MSC/M/38/2014
(Adopted at MSC-39)

Minutes
of the 38th Meeting of the Member State Committee (MSC-38)
28-29 October 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 38th 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 (final Agenda is attached to these minutes).

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-38.

Item 4 - Administrative issues

No administrative issues were announced or discussed.

Item 5 – Adoption of the minutes of the MSC-37 meeting

The minutes of MSC-37 were adopted as provided for the meeting and slightly modified at the meeting based on a member's additional comments.

Item 6 - Substance evaluation

1. *Decision making process*

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

SECR gave a report on the outcome of the written procedure (WP) for agreement seeking on one substance evaluation case: SEV-IE-020/2013, 7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate (EC No 219-207-4). WP was launched on 2 October 2014. By the closing date 13 October 2014, responses to WP were received from 21 members with voting right and from the Norwegian member. As unanimous agreement was reached for the (one) draft decision, ECHA will continue processing the draft decision and the final documents will be available on MSC CIRCABC.

b. Short general update by the secretariat

SECR gave a general update on the number of substance evaluation (SEV) cases booked by eMSCAs per MSC meeting for 2015, in the excel table available on evaluation CIRCABC and reminded the MSC of the deadlines for consistency screening of the DD for substances evaluated in 2014. Acknowledging many of the inherent uncertainties in the current assessment for the planning and workload management of MSC-meetings it is clear from the table that the April and June meeting are overbooked, and the September meeting underbooked. Concerns were raised by the members on how and when to agree on the SEV cases since the number of substances to be evaluated per year in the CoRAP list is increasing. Even though it seemed that MSC members were not embracing the idea of having a two week MSC meeting, it was noted that the aim of the booking table is to guide the MSC-S to have a more even distribution of cases. It is not a measure to delay cases as the estimated maximum number of cases is an indicator for MCS members to engage in more detailed meeting agenda planning with MSC-S. Cases from 2012/2013 need to be finalised as soon as possible.

c. Short update on appeals

SECR provided some clarification upon request of one member on the appeal process for SEV cases, in particular as regards the possibility to intervene in the process. MSC was

explained how the MSCAs might be involved in the process, noting that the process in place is not yet mature but being developed.

2. *CoRAP update*

Community Rolling Action Plan (CoRAP) & MSC opinion development

Introduction of the draft CoRAP update by ECHA and first exchange of views on the draft CoRAP

SECR presented the draft CoRAP update for 2015-2017. As per previous years, each substance has an accompanying justification document. The draft CoRAP including the initial grounds for concern and grouping for five groups of substances was to be published shortly after the MSC meeting. Substances in the CoRAP list were identified through the common screening activities across ECHA through IT pre-selection and then through manual screening. The draft CoRAP update for years 2015-2017 has a total of 134 substance, 65 new and 69 already included in the 2014-2016 CoRAP update. During the discussion the Chairman clarified that even though the expert group of ECHA, like the PBT expert group and the endocrine disruption expert group, are available to provide advice to evaluating MSCAs on the planned testing strategy, there is no requirement for SEV cases to go through these informal processes. It was also mentioned that even though the draft CoRAP will be published on ECHA website, yet still changes are possible until the final CoRAP is published in March 2015.

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 WP for agreement seeking on 16 dossier evaluation draft decisions (DD) (see Section V for more detailed identification of the cases). WP was launched on 2 October 2014 and closed on 13 October 2014. For six cases, the DD were split thus resulting in 12 DDs and overall 16 DDs for the 10 cases. A member declared an interest for one of the cases, and its assessment by the MSC Chairman is attached to the written procedure report. By the closing date, responses to WP were received from 23 members with voting right and from the Norwegian member. Unanimous agreement was reached on six DDs. The MSC Chairman stopped the written procedure for four DDs to allow discussion at the MSC-38 meeting. For the other six DDs MSC did not find unanimous agreement due to divergent opinions on the appropriate test method to fulfil the two-generation reproductive toxicity endpoint. 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-237A&B/2014 ethylene carbonate (EC No 202-510-0)

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.

Nine PfAs were submitted of which three PfAs were related to the extended one generation reproductive toxicity study (EOGRTS) that led to the splitting of DD into two parts prior to the meeting: CCH-237A/2014 and CCH-237B/2014. Part A addresses the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity study) and part B other information requirements.

In relation to part A, three PfAs were submitted 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 PfAs additionally suggested including the DNT/DIT cohorts and one PfA considered the read-across to ethylene glycol plausible.

MSC was satisfied with ECHA's response to three PfAs whilst six PfAs were discussed by MSC at the meeting.

Two PfAs, specifically on sub-chronic toxicity study (90-day) and on pre-natal developmental toxicity (PNDT) study, considered that the Registrant's proposed read-across to ethylene glycol was plausible, as ethylene carbonate rapidly metabolises to ethylene glycol (and presumably formic acid), indicating little or no systemic exposure to unchanged parent compound. The toxicology of ethylene carbonate would be dominated by that of ethylene glycol. Therefore the PfAs proposed that the requests for the 90-day and PNDT studies should be rejected.

A general PfA on information related to chemical safety assessment (CSA) and chemical safety report (CSR) suggested, firstly, to request the Registrant to submit in the CSR information on revised exposure assessment and risk characterisation for workers via dermal route using the pre-defined values for gloves efficiency of 90 and 95 %, or to provide a justification explaining why in this specific case using higher efficiency values for gloves (98 and 99 %) is considered adequate. Secondly, the requirements for hand protection to avoid dermal exposure needed to be provided consistently in the safety data sheet (SDS) and CSR: type of glove material and its thickness, and typical or minimum breakthrough times.

Another general PfA on detailed specification of Personal Protective Equipment (PPE) suggested requesting the Registrant to provide documentation for the recommended material type, its thickness and the typical or minimum breakthrough time of the glove type recommended, with regard to the amount and duration of dermal exposure in the CSR.

In addition, a general PfA on the justification that risks to workers are adequately controlled noted that high risk characterization ratios (RCR) close to 1, related to exposure via combined routes (inhalation and dermal), have been identified in the CSR. Therefore, the Registrant was requested to refine these estimations, or to submit further justification that risk related to exposure via inhalation and combined routes are controlled, in particular as the Registrant has not been using the assessment factors recommended by ECHA in the derivation of the derived no-effect levels (DNEL).

Another general PfA related to CSA/CSR suggested, firstly, to revise the consumer exposure assessment and risk characterisations (Annex I, Sections 5 and 6) to take into account consumer activities, and the duration and frequency of exposure to the registered substance. Secondly, to revise the consumer exposure assessment and risk characterisations using the recommended fraction released to air and to reassess related risks according to ECHA Guidance. Alternatively, a full justification would be needed for not using the recommended fraction released to air in the consumer exposure estimates.

The Registrant provided comments on the PfAs further justifying his read-across approach He stressed that they had prepared weight of evidence using all data available for both source and target substances. He agreed that the read-across is valid and has enough scientific and bibliographic basis, although there was not yet enough justification included in the dossier for read-across endpoint by endpoint. . The Registrant informed that they will update the dossier without delay to include all complementary documentation and also indication of read-across basis for each endpoint. The PPE will be addressed also in the dossier update.

SECR explained that it would appear confusing if member dossiers were not updated at the same time as the lead dossier. The Chairman also clarified that the recent dossier update on information sources discussed has not been taken into account as the decision making

process is based on information that was available in the dossier when the draft decision was notified to MSCAs.

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MSC agreed to keep unchanged the rejection of the read-across approach and to modify Section III Statement of reasons on the read-across rationale in order to highlight the concern of the potential systemic exposure of the parent substance, and on the necessity of availability of full information in the technical dossier.

MSC concluded that the Registrant is to be requested to provide documentation for the recommended PPE, to request a revised exposure assessment and risk characterisation for workers via dermal route or a justification why the efficiency values used for gloves are considered appropriate, and to request a revised consumer exposure assessment and risk characterisation, taking into account the consumers' activities and the duration and frequency of their exposure and using the fraction released to air recommended by ECHA Guidance R.15 or a full justification for not using the recommended values in the consumer exposure estimates.

In addition, MSC agreed on the extent of information to be requested with respect to PPE. REACH Regulation requires registrants to identify and apply appropriate measures to adequately control the risks. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures (RMM) to reduce or avoid direct and indirect exposure of humans have been implemented. Also, the CSR needs to contain sufficient information to allow ECHA to gain assurance that the risks are adequately controlled and that appropriate RMMs can be prescribed by actors in the supply chain. The supplier is required to describe the relevant RMM in detail in the SDS in order to minimise the exposure for workers handling the registered substance (e.g. the type of gloves to be worn shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure). The information provided in the SDS shall be consistent with information in the CSR. Gloves are reported in the CSR and IUCLID Section 11 as required PPE to prevent dermal exposure to the substance. This information, as a minimum, has to specify the glove material and, depending on the exposure scenarios, may also need to include the breakthrough time and thickness of the glove material. The registrant is required to provide in the CSR a description of the gloves to be used when handling the substance. The information provided by the Registrant shall be sufficiently detailed to allow suppliers to fulfil their obligations specified under Annex II for the compilation of the SDSs.

MSC agreed unanimously on ECHA's split of the DD 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 Chairman 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 DD to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

CCH-238/2014 ethylene carbonate (EC No 202-510-0)

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.

Two PfAs were received in total to ECHA's DD.

A PfA related to CSA/CSR, similar to one general PfA in the case above, suggests, firstly, to revise the consumer exposure assessment and risk characterisations (Annex I, Sections

5 and 6) to take into account consumer activities, and the duration and frequency of exposure to the registered substance. Secondly, there is a need to revise the consumer exposure assessment and risk characterisations using the recommended fraction released to air and to reassess related risks according to ECHA Guidance. Alternatively, a full justification would be needed for not using the recommended fraction released to air in the consumer exposure estimates.

Another PfA suggested to request the Registrant to provide information on PPE (gloves, goggles and other protection) e.g. type of gloves and type respiratory protection where relevant, taking into account e.g. breakthrough times for gloves and clothing and type of filter.

The Registrant provided comments on the PfAs. He considered the existing information in CSR on the use of gloves and its effectiveness to be sufficient. Further details on the type of gloves and the conversion of their effectiveness to type of material, its thickness and breakthrough times are already included in IUCLID (Section 11 Guidance on safe use) and in SDS. The Registrant also stated that the exposure/risk part of CSR should not be regarded as a stand-alone document but rather referring to additional information available in IUCLID and in the eMSDS. He was of the opinion that the European Council Directive 89/391/EEC regulates the necessity for safety instruction and training to workers, being implemented by national laws, and therefore this general information does not need to be repeated in the exposure assessment. The Registrant has updated his dossier on 23.09.2014 which is after the DD was notified to MSCAs. He informed that the dossiers for CCH-237 and CCH-238 were then in line with each other. He noted that he had not commented on the PfA on consumer uses, as those were removed since no consumer uses are known.

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MSC concluded to add a request for revised consumer exposure assessment and risk characterisation, taking into account the consumers' activities and the duration and frequency of their exposure and using the fraction released to air recommended by ECHA Guidance R.15 or a full justification for not using the recommended values in the consumer exposure estimates. In addition, MSC concluded that the Registrant is to be requested to provide documentation for the recommended PPE.

Based on the above considerations, MSC found unanimous agreement on ECHA's DD as amended for the meeting. In addition, following the change in deadline for CCH-237B, from 36 months to 24 months from the date of the adoption of the decision and to ensure consistency in DNELs and co-ordination of updates, also the deadline of the DD of CCH-238 was modified accordingly.

CCH-239/2014 ethylene carbonate (EC No 202-510-0)

Session 1 (open)

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

A PfA was received to ECHA's DD on PPE, same as the PfA in the case above.

MSC was satisfied with ECHA's response to the PfA being in line with replies to the related case CCH-238.

The Registrant did not provide comments on the one PfA received.

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Based on the above considerations, MSC found unanimous agreement on ECHA's DD as amended for the meeting. In addition, following the change in deadline for CCH-237B, from 36 months to 24 months from the date of the adoption of the decision and to ensure consistency in DNELs and co-ordination of updates, also the deadline of the DD of CCH-239 was modified accordingly.

CCH-242/2014 buta-1,2-diene (EC No 209-674-2)

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.

SECR explained that six PfAs were received in total to ECHA's DD.

A MSCA's PfA agreed with ECHA's request for Transgenic rodent somatic and germ cell gene mutation assays (OECD TG 488) and proposed recommending germ cells to be stored when performing the requested OECD 488, so that potential germ cell mutagenicity can be investigated in case of somatic mutations.

Another MSCA submitted four PfAs suggesting the proposed QSAR approach using the ECOSAR program in this case should be rejected due to lack of adequate supporting information (no QSAR Model Reporting Format and QSAR Prediction Reporting Format was delivered). To fulfil the information requirements of Annex VII, 9.1.2. and 9.1.3, and Annex IX, 9.1.5 and 9.1.6.1) these PfAs proposed to request the Registrant to conduct the Growth inhibition study with aquatic plants (algae preferred) (OECD TG 201), the Short-term toxicity testing on fish (OECD TG 203), the Long-term toxicity testing on aquatic invertebrates (preferred species Daphnia) (OECD TG 211) and the Long-term toxicity testing on fish (OECD TG 210). In another PfA the same MSCA proposed that the Registrant is requested to revise the PNECs for freshwater, marine water, sediments and soil, as the Registrant has reported an experimental key study (Short-term toxicity testing on aquatic invertebrates) and QSAR predictions for the other endpoints in the IUCLID file in Section 6, however the result of this key study was not used for deriving PNEC values according to Annex I, 3.3.1. of REACH.

The Registrant provided comments on four PfAs regarding the aquatic testing and on the DD. In his comments to the PfAs concerning the QSAR approach applied, the Registrant noted that the ECOSAR QSAR programme is part of the OECD toolbox, and that as such is accepted by the regulatory community. He also underlined that although a short-term test on aquatic invertebrates has been conducted on the registered substance, this was only possible with significant methodological adaptations. He also indicated that adaptations to the fish studies could not be applied while with respect to the algal growth inhibition test and long-term test of aquatic invertebrates, the timescales for these are longer than for the short-term test of aquatic invertebrates, which would lead to higher losses. The Registrant proposed to waive the OECD 201, OECD 203 and OECD 211 tests as he considered it is technically not possible to conduct them.

Following the first PfA, MSC considered the proposed recommendation to store germ cells during the requested OECD 488, so that germ cell mutagenicity can be investigated in case of somatic mutations. MSC decided to include in this regard some remarks for the Registrant's consideration in Section III of the DD.

Motivated by the other PfAs on the rejection of the proposed QSARs for aquatic toxicity, MSC discussed the need for testing in order to fulfil the standard information requirements for these aquatic endpoints, technical feasibility of such testing and the proportionality in gaining the required information to fill-in the data gaps versus the efforts of its gathering.

Session 2 (closed)

Based on the above considerations, MSC concluded that the QSARs presented by the Registrant for these aquatic endpoints are not valid. The Registrant has not provided adequate and reliable documentation of the applied QSAR models, and that the aquatic toxicity predictions are outside the applicability domain of the QSARs used. Thus, there are information gaps for these aquatic endpoints which need to be filled-in, in order to bring the registration dossier into compliance with relevant information requirements.

Further, MSC also considered the Registrant's arguments regarding the technical feasibility of the aquatic toxicity testing with a very volatile substance and concluded that the Registrant failed to sufficiently present the reasons for the irrelevance of the aquatic toxicity testing or the impossibility to modify some test conditions and design and perform

a valid test according to the guidelines. In particular, MSC felt that the Registrant has not adequately considered the guidance in section 3.4 of the OECD Guidance document on aquatic toxicity testing of difficult substances and mixtures (Environmental health and safety publications, Series on testing and assessment No. 23; ENV/JM/MONO(2000)6, pages 26 to 28), which deals with testing of volatile substances such as the registered substance.

In conclusion, referring to Annex VII, 9.1.2., Annex VIII, 9.1.3. and Annex IX, 9.1.5. and 9.1.6., MSC decided that the Registrant should be requested to fill in the identified information gaps by conducting the Growth inhibition study with aquatic plants (algae preferred) (OECD TG 201), the Short-term toxicity testing on fish (OECD TG 203), the Long-term toxicity testing on aquatic invertebrates (preferred species Daphnia) (OECD TG 211) and the Long-term toxicity testing on fish (OECD TG 210) or by providing proper solid scientific justification if the testing proves unfeasible, as well as to revise the PNECs for freshwater, marine water, sediments and soil. Furthermore, MSC included notes for the Registrant's consideration in section III of DD.

MSC found unanimous agreement on ECHA's DD as modified at the meeting.

CCH-247/2014 2-mercaptoethanol (EC No 200-464-6)

Session 1 [open]

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

Seven PfAs were submitted of which four PfAs were related to EOGRTS that lead to the splitting of DD into two parts prior to the meeting: CCH- 247A/2014 and CCH- 247B/2014. Part A addresses the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity study) and part B other information requirements.

MSC was satisfied with the responses of ECHA to the other three PfAs, hence there was no discussion of these PfAs. These PfAs led to a request in the DD for detailed specification of personal protective equipment (Art. 14(6), Annex I, 5.1.1), and simulation testing on ultimate degradation in surface water (Annex IX, 9.2.1.2), as well as an inclusion of a reminder that use of 98% glove effectiveness requires justification.

Session 2 [closed]

MSC agreed unanimously on ECHA's split of the DD addressing the above studies in part B, as amended for the meeting without further modifications during the plenary.

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 Chairman 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-227/2014 p-xylene (EC No 203-396-5)

Session 2 [closed]

SECR explained that agreement was initially sought in written procedure. The written procedure was terminated by the Chairman of MSC on request of one MSC member suggesting a MSC discussion.

SECR shortly introduced the PfA requesting for a ready biodegradability test Annex VII, 9.2.1.1 (OECD 301) because of invalid or unreliable studies available. The MSC member

requesting the MSC discussion explained that because the key study does not meet one validity criterion (>20% variability between replicates) and the other two supporting studies are considered unreliable, the substance is produced in high volumes and the test is relatively inexpensive, they would prefer to request for the ready biodegradability test. SECR considered that the Registrant did not provide all the necessary information, making it difficult to assess whether the validity criteria in all studies were met; hence a weight of evidence approach was used when addressing this endpoint in the compliance check.

MSC found unanimous agreement on ECHA's draft decision as modified in the meeting by requesting for a ready biodegradability test Annex VII, 9.2.1.1 (OECD 301).

CCH-229/2014 m-xylene (EC No 203-576-3)

Session 2 [closed]

SECR explained that agreement was initially sought in written procedure. The written procedure was terminated by the Chairman of MSC on request of one MSC member suggesting a MSC discussion.

SECR shortly introduced the PfA requesting for a ready biodegradability test Annex VII, 9.2.1.1 (OECD 301) because of invalid or unreliable studies available. The MSC member requesting the MSC discussion explained that because the two available studies are considered unreliable, the substance is produced in high volumes and the test is relatively inexpensive, they would prefer to request for the ready biodegradability test. SECR considered that the Registrant did not provide all the necessary information, making it difficult to assess whether the validity criteria in all studies were met; hence a weight of evidence approach was used when addressing this endpoint in the compliance check.

MSC found unanimous agreement on ECHA's draft decision as modified in the meeting by requesting for a ready biodegradability test Annex VII, 9.2.1.1 (OECD 301).

CCH-243A&B/2014 sodium dodecyl sulphate (EC No 205-788-1)

Session 2 (closed)

MSC Chairman informed the MSC members on PfAs and on the splitting of the DD into part A and B, where part A addressed the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity) and part B addressed the other information requirements, and explained to members that the written procedure for this CCH case had been terminated due to identified technical inconsistence in the documentation provided. Thus, the draft decisions were brought to MSC for agreement seeking in the meeting.

MSC agreed unanimously on part B of the DD relating to the information requests for *in vitro* gene mutation study in bacteria (Annex VII, 8.4.1.) and Revised Predicted No Effects Levels (PNECs) for the aquatic and marine environmental spheres using assessment factors recommended by ECHA and re-assessment of related risks or a full justification for not using the recommended assessment factors in PNEC derivation (Annex I, 3.3.1.).

MSC did not reach a unanimous agreement on the DD, part A relating to the two-generation reproductive toxicity study, in consequence ECHA will refer this DD to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

d. General topics

Status report on on-going evaluation work

SECR gave detailed statistics and update on the status of evaluation work. SECR also provide tentative results from recent workshops. MSC took note of the report. A member commented on the need to have such presentation available in advance of the meeting

due to the level of detail covered. MSC Chairman indicated that he would bring this request for timely sharing of the presentation also to the attention of the other process owners in ECHA (substance evaluation, and authorisation). MSC and its stakeholder will be invited to provide comments on the dossier evaluation presentation template.

Item 8 – SVHC identification

Statistics on comments received in the public consultation on SVHC proposals

MSC Chairman informed MSC that the 45-days public consultation on the 10 proposals for identification of substances of very high concern (SVHC) ended several days before the plenary meeting and statistical information on its outcome has been provided in a presentation available to members and observers in MSC CIRCABC.

Following the Chairman's query on the need for providing MSC with such statistical background information, several members indicated that such statistics are appreciated by their MSCAs and requested the statistics to continue to be provided. However, it was also pointed out that it should be made very clear to the public at the commenting stage that comments on uses are not relevant for SVHC identification process and will be considered only at the prioritisation stage. Similarly, it was noted that the number of comments submitted is not a meaningful measure to be used as one comment may represent one large sector or high number of actors or impacted persons. Furthermore, reporting numbers may give the wrong message that quantity instead of quality matters.

SECR noted that such distinction of the comments relevant for SVHC process and comments for later Authorisation stages has been clearly made on the ECHA's website and in the updated webform for submitting comments under SVHC consultations. Nevertheless, it was pointed out that SECR would appreciate suggestions on possible improvements in this regard. Furthermore, SECR repeated its appreciation of the efforts made for consolidated comments.

MSC was also informed of the timeline for the MSC agreement seeking under the current SVHC round.

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

- **Status update on public consultation on 6th draft recommendation**

SECR provided an update on the on-going public consultation on the 6th ECHA's draft recommendation for inclusion of substances in Annex XIV that started on 1 September and ended on 30 November 2014. It was noted that similarly to the previous consultations, only few comments have been received at this point in time and most comments are expected to be submitted towards the end of the consultation period.

- **Time plan for the 7th recommendation process**

SECR shared some ideas regarding the timeframe of the ECHA's 7th draft recommendation development process: preliminary prioritisation results regarding the SVHCs that have not been previously assessed to be presented for information in MSC plenary in February 2015; first discussion of prioritisation results in June 2015; discussion of draft recommendation in Sept. 2015 MSC, public consultation expected to be launched in mid-October 2015 lasting till mid-January 2016, the revised draft Recommendation will be presented to MSC in April 2016 and the discussion and adoption of the MSC opinion on the 7th draft recommendation would then take place in June 2016. It was stressed that this is a tentative time plan and that SECR will further consider the practical aspects of the suggested 7th recommendation timeframe. It is foreseen to present a time plan for the MSC opinion development on the 7th draft recommendation at MSC-39 in December 2014.

A member and an ASO observer made remarks regarding the overlap of the 6th and the 7th recommendation processes where substances for prioritisation in the 7th draft recommendation should be considered before confirming the substances to be included in

the 6th recommendation. The envisaged public consultation covering Christmas holiday period was also seen as problematic.

SECR clarified that in Feb. 2015 only substances not yet assessed for their priority would be presented. It was also highlighted that the parallel running of the two processes would provide MSC with longer time to consider 'in portions' all the substances which if not included in the 6th recommendation, will be then re-considered for inclusion in the 7th draft recommendation.

The MSC Chairman reminded that this time plan is still tentative and the discussion on it will continue at MSC-39 in December 2014.

Item 10 – Request to MSC for an opinion in accordance with Article 77(3) c of REACH Regulation

a. Introduction of the ED request for an MSC opinion to RAC on persistency and bioaccumulation of the substances octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5)

SECR presented to MSC the recently received request under Article 77 (3) (c) of the REACH Regulation from ECHA's Executive Director (ED) for an MSC opinion to the Risk Assessment Committee (RAC) on persistency and bioaccumulation of the substances D4 and D5. It was explained that MSC is asked to provide such an opinion, because the Community wide opinion forming on the PBT or vPvB hazard assessment is generally performed through identification of a substance as a Substance of Very High Concern in accordance with REACH where MSC involvement may be triggered. Thus, the ED request was made to avoid that RAC has to prepare an opinion on whether the P and B criteria in Annex XIII are met (and introduce a potential risk of divergent opinions between ECHA committees), on the persistence and bioacummulative properties of the substances D4 and D5, which can then be used in the further deliberation of RAC.

The Committee was further informed that following the receipt of the PBT reports for D4 and D5 as prepared by the UK CA, on 15 October 2014, SECR launched a 45-day public call for evidence for collecting information on the PBT properties of these substances. The MSC opinion will be based on the PBT information on D4 and D5 provided by the UK CA and by the commenting parties during the above-mentioned 45-day consultation period.

In the following discussion, the member from the UK CA that intends to submit restriction proposals for these two substances early 2015 explained that his CA has considered the restriction pathway to be the most appropriate to further regulate D4 and D5 and therefore, does not intend to consider these substances' inclusion in the Candidate List or to expand the scope of the future restriction entries for covering potential endocrine disruptive properties of D4. SECR reminded that when a restriction does not cover all uses of a substance and a need for its further regulation is identified, an authorisation route can be followed for those uses outside the restriction scope by making a well-justified proposal for this.

It was further clarified that the ED request was made in order to avert the potential diverging ECHA Committees' views on the vPvB/PB properties. Since these properties are within the competence of MSC, the MSC opinion is expected to be made solely on the vPvb/PB properties as an input for the purpose of the RAC opinion development on the restriction proposal (to be submitted early 2015) and the further Commission's decision-making and will not lead to a Candidate List listing, as this ad-hoc process is different from the one under Article 59 of the REACH Regulation.

b. Time plan for MSC opinion development

SECR presented the indicative time plan for the MSC opinion development on this Article 77(3)(c) request. MSC agreed on the time plan as presented.

c. Task of the Rapporteur in drafting the opinion of MSC

SECR presented the draft Terms of reference for the Rapporteur on the MSC opinion development on this Article 77(3)(c) request provided in document ECHA/MSC-38/2014/018. MSC agreed on the Terms of reference document with a minor modification.

d. Appointment of Rapporteur

MSC Chairman informed the Committee that as no expressions of interest to a rapporteurship for the opinion development under this ED's request have been received by that point in time, it is not possible to appoint a rapporteur at MSC-38 meeting. It was also explained that due to the main concerns expressed by most of the members with regard to their high workload and the new type of the MSC opinion as compared to the other MSC opinions, SECR committed to offer full procedural and additional expert support to the rapporteur during this opinion development process.

Following the MSC Chairman's proposal, MSC agreed to mandate the MSC Chairman to identify and appoint a volunteering MSC member as a MSC rapporteur in accordance with Article 17 (2) of the MSC Rules of procedure. If such volunteers could not be identified by 1 December 2014, the members requested the Chair to inform the committee of this, to investigate possible reasons and plan for further discussions at MSC-39.

MSC agreed to mandate the MSC Chairman to identify an MSC member willing to act as a rapporteur for this opinion development.

Item 11 – Any other business

No suggestions have been received by members under this agenda item.

Item 12– Adoption of conclusions and action points

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

SIGNED

Watze de Wolf

Chairman of the Member State Committee

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ANDRIJEWSKI, Michal (PL)
BASTIJANCIC-KOKIC, Biserka (HR)
COSGRAVE, Majella (IE)
DOUGHERTY, Gary (UK)
DUNAUSKIENE, Lina (LT)
GAIDUKOVS, Sergejs (LV)
HUMAR-JURIC, Tatjana (SI)
KULHANKOVA, Pavlina(CZ)
LUNDBERGH, Ivar (SE)
MARTÍN, Esther (ES)
MIHALCEA UDREA, Mariana (RO)
REIERSON, Linda (NO)
RUSNAK Peter (SK)
SCHWÄGLER, Mark (DE)
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)
BERZANSKIS, Laurel (HCWH)
BUONSANTE, Vito (ClientEarth)
DEL CASTILLO, Francisco (CONCAVE)
DROHMANN, Dieter (ORO)
POOLE, Alan (ECETOC)
ROBLOT, Ophelie (CEPE)
STAIRS, Kevin (Greenpeace)
STODDART, Gilly (PETA)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
ANDERSSON, Niklas
BERCARU, Ofelia
BERNASCONI, Giovanni
BLAINEY, Mark
BROERE, William
CARLON, Claudio
CONSTANTIN, Camelia
DELOFF-BIALEK, Anna
DE WOLF, Watze
DREVE, Simina
FEEHAN, Margaret
IBER, Andrea
JOHANSSON, Matti
KARHU, Elina
KORJUS, Pia
MAZZEGA SBOVATA, Silvia
MÜLLER, Birgit
NAUR, Liina
RODRIGUEZ IGLESIAS, Pilar
RÖNTY, Kaisu
SIMON, Rupert
SOBANSKA, Marta
TAI, Kaihsu
VAHTERISTO, Liisa
VALENTINI, Marco
VASILEVA, Katya

Proxies

- COSGRAVE, Majella (IE) also acting as proxy of DEIM, Szilvia (HU)
- HUMAR JURIC, Tatjana (SI) also acting as proxy of BUSUTTIL, Ingrid (MT)
- MARIN, Esther (ES) also acting as proxy of DRUGEON, Sylvie (FR) and PISTOLESE, Pietro (IT)
- MIHALCEA UDREA, Mariana (RO) also acting as proxy of LULEVA, Parvoleta (BG)
- VESKIMÄE, Enda also acting as proxy of KOUTSODIMOU, Aglaia (EL) and KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
- WIJMENGA, Jan (NL) also acting as proxy of DUNAUSKIENE, Lina (LT) on the afternoon of 28 October

Experts and advisers to MSC members

BALCIUNIENE, Jurgita (LT) (expert to DUNAUSKIENE, Lina)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
DRAGUSANU, Mihaela (RO) (expert to MIHALCEA UDREA, Mariana)
GOMEZ CONTRERAS, Jeannette (NL) (expert to WIJMENGA, Jan)
INDANS, Ian (UK) (Expert to DOUGHERTY, Gary)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)

MALKIEWICZ, Katarzyna (SE) (expert to LUNDBRGH, Ivar)
NYITRAI, Viktor (expert replacing DEIM, Szilvia)
ZELJEZIC, Davor (HR) (expert to BASTIJANCIC-KOKIC, Biserka)

By WEBEX-phone connection:
During agenda item 10 from the European Commission: Giuseppina LUVARA and Jacek ROZWADOWSKI,

Case owners:
Representatives of the Registrants were attending under agenda item 7b for CCH-237/2014 and CCH-238/2014

Apologies:
BUSUTTIL, Ingrid (MT)
DEIM, Szilvia (HU)
DRUGEON, Sylvie (FR)
FINDENEGG, Helene (DE)
KOUTSODIMOU, Aglaia (EL)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
LULEVA, Parvoleta (BG)
PISTOLESE, Pietro (IT)

III. Final Agenda

ECHA/MSC-38/2014/A/38

Agenda
38th meeting of the Member State Committee

28-29 October 2014
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

28 October: **starts at 9:00 am**
29 October: **ends at 6:00 pm**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/038/2014
For adoption

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

Item 4 – Administrative issues

For information

Item 5 – Adoption of minutes of the MSC-37

- Adoption of draft minutes of MSC-37

MSC/M/37/2014
For adoption

Item 6 – Substance evaluation

3. *Decision making process*

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

ECHA/MSC-38/2014/001
For information

b. Short general update by the secretariat

For information

c. Short update on appeals

For information

4. *CoRAP update*

Community Rolling Action Plan (CoRAP) & MSC opinion development

Introduction of the draft CoRAP update by ECHA and first exchange of views on the draft CoRAP

ECHA/MSC-38/2014/014 with Annexes,
ECHA/MSC-38/2014/015 (Justification documents per substance)
For information and discussion

Item 7 – Dossier evaluation

Closed session for 7c
Indicative time plan for 7b is Day 1

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

ECHA/MSC-38/2014/002
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-38/2014/013

Compliance checks

MSC code	Substance name	EC number	Doc number
CCH-237/2014	ethylene carbonate	202-510-0	ECHA/MSC-38/2014/003-004
CCH-238/2014	ethylene carbonate	202-510-0	ECHA/MSC-38/2014/005-006
CCH-239/2014	ethylene carbonate	202-510-0	ECHA/MSC-38/2014/007-008
CCH-242/2014	buta-1,2-diene	209-674-2	ECHA/MSC-38/2014/009-010
CCH-247/2014	2-mercaptoethanol	200-464-6	ECHA/MSC-38/2014/011-012

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 cases returned from written procedure for agreement seeking in the meeting:

- CCH-227/2014[1] p-xylene EC No. 203-396-5
- CCH-229/2014[1] m-xylene EC No. 203-576-3
- CCH-243/2014[1] sodium dodecyl sulphate EC No. 205-788-1

For agreement

[1] Documents available in substance specific folders in MSC CIRCABC

d. General topics

Status report on on-going evaluation work

For information

Item 8 – SVHC identification

- Statistics on comments received in the public consultation on SVHC proposals

For information

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

- Status update on public consultation on 6th draft recommendation
- Time plan for the 7th recommendation process

For information and discussion

Item 10 – Request to MSC for an opinion in accordance with Article 77(3) c of REACH Regulation

a. Introduction of the ED request for an MSC opinion to RAC on persistency and bioaccumulation of the substances octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5)

ECHA/MSC-38/2014/016
For information

b. Time plan for MSC opinion development

ECHA/MSC-38/2014/017
For information

c. Task of the Rapporteur in drafting the opinion of MSC

ECHA/MSC-38/2014/018
For discussion & decision

d. Appointment of Rapporteur

For decision

Item 11 – Any other business

- Suggestions from members

For information

Item 12– Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-38

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	Update on Test method developments	ECHA/MSC-38/2014/019

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-38, 28-29 October 2014
(adopted at the meeting on 29 October 2014)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 5 – Adoption of draft minutes of MSC-37	
MSC adopted the revised draft minutes of MSC-37.	**MSC-S** to upload final version of the minutes on MSC CIRCABC and ECHA website by 4 November 2014.
Item 6 - Substance evaluation **5. *Decision making process*** **a. Written procedure report on seeking agreement on a draft decision on substance evaluation**	
MSC took note on the report.	**MSC-S** to upload on MSC CIRCABC the final ECHA decision agreed in written procedure, as indicated in document ECHA/MSC-38/2014/001.
b. Short general update by the secretariat	
MSC took note of the short update.	**MSC members** to inform their colleagues responsible for Substance evaluation planning and coordination about the information presented in the report and to encourage them to confirm with the respective Substance Managers the planning indicated in the booking table as the deadline for consultation with MSCA/ECHA approaches.
6. *CoRAP update* *Community Rolling Action Plan (CoRAP) & MSC opinion development* **Introduction of the draft CoRAP update by ECHA and first exchange of views on the draft CoRAP**	
MSC took note of the update.	**SECR** to publish the draft CoRAP as referred to MSC on the ECHA website, soon after MSC meeting. **MSC members** to inform their CoRAP counterparts on the receipt of potential clarifying questions by (co-)rapporteur during the context of the opinion drafting within the deadline given.
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-38/2014/002. **MSC-S** to provide COM for further decision making with documents (Draft Decision (DD), Response to comments (RCOM), outcome of the vote, justifications for "no" votes) of cases on which MSC did not reach agreement, as

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	indicated in document ECHA/MSC-38/2014/002.
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 (where appropriate): • CCH-227/2014 p-Xylene • CCH-229/2014 m-Xylene • CCH-237B/2014 Ethylene carbonate • CCH-238/2014 Ethylene carbonate • CCH-239/2014 Ethylene carbonate • CCH-242/2014 Buta-1,2-diene • CCH-243B/2014 Sodium dodecyl sulphate • CCH-247B/2014 2-mercaptoethanol MSC could not reach unanimous agreement on the following draft decisions as modified in the meeting, where appropriate: • CCH-237A/2014 Ethylene carbonate • CCH-243A/2014 Sodium dodecyl sulphate • CCH-247A/2014 2-mercaptoethanol	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases. **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 9 – Prioritisation of Candidate List substances for inclusion in Annex XIV Status update on public consultation on 6th draft recommendation Time plan for the 7th recommendation process	
MSC took note of the SECR's considerations regarding the Time plan for the 7th recommendation development process.	**SECR** to further consider the practical aspects of the suggested 7th recommendation timeframe and to present the Time plan for the MSC opinion development on the 7th draft recommendation at MSC-39 in December 2014.
Item 10 – Request to MSC for an opinion in accordance with Article 77(3) c of REACH Regulation a. Introduction of the ED request for an MSC opinion to RAC on persistency and bioaccumulation of the substances octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) b. Time plan for MSC opinion development c. Task of the Rapporteur in drafting the opinion of MSC d. Appointment of Rapporteur	
MSC agreed on the Indicative Time plan for MSC opinion development on this Article 77(3)(c) request and the Terms of reference (ToR) for the Rapporteur. Further, MSC agreed to mandate the MSC Chairman to identify and appoint a volunteering MSC member as a MSC rapporteur. If unsuccessful by 1 December, inform MSC and plan for further discussions at MSC-39.	**MSC Chairman** to identify the MSC member willing to act as a rapporteur for this opinion development and formalise its appointment by 1 December 2014 before MSC-39 plenary meeting.
Item 12– Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-38 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC CIRCABC by 30 October 2014.

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

Draft decisions unanimously agreed by MSC in WP:

Compliance checks (CCH)

MSC ID number	Substance name used in draft decision	EC number
CCH-226B/2014	Reaction products of propane-1,2-diol, propoxylated by amination of the terminal hydroxyl groups	618-561-0
CCH-240B/2014	Citral	226-394-6
CCH-241B/2014	N,N''-(isobutylidene)diurea	228-055-8
CCH-244B/2014	Sulphur hexafluoride	219-854-2
CCH-246B/2014	Reaction mass of ((propane-2,2-diylbis(4,1-phenylene))bis(oxy)) bis(2-hydroxypropane-3,1-diyl) bis(2-methylacrylate) and 1-hydroxy-3-(4-(2-(4-(2-hydroxy-3-(methacryloyloxy)propoxy)phenyl)propan-2-yl)phenoxy)propan-2-yl methacrylate	500-089-0
CCH-248/2014	Tetrasodium (1-hydroxyethylidene) bisphosphonate	223-267-7

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

Testing proposal examinations (TPE)

MSC ID number	Substance name used in draft decision	EC number
TPE 053/2014	Middle distillate from refinery process cofeeding vegetable oil	938-793-9

Compliance checks (CCH)

MSC ID number	Substance name used in draft decision	EC number
CCH-226A/2014	Reaction products of propane-1,2-diol, propoxylated by amination of the terminal hydroxyl groups	618-561-0
CCH-240A/2014	Citral	226-394-6
CCH-241A/2014	N,N''-(isobutylidene)diurea	228-055-8
CCH-244A/2014	Sulphur hexafluoride	219-854-2
CCH-246A/2014	Reaction mass of ((propane-2,2-diylbis(4,1-phenylene))bis(oxy)) bis(2-hydroxypropane-3,1-diyl) bis(2-methylacrylate) and 1-hydroxy-3-(4-(2-(4-(2-hydroxy-3-(methacryloyloxy)propoxy)phenyl)propan-2-yl)phenoxy)propan-2-yl methacrylate	500-089-0

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-227/2014	p-Xylene	203-396-5
CCH-229/2014	m-Xylene	203-576-3
CCH-243A/2014	Sodium dodecyl sulphate	205-788-1
CCH-243B/2014	Sodium dodecyl sulphate	205-788-1