The other PfA on documentation for the recommended PPE refers to type of gloves to be worn when handling the substance or a mixture which have to be clearly specified based on the hazard of the substance or of the mixture and potential for contact (including the type of material and its thickness and the typical or minimum breakthrough times of the gloves material) requiring to report this information both in the CSR and in section 11 of IUCLID.

Furthermore, the use by the Registrant of a 95% gloves efficiency in the ECETOC TRA version 2 model was challenged through one PfA.

SECR had modified the DD based on PfAs, except for the last one, and amended section II and section III accordingly.

The Registrant provided comments on the PfAs and the DD. Regarding the PfA on CSA and CSR the Registrant showed surprise on such a PfA and considered it outside the scope of the DD, and further commented that appropriate and relevant information has already been provided in the SDS and Section 11 in IUCLID. Hence they considered it redundant to mention them also in the CSR.

The representative of the Registrant further highlighted that PPE experiments and estimations presented align closely with ECHA's use descriptors, and that where increased attention to training on wearing the appropriate gloves in combination with intense supervision is applied, 98% gloves efficiency can be reached. Regarding thickness and material of the gloves the registrants representative acknowledged several limitations of the ECETOC TRA model version 2, and they agreed to use version 3 in a dossier update.

Session 2 (closed)

In line with the more general discussion on the PPE and glove efficiency for comparable CCH cases discussed at the meeting, and based on the above considerations, MSC decided

to modify DD in Section II and in Section III and to add a note for consideration referring to clarifications on ECETOC TRA model.

MSC found unanimous agreement on ECHA's draft decision as modified in the meeting.

CCH-199/2014 Reaction mass of l-xylo-hex-2-ulosonic acid and ascorbic acid (List No. 932-019-3)

Session 1 (open)

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

SECR explained that four PfAs to ECHA's DD were submitted by two MSCAs.

One PfA on a 90-day sub-chronic toxicity study in rats, oral route suggested that the read-across proposed by the Registrant has not been fully justified. Therefore, an information gap existed. However, ECHA's rejection was considered to be poor therefore suggesting to rephrase the reasoning in section III. Another PfA on the same endpoint also pointed out shortcomings in ECHA's reasoning and proposed to revise the wording of section III highlighting the relatively low exposure levels and the lack of toxicological potential.

Two PfAs on a pre-natal developmental toxicity study in rats or rabbits, oral route, were similar to those made for the first endpoint.

SECR had modified the reasoning of the DD based on PfAs.

The Registrant provided comments on the PfAs where (further) arguments were presented on the concerns expressed by ECHA regarding the read-across approach employed by the Registrant. These concerns included structural similarity, metabolism, and similarity with respect to repeated dose toxicity and reproductive toxicity, and evaluation of other components of the registered substance. He agreed with the PfAs that ECHA's reasons for the rejection were flawed and unjustified and considered that the requests for the two tests were not warranted.

The Registrant further considered that ECHA had amended its read-across considerations in section III of the DD and had not addressed to the substance of the PfAs on which the Registrant had submitted comments. The Registrant also considered that the short time afforded to him was insufficient to allow the Registrant the right to be heard, and had not been full in opportunity to respond to the new ECHA arguments at the MSC meeting.

The representatives of the Registrant further explained their justification for read-across, inter alia, the 60% share of non-toxic material in the substance, the use of the substance as fodder, and the structural similarity of the parent substance and its metabolites.

One MSC member noted that their PfA was not to oppose to ECHA's rejection of read-across but to address some aspects of the reasons for rejection.

SECR explained that the interaction with the Registrant at the MSC meeting is an informal part of the procedure, as the REACH regulation does not foresee that such hearing would be granted, but ECHA tries to get as much clarity as possible on the Registrant's comments on the PfAs at this phase to take them properly into account.

SECR also reminded that the original dossier did not have any read-across at all but a different waiving statement; the read-across was brought in only after the original DD was sent out to the Registrant. This information was taken into account in the amended DD referred to the MSCAs for proposals for amendment. The DD referred to the MSC reflects the PfAs received calling for a better description of the deficiencies in the Registrant's read-across arguments. This could help the Registrant improve the read-across arguments, which he can still provide in an updated dossier instead of the testing required at his own risk.

In summary, SECR explained that the read-across is not properly documented and that the issues were identified in the DD, in particular the gaps in the metabolic pathway. Therefore, having taken into account further explanations provided by the Registrant in the comments on the PfAs, the decision is to be taken on the basis of the information currently contained in the technical dossier.

Session 2 (closed)

During the discussion MSC agreed that it is the Registrant who has to build and properly justify the read-across; hence it is up to the Registrant to prepare a good read-across case.

MSC agreed unanimously on the DD as modified during the meeting.

d. General topics

1) Status report on on-going evaluation work including further developments on EOGRTS

SECR gave detailed statistics and update on the status of evaluation work on dossier evaluation for MSC-38 and MSC-39. SECR reflected on the evolution of the standard PfAs and MSC-comments as regards case-specific inputs in the context of the 2-generation issue that were received for MSC-37 and considered their impact on the possibility to use written procedure for agreement seeking, as well as their referral to the Commission. MSC took note of the report.

2) Update to MSC Working Procedures on evaluation

SECR introduced the update to MSC Working Procedures on dossier evaluation. SECR explained that the update of the working procedure included elements that had been discussed and commented by MSC in April-May this year as part of the aim to streamline the process and document flow. Several editorial changes were also included in the updated version, consisting of removal of outdated references and introduction of revised terms, mainly aiming to improve readability of the document.

The Chair summarised the necessary actions to update MSC Working Procedure for Dossier Evaluation process and indicated that, after possible adoption of the revised version similar update of SEV working procedures could be addressed using written commenting and adoption, or during MSC-38. After introduction of some further changes at the meeting MSC adopted the updated working procedures on dossier evaluation.

Item 8 – SVHC identification

As agreed with the adoption of the agenda, this item was not dealt with in the meeting.

Item 9 – Prioritisation of Candidate List substances for inclusion in Annex XIV

As agreed with the adoption of the agenda, this item was not dealt with in the meeting.

Item 10 – Opinion on the draft recommendation of priority substances to be included in Annex XIV

- Revised timeline for MSC opinion development
- Establishment of a MSC Working Group to support the Rapporteur

SECR presented to MSC the revised time plan for the opinion forming on the 6th ECHA's draft recommendation for inclusion of priority substances in Annex XIV.

MSC agreed on the establishment, mandate and objectives of the working group to support the MSC rapporteur (appointed in MSC-36) in drafting the MSC opinion on the 6th draft recommendation of ECHA.

Further, MSC appointed volunteering MSC members as members of the working group for this opinion development.

Item 11 – Update of stakeholder observers' participation at MSC (closed session)

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

A MSC observer representing the Animal Welfare NGOs was granted the possibility for an intervention prior to the MSC annual review on participation of accredited stakeholder organisations (ASO) in the work of MSC. Pointing out on the ASO attendance rate for the last year and the increased interest for a more active involvement of the four animal welfare NGOs in the MSC plenary discussions, she requested MSC to re-consider the current NGO quotas[1] and proposed that either two seats are allocated to the Animal Welfare NGOs group (while reducing from five to four the allocated seats of the Environmental and Health Care NGOs (ENV&HH NGOs)) on a permanent basis or allocate one permanent seat and allow the use of a possibly vacant ENV&HH NGOs' seat if less than five representatives of ENV&HH NGOs register for a meeting by the specified deadline.

The observer representing the ENV&HH NGOs group responded to the previous intervention by reminding that their group of 9 NGOs applies rotative participation[2] for five seats that worked very well for all of them. Further, the ENV&HH NGOs group represents interests spread over the entire range of the MSC work, all processes and any other MSC matters. Although the recent low participation was acknowledged, the observer noted that more active participation is envisaged in the light of Roadmap 2020 implementation and requested MSC to keep the current arrangement where 5 seats are allocated to this NGOs group.

In closed session, MSC thoroughly discussed and considered the ASO participation in the past one year, the Animal Welfare NGOs' proposal regarding the ASO quota allocations, the expressions of interest in MSC work of new ASOs and the retracted interests of some MSC regular or sector-specific observers.

Recognising the importance of ensuring the proper balance of ASO interests at the MSC meetings, the ASO areas of interests in different aspects of the MSC work and the envisaged workload under the MSC processes, members discussed the proposal of the Animal Welfare NGOs. Some members expressed their support for it, taking into account that for most meetings the ENV&HH NGOs have not used all of their allocated seats. These members favoured an option in which the NGOs quota is optimally used. However, MSC decided to maintain the existing seat allocation between Animal Welfare NGOs and ENV & HH NGOs. Taking into account that experience in the past has shown that the ENV&HH NGOs quota is not always used fully, MSC requested SECR to prepare a briefing note which may be brought to the attention of the ECHA's Management Board members regarding the Animal Welfare group's proposal to use one seat from the ENV & HH NGO quota in case not all seats are used for a meeting. The note should reflect on concerns of some MSC members regarding the overall balancing of ASO interests at the meetings, the positive aspect of a full use of available seats and the practical aspects regarding the implementation of the proposal.

Further, MSC agreed to keep the quotas for ASOs representing different interests unchanged as followed in the past years[3].

MSC agreed to invite CHEM Trust as a new MSC observer and re-confirmed the MSC observers' status of ChemSec, Client Earth, EEB, Greenpeace, HEAL, Health Care without harm Europe, Women in Europe for Common Future to follow the Committee's work by applying a rotative participation in MSC meetings for the five observer seats allocated for "ENV&HH NGOs" quota. Further, MSC re-confirmed the MSC observer status of ETUC within this quota to continue without changes.

[1] Where seven seats are allocated to the Environmental and Health Care NGOs (five seats per plenary shared by rotation among nine NGOs), Animal Welfare NGOs (one seat per plenary shared among four NGOs) and Trade Unions (one seat)

[2] This in practical terms means that all organisations which are part of the rotation group are allowed to follow the MSC work by granting access to MSC CIRCABC and all receive an invitation to a MSC meeting. The organisations by themselves coordinate who will participate in the meeting and that the number of meeting participants will not exceed the number of seats for that specific quota of the group of the ASOs.

[3] 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 (i.e six seats General Interest/Sectorial Industry Organisations and one Academic Organisation) and 7 seats assigned to the NGOs quota (i.e. one seat to trade unions, five seats to Environmental and Human health NGOs and one seat to Animal Welfare NGOs)

MSC re-confirmed also the MSC observers' status of ECEAE, Eurogroup for Animals, PISC and HSI to follow its work by applying a rotative participation in MSC meetings for one observer seat allocated for "Animal Welfare NGOs" quota.

MSC agreed to invite FECC as a MSC observer and re-confirmed the MSC observers' status of CEPE to follow the Committee's work by applying a rotative participation in MSC meetings for one observer seat from the 'General interests and wider Industry' quota. Further, MSC re-confirmed the MSC observers' status of other representatives (CEFIC, EUROMETAUX, CONCAWE, UEAPME, ORO and ECETOC) of this quota to continue without changes.

MSC agreed to add EFCA, EFFCI, IFRA, AMFEP, ECI and NIA to the list of MSC sector-specific observers to be invited to MSC on a case-specific basis[4].

MSC agreed to remove Friends of Earth Europe and WWF from the List of MSC regular observers and to remove FEA from the list of the MSC sector-specific observers.

MSC agreed to mandate the SECR to approach a newly-registered ECHA's ASO (ECOPA) and to explore in more details their interests to MSC work. Further, MSC agreed to consider the potential involvement of this ASO in the MSC work within the ASO review in 2015.

The MSC Chair thanked MSC for the interesting discussion and decisions taken and pointed out that SECR will report back on the steps undertaken in the following meetings.

Item 12 – Report from other ECHA bodies and activities

As agreed with the adoption of the agenda, this item was not dealt with in the meeting.

Item 13 – Any other business

- **Annexes amendments in REACH Regulation- update by COM observer**

One of the Commission observers debriefed MSC on the progress made on the update of the REACH Regulation Annexes with regard to the introduction of the extended one generation reproductive toxicity study (EOGRTS). Members were informed that the issue will be brought for voting in the REACH Committee in the following week and the publication of this REACH Regulation update is envisaged for the beginning of 2015. MSC was also informed that the implementation of this REACH amendment should lead to an update of the ECHA's Guidance documents where EOGRTS should be introduced. It was also mentioned that COM has developed a strategy to be presented to the next CARACAL meeting with regard to the processing of ECHA's DDs dealing with the reproduction endpoint that have been referred to it according to Article 133(3) of the REACH Regulation.

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

Watze de Wolf

Chairman of the Member State Committee

[4] In accordance with the MSC General approach for admission of ASOs in MSC work (http://echa.europa.eu/documents/10162/13578/general_approach_aso_in_msc_work_en.pdf)

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ANDRIJEWSKI, Michal (PL)
BASTIJANCIC-KOKIC, Biserka (HR)
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
GAIDUKOVS, Sergejs (LV)
HUMAR-JURIC, Tatjana (SI)
KOUTSODIMOU, Aglaia (EL)
KOZMIKOVA, Jana (CZ)
KYPRIANIDOU LEONTIDOU, Tasoula (CY)
LUNDBERGH, Ivar (SE)
MARTÍN, Esther (ES)
MIHALCEA UDREA, Mariana (RO)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
WAGENER, Alex (LU)
WIJMENGA, Jan (NL)
Representatives of the Commission
KOBE Andrej (DG ENV)
Observers
ANNYS, Erwin (CEFIC)
DEL CASTILLO, Francisco (CONCAWE)
HÖK, Frida (CHEMSEC)
TAYLOR, Katy (ECEAE)
VAN VLIET, Lisette (HEAL)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
ANDERSSON, Niklas
BERCARU, Ofelia
BIGI, Elena
BONNOMET, Vincent
BROERE, William
CARLON, Claudio
CONSTANTIN, Camelia
DE RAAT, Karel
DE WOLF, Watze
DREVE, Simina
FEEHAN, Margaret
JOHANSSON, Matti
KARHU, Elina
KOJO, Anneli
KORJUS, Pia
LE CURIEUX, Frank
MAZZEGA SBOVATA, Silvia
MELZER, Kai
NAUR, Liina
PHILLIPS, Andrew
REUTER, Ulrike
ROBERTS, Julian
RODRIGUEZ IGLESIAS, Pilar
RÖCKE, Timo
RÖNTY, Kaisu
SOBANSKA, Marta
VAHTERISTO, Liisa
VASILEVA, Katya
VAZQUEZ RODRIGUEZ, Jesus

Proxies

- KOUTSODIMOU, Aglaia (EL) also acting as proxy of LULEVA, Parvoleta (BG)
- PISTOLESE, Pietro (IT) also acting as proxy of BUSUTTIL, Ingrid (MT)
- STESSEL, Helmut (AT) also acting as proxy of DUNAUSKIENE, Lina (LT) on Tuesday from 10:30 until mid afternoon

Experts and advisers to MSC members

ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBRGH, Ivar)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
TISCHER, Martin (DE) (expert to FINDENEGG, Helene)
TRAAS, Theo (NL) (expert to WIJMENGA, Jan)
VILNISKE, Lina (LT) (expert to DUNAUSKIENE, Lina)

By WEBEX-phone connection:
During agenda item 7, CCH-214/2014 Sandrine Charles, Valérie Larno and Elodie Pasquier from FR
During agenda items 6.2.a, 7d, 10 and 11 Enrique GARCÍA-JOHN from the European Commission

Case owners:
Representatives of the Registrants were attending under agenda item 7b for CCH-219/2014, CCH-214/2014, CCH-211/2014, CCH-221/2014 and CCH-199/2014

Apologies:
BUSUTTIL, Ingrid (MT)
KULHANKOVA, Pavlina (CZ)
LULEVA, Parvoleta (BG)

III. Final Agenda

ECHA/MSC-37/2014/A/037

Agenda
37th meeting of the Member State Committee

16-18 September 2014
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

16 September: **starts at 10:00**
18 September: **ends at 17:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/037/2014
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-36

- Final minutes of MSC-36

For information

Item 6 – Substance evaluation

Closed session for 6.2 b

6.1 Community Rolling Action Plan (CoRAP) & MSC opinion development

c. Update by ECHA on the work on the next annual CoRAP update

For information and discussion

d. Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update and for Working Group membership

b1. Draft Terms of Reference and possible appointment of Rapporteur and Co-Rapporteur

ECHA/MSC-37/2014/022

For discussion and decision

b2. Discussion and possible establishment of a MSC Working Group to support the Rapporteur

ECHA/MSC-37/2014/024

For discussion and decision

6.2 Decision making process

a. Short general update by the secretariat on ongoing substance evaluations

For information

b. Update on appeals *(Closed session)*

For information

Item 7 – Dossier evaluation

Closed session for 7c

Indicative time plan for 7b is Day 1-Day 2

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

ECHA/MSC-37/2014/002

For information

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

For discussion followed by agreement seeking under 7c:

ECHA/MSC-37/2014/003

Compliance checks

MSC code	Substance name	EC/List No.	Document
CCH-199/2014	Reaction mass of l-xylo-hex-2-ulosonic acid and ascorbic acid	932-019-3	ECHA/MSC-37/2014/004-005
CCH-211/2014	Manganese carbonate	209-942-9	ECHA/MSC-37/2014/006-007
CCH-213/2014	2-diethylaminoethanol	202-845-2	ECHA/MSC-37/2014/008-009
CCH-214/2014	2-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate	239-701-3	ECHA/MSC-37/2014/010-011
CCH-215/2014	Dimethylamine	204-697-4	ECHA/MSC-37/2014/012-013
CCH-219/2014	4-hydroxy-4-methylpentan-2-one	204-626-7	ECHA/MSC-37/2014/014-015
CCH-221/2014	4-methylpentan-2-one	203-550-1	ECHA/MSC-37/2014/016-017
CCH-222/2014	Dimethylamine	204-697-4	ECHA/MSC-37/2014/018-019
CCH-223/2014	Dimethylamine	204-697-4	ECHA/MSC-37/2014/020-021

For information and discussion

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

Cases as listed above under **7b** and any cases returned from written procedure for agreement seeking in the meeting[5]

- CCH-218/2014 1,1-dichloroethylene EC No. 200-864-0

ECHA/MSC/D/2014/183AB&184

For agreement

d. General topics

1) Status report on on-going evaluation work including further developments on EOGRTS

For information

2) Update to MSC Working Procedures on evaluation

ECHA/MSC-37/2014/001

For adoption

Item 8 – SVHC identification

Pro memory

Item 9 – Prioritisation of Candidate List substances for inclusion in Annex XIV

Pro memory

Item 10 – Opinion on the draft recommendation of priority substances to be included in Annex XIV

- Revised timeline for MSC opinion development
- Establishment of a MSC Working Group to support the Rapporteur

ECHA/MSC-37/2014/023&026

For decision

Item 11 – Update of stakeholder observers' participation at MSC

Closed session

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

ECHA/MSC-37/2014/027

For decision

Item 12 – Report from other ECHA bodies and activities

Pro memory

Item 13 – Any other business

- Suggestions from members

For information

[5] Note to members: The documents listed below are available in the substance specific folders in CIRCABC, as were made available for the written procedure, and are not available in the MSC-37 folder.

Item 14 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-37

For adoption

Information documents

Information documents are not allocated a specific agenda time but the documents are available on MSC CIRCABC before the meeting. Based on the listed documents and the meeting agenda, if any MSC member considers that information documents may merit a discussion under any agenda point, they should inform MSC Secretariat

#	Document title	Identification number
1	Note on start of SVHC public consultation	ECHA/MSC/I/2014/023[6]
2	Information note on the substances in the draft 6th Annex XIV recommendation subject to the public consultation	ECHA/MSC/I/2014/022[2]
3	Report from other ECHA bodies and activities	ECHA/MSC-37/2014/028

[6] Note to members: These documents are available in the process specific folders in CIRCABC, and not in the MSC-37 folder.

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-37, 16-18 September 2014
(adopted at the meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 6 - Substance evaluation *6.1 Community Rolling Action Plan (CoRAP) & MSC opinion development* **e.** Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update and for Working Group membership b1. Draft Terms of Reference and possible appointment of Rapporteur and Co-Rapporteur b2. Discussion and possible 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 6 - Substance evaluation *6.2 Decision making process* a. Short general update by the secretariat on ongoing substance evaluations	
MSC took note of the update.	**MSC** to inform their eMSCA colleagues to indicate their SEV plans in the booking table found on Evaluation CIRCABC.
Item 7 – Dossier evaluation **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 agreed in written procedure, as indicated in document ECHA/MSC-37/2014/002. **MSC-S** to provide COM for further decision making with documents (DD, RCOM, outcome of the vote, justifications for NO votes) of cases on which MSC did not reach agreement, as indicated in document ECHA/MSC-37/2014/002.
b. Introduction to and preliminary discussion on draft decisions on compliance checks after MS-CA reactions *(Session 1, open session)* **c. Seeking agreement on draft decisions on compliance checks when amendments were proposed by MS-CA's *(Session 2, closed session)***	
MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting: • CCH-199/2014 Reaction mass of l-xylo-hex-2-ulosonic acid and ascorbic acid • CCH-211/2014 Manganese carbonate • CCH-213B/2014 2-diethylaminoethanol • CCH-214B/2014 2-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3-	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
propanediyl diacrylate • CCH-215B/2014 Dimethylamine • CCH-218B/2014 1,1-dichloroethylene • CCH-219B/2014 4-hydroxy-4-methylpentan-2-one • CCH-221/2014 4-methylpentan-2-one • CCH-222/2014 Dimethylamine • CCH-223/2014 Dimethylamine	
MSC could not reach unanimous agreement on the following draft decisions as modified in the meeting, where appropriate: • CCH-213A/2014 2-diethylaminoethanol • CCH-214A/2014 2-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate • CCH-215A/2014 Dimethylamine • CCH-218A/2014 1,1-dichloroethylene • CCH-219A/2014 4-hydroxy-4-methylpentan-2-one	**MSC-S** to provide COM for further decision making with documents (DD, RCOM, outcome of the vote, justifications for NO votes) of cases on which MSC did not reach agreement
Item 7 – Dossier evaluation **d. General topics** 1) Status report on on-going evaluation work including further developments on EOGRTS 2) Update to MSC Working Procedures on evaluation	
MSC agreed to consider whether there is a need for a working group after identifying the key issues.	Reflecting on recent meeting discussions as regards CSR-related issues, e.g. PPE, **MSC members** to inform the Chairman of the key issue(s) they wish to have discussed in one of the next meetings.
MSC adopted the update to the MSC Working procedures as edited at the meeting.	**SECR** to upload to CIRCABC and ECHA website the adopted MSC working procedure on DEV. **SECR** to prepare an update of MSC SEV Working procedures for MSC adoption at a later stage.
Item 10 – Opinion on the draft recommendation of priority substances to be included in Annex XIV • Revised timeline for MSC opinion development • Establishment of a MSC Working Group to support the Rapporteur	
MSC took note of the revised time plan for the MSC opinion development on the 6th draft recommendation. Further, MSC established a working group to support the Rapporteur and appointed volunteering members and experts to it.	**MSC-S** to upload the updated meeting document ECHA/MSC-37/2014/026 with the WG member composition.
Item 11 – Update of stakeholder observers' participation at MSC	
MSC took the following decisions regarding the ASOs participation in their work: • MSC agreed to keep the quotas for ASOs representing different interests unchanged as followed in the past years[7], • MSC agreed to invite CHEM Trust as a MSC observer and re-confirmed the MSC observers' status of ChemSec, Client Earth, EEB, Greenpeace, HEAL, Health Care without harm Europe, Women	**SECR** to inform the concerned ASOs of the outcome of the MSC decisions and to follow their implementation when organising the Committee's work. **SECR** to prepare a briefing note to the MB regarding the Animal Welfare group proposal to use one seat from the ENV & HH NGO quota if not all seats are

[7] 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 (i.e six seats General Interest/Sectorial Industry Organisations and one Academic Organisation) and 7 seats assigned to the NGOs quota (i.e. one seat to trade unions, five seats to Environmental and Human health NGOs and one seat to Animal Welfare NGOs)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
in Europe for Common Future to follow the Committee's work by applying a rotative participation in MSC meetings for the five observer seats allocated for "ENV&HH NGOs" quota, • MSC re-confirmed the MSC observers' status of ECEAE, Eurogroup for Animals, PISC and HSI to follow its work by applying a rotative participation in MSC meetings for one observer seat allocated for "Animal Welfare NGOs" quota, • MSC agreed to invite FECC as a MSC observer and re-confirmed the MSC observers' status of CEPE to follow the Committee's work by applying a rotative participation in MSC meetings for one observer seat from the 'General interests and wider Industry' quota, • MSC re-confirmed the MSC observers' status of other representatives (CEFIC, EUROMETAUX, CONCAWE, UEAPME, ORO ETUC and ECETOC) of this quota to continue without changes. • MSC agreed to add EFCA, EFFCI, IFRA, AMFEP, ECI and NIA to the list of MSC sector-specific observers to be invited to MSC on a case-specific basis, • MSC agreed to remove Friends of Earth Europe and WWF from the List of MSC regular observers and to remove FEA from the list of the MSC sector-specific observers, • MSC agreed to mandate the SECR to approach ECOPA and explore in more details their interests to MSC work. Further, MSC agreed to consider the potential involvement of this ASO in the MSC work within the ASO review in 2015.	used for a meeting and the MSC concerns regarding the balance of interests after the meeting. **SECR** to report back the outcome of the MB discussion. **SECR** to approach ECOPA after the meeting, collect the relevant information regarding their potential involvement in the MSC work and provide it to MSC consideration within the ASO annual review in 2015.
Item 14– Adoption of conclusions and action points	
MSC adopted the main conclusions and action points of MSC-37 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC CIRCABC by 19 September 2014.

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

Draft decisions unanimously agreed by MSC in WP:

Testing proposal examinations (TPE)

MSC ID number	Substance name used in draft decision	EC number
TPE 048/2014	A mixture of: 2-ethylhexyl mono-D-glucopyranoside; 2-ethylhexyl di-D-glucopyranoside	414-420-0

Compliance checks (CCH)

MSC ID number	Substance name used in draft decision	EC number
CCH-142B/2014	2-acetone, condensation product with phenol	931-252-8
CCH-146/2014	Ammonium thiosulphate	231-982-0
CCH-157/2014	Antimony nickel titanium oxide yellow	232-353-3
CCH-158/2014	Zirconium praseodymium yellow zircon	269-075-7
CCH-159B/2014	Phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts	270-608-0
CCH-160B/2014	Zinc bis[O,O-bis(2-ethylhexyl)] bis(dithiophosphate)	224-235-5
CCH-162/2014	Tetrabromophthalic anhydride	211-185-4
CCH-163/2014	Alcohols, C9-11-branched	271-360-6
CCH-164/2014	Alcohols, C7-9-iso-, C8-rich	271-231-4
CCH-165/2014	Alcohols, C11-14-iso-, C13-rich	271-235-6
CCH-166/2014	Alcohols, C9-11-iso-, C10-rich	271-234-0
CCH-172/2014	Tert-butyl 2-ethylperoxyhexanoate	221-110-7
CCH-198B/2014	Dibutyl maleate	203-328-4
CCH-201/2014	Thionyl dichloride	231-748-8
CCH-203B/2014	Slags, silicomanganese-manufg.	273-733-9
CCH-204B/2014	Magnesium, bis(2-hydroxybenzoato-O1,O2)-, ar,ar'-di-C14-18alkyl derivs.	931-371-5
CCH-205B/2014	Benzoic acid, 2-hydroxy-, mono-C14-18-alkyl derivs., calcium salts (2:1)	931-276-9
CCH-206B/2014	Alcohols, secondary C11-15, ethoxylated	614-295-4
CCH-210B/2014	Hexahydro-4-methylphthalic anhydride	243-072-0
CCH-212/2014	Butan-2-ol	201-158-5
CCH-216/2014	Manganese dioxide	215-202-6
CCH-217B/2014	1,3-dioxolane	211-463-5

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

Compliance checks (CCH)

MSC ID number	Substance name used in draft decision	EC number
CCH-142A/2014	2-acetone, condensation product with phenol	931-252-8
CCH-159A/2014	Phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts	270-608-0
CCH-160A/2014	Zinc bis[O,O-bis(2-ethylhexyl)] bis(dithiophosphate)	224-235-5
CCH-198A/2014	Dibutyl maleate	203-328-4
CCH-203A/2014	Slags, silicomanganese-manufg.	273-733-9
CCH-204A/2014	Magnesium, bis(2-hydroxybenzoato-O1,O2)-, ar,ar'-di-C14-18alkyl derivs.	931-371-5
CCH-205A/2014	Benzoic acid, 2-hydroxy-, mono-C14-18-alkyl derivs., calcium salts (2:1)	931-276-9
CCH-206A/2014	Alcohols, secondary C11-15, ethoxylated	614-295-4
CCH-210A/2014	Hexahydro-4-methylphthalic anhydride	243-072-0
CCH-217A/2014	1,3-dioxolane	211-463-5

Draft decisions terminated in WP and discussed at the MSC-37 meeting:

Compliance checks (CCH)

MSC ID number	Substance name used in draft decision	EC number
CCH-218A/2014	1,1-dichloroethylene	200-864-0
CCH-218B/2014	1,1-dichloroethylene	200-864-0