MSC/M/33/2013
ADOPTED AT MSC-34

Minutes
of the 33rd Meeting of the Member State Committee (MSC-33)
10-13 December 2013

I. Summary Record of the Proceedings

Item 1 - Welcome and Apologies

The Chair of the Committee, Ms Anna-Liisa Sundquist, opened the meeting and welcomed the participants to the 33rd meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

Item 2 - Adoption of the Agenda

The Agenda was adopted as modified at the meeting based on the draft agenda as provided for the meeting by the MSC Secretariat and a member's suggestion for inclusion of one sub-item under AOB (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-33.

Item 4 - Administrative issues

No administrative issues were announced or discussed.

Item 5 – Adoption of the minutes of the MSC-32 meeting

SECR presented the revised version of the MSC-32 minutes informing MSC that written comments on the draft minutes were received in advance of the meeting and at the meeting. The minutes were adopted with some changes to the draft. SECR would upload the minutes on MSC CIRCABC and ECHA website.

During the discussion it was agreed that, following a request to do so, the representative of the Member State abstaining from any vote taken during MSC meetings would be reflected in the MSC meeting minutes.

Item 6 – Substance evaluation decision-making

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

SECR gave a report on the outcome of the written procedure (WP) for agreement seeking on one substance evaluation case[1]. WP was launched on 14 November 2013. On the closing date 25 November 2013, WP on this draft decision (DD) was terminated by the MSC Chair on the basis of Article 20.6 of the MSC Rules of Procedure due to a receipt of a MSC member's comments suggesting discussion on a specific issue in the draft decision, without challenging the possibility for agreement on the DD.

b. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA/ECHA reactions (Session 1, tentatively open session)

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

SEV-SE-029/2012 2-(4-tert-butylbenzyl) propionaldehyde (EC No. 201-289-8)

Session 1 (open)

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

eMSCA expert from Swedish CA presented the outcome of SEv of the above-mentioned substance performed by SE CA on the basis of the initial grounds for concern, i.e. relating to human health effects for reproductive toxicity, worker and consumer exposure and wide dispersive use. The members were guided through the information

[1] Decahydronaphtalene (EC No. 202-046-9), evaluated by Finnish CA

requirements and explained that potential endocrine disrupting (ED) properties and potential developmental toxicity were identified as additional grounds for concern during evaluation by SE CA.

PfAs were submitted by five MSCAs and ECHA.

PfAs recommended specifying in the DD the test substance to be used, since there are two different purity grades registered for the same EC and CAS number;

PfAs for the potential endocrine disrupting properties, suggested rejecting the OECD 234 Fish Sexual Development study because of a large number of fish to be used in the test and instead proposed that OECD level 3 environmental ED testing be performed (OECD TG 229 or 230); proposed the request for an uterotrophic bioassay in rodents (test method OECD TG 440) to be removed from the DD and the need for such study to be re-considered by the eMSCA when assessing the results of the tests required by the decision. On the other hand, another PfA on the same endpoint, proposed to keep this information request for an OECD 440 study (as well as for OECD 443 study) but to delete the sentence making the uterotrophic study dependent on the results of OECD 443.

PfAs for the reproductive toxicity endpoint supported the request for Extended one generation reproductive toxicity study (EOGRTS) (OECD TG 443), but proposed the test to be performed without the extension of Cohort 1B to mate the F1 animals to produce an F2 generation and with the assessment of the developmental immunotoxicity (DIT) cohort in addition to originally proposed assessment of the developmental neurotoxicity (DNT cohort). In another PfA on this endpoint, three options were proposed to be considered by eMSCA, as follows: Option 1 - Rejection of the EOGRTS on the basis that sufficient information is available; Option 2 – Reject EOGRTS but conduct a DNT (OECD TG 426) study with inclusion of specific investigations for choline esterase inhibition or Option 3 - Conduct of the EOGRTS without extension to include the F2 generation. ECHA also made proposals for a few further specifications in sections II and III of the DD for this endpoint.

The eMSCA responded to the PfAs (RCOM) and amended the DD provided for the meeting in accordance with the PfAs regarding uterotrophic study by deleting the request for this study provided that the request for EOGRTS remains in the DD, since it may be sufficient to conclude about the ED properties on health based on EOGRTS. eMSCA included a request for DIT cohort and modified the justification for F2.

Registrant's comments on PfAs and discussion

The Registrants in the extensive written comments and during the discussion in the meeting on the PfAs opposed the requirements to carry out an OECD 234 Fish Sexual Development Test based on the claim that there is no relevant environmental exposure, no evidence of bioaccumulation and that 90% removal of the substance within 24 hours has been seen in sewage treatment plants. Furthermore, the Registrants opposed the OECD 234 with respect to the scientific value of the *in vitro* study which leads to the suspicion of endocrine potential. According to the Registrant, no effects would be observed in a guideline study and numerous test animals would be sacrificed without any scientific benefit because the tested concentrations were 450.000 fold higher than the reported environmental concentration (Gargosova *et al*. 2013).

The Registrants gave additional information on the purity grades registered and an overview on the use of the substance, i.e. trace amounts in fragrance mixes (no food use) for household and cosmetic products (pure grade) or intermediate use (technical grade), resulting in low and solely dermal exposure. The Registrants pointed out that the substance is not and will not be used in oral applications and further referred to the existing IFRA Standard which restricts the use of the substance in dermal applications due to its allergenic property.

The Registrants agreed with deleting the requirement for an Uterotrophic bioassay. The Registrants considered that there is no confirmation or evidence for an endocrine disrupting potential (no effects observed in female reproductive organs, fast metabolism of substance, testes toxicity not ED dependent). The Registrants had the view that overall the blood plasma choline esterase depression induced by the substance does not justify a study on developmental neurotoxicity and state that DNT module of OECD TG 443 needs to be triggered and that the current database does not suffice as such a trigger. The Registrants stated that there are no clinical signs for neurotoxic effects seen in six different species and brain choline esterase activities (measured with low standard deviations) were not affected in a repeated dose, a developmental toxicity and a reproductive toxicity study. On a practical aspect, the Registrants foresaw technical complications and the need for method development related to the proposed examination of acetyl cholinesterase activity tissues (e.g. peripheral neurons) especially in rat pups with low body weights. Furthermore, the Registrants agree with option 1 of the MSCA making the PfA and are of the view that there are no remaining concerns justifying options 2 or 3 given above due to a database sufficiently covering the endpoint "reproductive toxicity", testes toxicity as leading reproductive toxicity effect in rats and intended testing at a non-human relevant route, i.e. oral.

Session 2 (closed)

MSC concluded to request Fish Short Term Reproduction Assay; test method OECD TG 229 instead of to the originally proposed test OECD TG 234 because the evidence on the potential ED property is not very strong as it comes mainly from an *in vitro* study. According to the Fish Toxicity Testing Framework document (OECD Environment, Health and Safety Publications, Series on Testing and Assessment, No. 171 (ENV/JM/MONO(2012)16)) one of the key factors when deciding on testing requirements for ED properties in the aquatic environment is the strength of the evidence indicating ED. It was recognised that OECD TG 229 would be only a screening test not providing confirmatory information on ED property but on the other hand using a lower number of fish when compared to the originally proposed test OECD TG 234. It includes diagnostic endpoints of hormonal activity and the apical endpoint fecundity (indicating apical effects on reproduction). It was also suggested that possibly the results of the EOGRTS could be used as supporting information when deciding whether there would be any need to continue with a further fish study when results of OECD 229 would be available.

Regarding EOGRTS in rats, oral route (OECD TG 443) MSC concluded to include the extension of Cohort 1 B to mate the F1 animals to produce the F2 generation which shall be kept until weaning and the Cohorts 2 and 3 to assess DNT and DIT. Regarding the F2 generation MSC concluded that in this case it is required so as to address the functional fertility and reproductive performance of the generation exposed already during development as justified by the concern related to endocrine disrupting potency together with the indication of reproductive toxicity after adult exposure. In addition to the standard clinical biochemistry / haematological parameters, examination of acetyl cholinesterase (AChE) activity in different compartments including plasma, erythrocytes, brain, peripheral neuronal system in parental animals F0 and offsprings F1 shall be undertaken. MSC found no reason to delete the DNT/DIT cohorts on the basis of the information on the substance. Furthermore, inhibition of blood (plasma or erythrocyte) AChE indicated a potential for adverse effects on the nervous system. Justification for testing of immunotoxic effects refers to aldehyde-structure of the compound, suspected ED mode of action, and signs of hypertrofi of zona fasciculata in adrenal glands. In Section III, statement of reasons, further clarifications were included as regards the justification and details for the Fish Short Term Reproduction Assay and the EOGRTS.

MSC concluded also not to request Uterotrophic bioassay in rodents at this stage of evaluation. Notes were included in Section III indicating that further testing maybe of relevance to address the mode of action depending on the results of the requested studies.

Following the above considerations, MSC unanimously agreed on this SEV DD as modified at the meeting. The members from UK and NL abstained from the vote.

SEV-ES-012/2012 2-Ethylhexanoic acid (2-EHA) (EC No. 205-743-6)
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.

eMSCA expert from the Spanish CA presented the outcome of SEV of the above-mentioned substance performed by Spain on the basis of the initial grounds for concern, i.e. those relating to human health/CMR, exposure/wide dispersive use, consumer use, high aggregated tonnage and risk characterisation ratio being close to 1. The presentation also introduced the issues related to additional concern that was identified during the evaluation for postnatal development due to potential neurodevelopmental toxicity. The members were introduced that the actual request in the draft decision was for reproductive toxicity (extended one generation reproductive toxicity study (EOGRTS) (OECD443) with F2 including DNT and DIT cohorts).

The eMSCA expert explained that four PfAs to the DD were submitted, all supporting the request to conduct EOGRTS but each with some amendments to the original request, either specifying that the study should be conducted without F2 generation and DIT and DNT cohorts, or with inclusion of the DIT/DNT cohorts.

eMSCA had modified the DD for the meeting based on PfAs from one MSCA and the version updated with procedural steps was provided to MSC for finding unanimous agreement.

Registrant's comments on PfAs of CAs and discussion

The Registrant provided comments on the PfAs and suggested using Weight of evidence approach to conclude the concern for fertility. The representative of the Registrant indicated agreement with the PfA that suggested that the requirement for Cohorts 2A and 2B for DNT and Cohort 3 for DIT should be waived. He stated also that the effects that were observed were not marked referring to the comments of one MSCA (no PfA in this respect), and not dose-related. In his view the request for OECD443 had no scientific justifications nor was justified due to animal welfare reasons. Reference to limited laboratory capacity to conduct the test including F2 and the two cohorts was also brought forward.

SECR responded that there were no PfAs to reject EOGRTS so only the 2nd generation and the need for the DIT/DNT cohorts will be further discussed.

One expert explained that a concern for an adverse effect on fertility may exist but was of the opinion that any adverse effects would be clear after one-generation. Regarding the exposure concerns which were considered for the 2nd generation request, the eMSCA expert explained further that it originates mainly from exposure to 2-EHA resulting from some other substances breaking down to 2-EHA and more specifically from some metal salts or esters.

Potential neurodevelopmental toxic effect of this substance was discussed based on the available data and further testing appeared clearly justified.

Session 2 (closed)

Based on the above considerations, MSC agreed unanimously to amend the draft decision. As regards the need for the 2nd generation MSC concluded that the extension of the Cohort 1B to produce the 2nd generation needs to be considered to be considered before termination of F1 is decided when the results from the study do not allow drawing a clear conclusion. MSC agreed that both the developmental immunotoxicity and developmental neurotoxicity concern of 2-EHA needs to be addressed because there is no scientific reason to omit these cohorts on the basis of available information and

substance specific justifications are included in the DD for request of DNT and DIT cohorts. MSC found unanimous agreement on ECHA's DD as amended at the meeting.

SEV-DE-008/2012 2,2'-Iminodiethanol (EC No. 203-868-0)
Session 1 (open)
Two representatives of the Registrants participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

eMSCA experts from German CA presented the outcome of SEV of the above-mentioned substance performed by DE CA on the basis of the initial grounds for concern, i.e. relating to human health/ potential formation of CMR transformation products, exposure/wide dispersive use and high aggregated tonnage. The members were guided through the information requirements and explained that human health effects of 2,2'-iminodiethanol (DEA) were additional grounds for concern identified during evaluation by DE CA.

Two PfAs were submitted.

One PfA supported the request for OECD TG 443 with the DNT and DIT Cohorts but without the extension of Cohort 1B to mate the F1 animals to produce an F2 generation and proposes to add a sentence in Section III.1 noting that even if the findings of the available RDT studies may be sufficient for classification as repro 1B (fertility) the results are not sufficiently robust for risk assessment for the endpoint fertility as only adult animals are studied in RDT studies (i.e. these do not investigate whether fertility later in life would be affected by exposure to the substance during earlier life stages of the organism which would be the case if investigated in the EOGRTS). In a PfA on OECD TG 443, it is suggested that substance specific reasons should be provided why the inclusion of Cohort 1B to mate the F1 animals to produce F2 generation should be omitted by reference to the wording of the test guideline on this subject. A justification is provided in the PfA why it is thought that F2 is needed and is of the view that substance specific reasons for requesting F2 can be included in DD. Furthermore, regarding exposure assessment and risk characterisation for the carcinogenic transformation product, it was suggested in one PfA that more clarity should be brought to the DD Section II with regard to the exposure assessment and risk characterisation for the carcinogenic transformation product resulting from the manufacturing and use of the registered substance, in particular concerning downstream uses. It is noted in the PfA that the registrant may not have access to monitoring information of downstream users, e.g. to biomonitoring data of downstream users (DU) to consider exposure via dermal route, in order to be able to support the uses and carry out the assessment for safe use. If the measures recommended to the downstream users are not able to ensure safety of the particular use, the registrants would need to advice against such use. Consequently, the DUs who wish to continue the use would need to prepare and submit their DU chemical safety assessment and submit it to ECHA. In one PfA it is proposed the eMSCA to include its summarised reflections on the Registrants' comments on the initial DD in Section III for transparency reasons.

eMSCA has responded to the PfAs (RCOM) and amended the DD prior the MSC meeting by including the sentence proposed for Section III.1 and substance specific reasons why the inclusion of Cohort 1B to mate the F1 animals to produce F2 generation should be omitted. Regarding the proposal for amendment to advise against a downstream use for which sufficient information is not available to assess the safe use the eMSCA considered that there are not sufficient grounds to require the Registrant to advice against such use as risk was not identified, and when the Registrant cannot provide information the risk is not clear. In such case the Registrant needs to withdraw the identified use. eMSCA amended the DD for the meeting by specifying further how the realistic information on exposures could be obtained for exposure assessment and risk characterisation for the carcinogenic transformation product.

Registrant's comments on PfAs and discussion

The Registrants provided written and oral comments on the amended DD and the PfAs received. In their comments, the Registrants agreed with OECD 443 request with DNT/DIT cohorts but without the extension of Cohort 1B to mate the F1 animals to produce an F2 generation and thus disagree with PfA to request the F2 generation. The Registrants provided substance specific arguments why in their view the F2 generation (Cohort 1B) should be omitted. The registrants also agreed to perform an exposure assessment and risk characterisation for the carcinogenic transformation product (2, 2´-(nitrosoimino) bisethanol (N-Nitrosodiethanolamine, NDELA), CAS No. 1116-54-7) resulting from the manufacture, using as the basis the defined safe dose and comparing it with the available DMEL as well using the latest publications on the substance and company specific data on measurements. Further, the Registrants disagreed with the sentence proposed to be included in Section III.1, as they are of the view that the existing data do not support classification for fertility effects and they express the view that they would withdraw the agreement to conduct OECD 443 if the substance was classified for fertility before test results are available. The Registrants provided substance specific arguments why in their opinion a classification for fertility is not justified. The Registrants did not agree to generate any new data before the CSA has been updated and the assessment would show a need for new data. The Registrant proposed to start with the exposure assessment and risk assessment based on the available literature data and risk management measures at the downstream users, followed by a step-wise measurement approach if necessary. However, they disagreed with the PfA to perform an exposure and risk assessment for the downstream users via measurements or to enter an advice against all downstream uses into their MSDS and registration dossier. The Registrant further clarified that as regards the identified uses, a revised use pattern and exposure sampling of the uses have been recently made and some of the previously announced uses in their registration dossiers are currently irrelevant. Therefore, as the list of the substance's uses has become shorter, the Registrant considers possible to examine all downstream uses for removing the burden to the downstream users in this regard.

SECR strongly encouraged the Registrants to ensure that the substance information provided in the CSR of their registrations, as well as in the MSDS is kept updated.

Session 2 (closed)

MSC concluded not to request the F2 generation when conducting OECD 443. MSC also concluded that the Registrants shall also submit in a revised version of the chemical safety report an exposure assessment and risk characterisation for the carcinogenic transformation product 2,2'-(nitrosoimino)bisethanol CAS No 1116-54-7 (EC No 214-237-4) resulting from the manufacturing and use of the registered substance in particular, in downstream use(s). In Section III, further clarifications were included relating to the above mentioned requirement and also related to the request for Extended One Generation Reproductive Toxicity Study and the information requests related to the registered substance. As regards the assessment of DU exposure, Section III was modified clarifying further the requirements for such data and also allowing for example that the information for that purpose can be obtained from several sources and not only based on measured data by specific DUs but also at the same time clearly stating that the exposure assessment cannot be based only on modelled data for all given scenarios. The real work place conditions to be used in the assessment should be representative for the European Union. The deadline for receipt of the information by ECHA was changed from 12 months to 15 months apart from the information on EOGRTS for which the deadline of 27 months was kept.

Following the above considerations, MSC unanimously agreed on this SEV DD as modified at the meeting.

SEV-FR-016/2012 1,3-diphenylguanidine (DPG) (EC No. 203-002-1)
Session 1 (open)

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

eMSCA expert from French CA presented the outcome of SEV of the above-mentioned substance performed by FR CA on the basis of the initial grounds for concern, i.e. relating to human health/CMR, exposure/high tonnage, risk characterisation ratio>1 (human health). The members were guided through the information requirements and explained that environmental fate of the substance and composition of the substance were additional grounds for concern identified during evaluation by FR CA.

Five PfAs were submitted by three MSCAs.

Regarding the mammalian erythrocyte micronucleus test *in vivo* and Ames mutagenicity study, one PfA proposed that a positive or equivocal finding for gene mutation *in vitro* should also be followed up and suggested adding under Section II a request for a comet assay in the case of a negative result in the requested micronucleus test. Likewise, based on equivocal or positive gene mutation tests *in vitro* another PfA proposed to request an *in vivo* comet assay to ensure sufficient information on genotoxicity but proposes to combine micronucleus test with the comet assay. In the absence of internationally adopted test guideline for the comet assay a PfA proposed to make a reference to EFSA (2012) guidance on the use of comet assay (or to use OECD guideline if adopted at the time of conducting the test) and the other PfA proposes to make a reference to a guideline published by *Tice et al* (2000).

Secondly, with respect to the study on toxicokinetics which was proposed to be requested in case of non-conclusive results of the micronucleus test, Section III is proposed to be modified by explaining further why and how the toxicokinetic study should be performed to provide further insight in the potential genotoxicity of the substance.

Thirdly, another PfA proposed to request (in Section II) conditionally an extended one generation reproductive toxicity study (EOGRTS, OECD 443) in rats, oral route, without F2 and with DIT and DNT cohorts to address toxicity on the complete reproductive cycle, unless other studies indicate the substance is a germ cell mutagen and appropriate risk management measures are implemented. This request was justified with findings in repeated dose toxicity studies and reproductive toxicity screening studies. Regarding quantification of aniline produced from 1,3-diphenylguanidine (DPG), one CA proposed to include explicitly a request for an occupational exposure assessment and a corresponding risk assessment for all life cycle stages and to make a reference to the specific ECHA guidance (R.14).

The eMSCA has responded to the PfAs (RCOM) and modified the DD prior the MSC meeting motivated by PfAs and the registrants' comments regarding micronucleus study and mutagenicity testing as well as regarding the PfA concerning toxicokinetic study and included the reference to ECHA guidance R14.

Registrant's comments on PfAs and discussion

The Registrants provided comments on the whole draft decision and other issues and not only on the PfAs. In their comments to the PfAs the Registrants agreed to perform a new mammalian erythrocyte micronucleus test. However, they would not consider justified the request for a comet assay because they have the view that present results of the several gene mutation tests, with exception of a few doubtful positive results, are negative or equivocal and would not justify a request for an *in vivo* mutagenicity study

(a comet assay). Due to the questionable results in the Ames test, the registrant proposes in first instance to perform a new Ames test using a test sample representative of the purity of the actual production. A step-wise approach is proposed by the registrant to first conduct the Ames test with and without S9 (OECD 471) and if the Ames test is negative to perform an *in vivo* micronucleus test (OECD 474) and if the Ames test is positive or equivocal to perform an *in vivo* combined comet/micronucleus test on rats by gavage. For the proposal on EOGRTS, the Registrants state that on weight of evidence based on the reliable experimental data, it can be concluded that DPG is not a reproductive toxicant. Necessity for DIT and DNT cohorts should be based on weight of evidence approach and based on the existing knowledge DPG is not suspected to be a neurotoxicant or an immunotoxicant.

The representative of the Registrants confirmed that they would be willing to conduct the tests in sequence as already indicated in their written comments and that they would accept to carry out the micronucleus test *in vivo*.

One member emphasised the possibility to ask for an *in vitro* mutagenicity test before proceeding to *in vivo* testing. The expert of eMSCA stated that *in vitro* tests and an *in vivo* micronucleus test (equivocal) are already available but could not lead to any conclusion. Thus another *in vivo* test is needed to be able to conclude on mutagenicity of DPG and its metabolites. Moreover an *in vitro* test would not be considered as conclusive in itself. The Registrant on the other hand stated that there is no need to perform other *in vitro* tests since if comet assay is negative they would prefer to perform another *in vivo* micronucleus test to remove the doubt.

Session 2 (closed)
MSC concluded to revise the tiered testing strategy for genotoxicity by requesting the Ames test as tier 1 and the combined *in vivo* Mammalian Erythrocyte Micronucleus test and *in vivo* rat comet assay as tier 2 if the Ames test is positive or equivocal and to request the Micronucleus test *in vivo* if the Ames test is negative and to include reference to ECHA guidance on occupational exposure estimation (R.14).

As response to one of the PfAs, MSC concluded to add further argumentation in Section III, statement of reasons on the way forward in dealing with the data gap in the registration dossiers compared with the standard information requirement on reproductive toxicity according to REACH Annex X, Section 8.7.3. since it is not currently possible for the evaluation MSCA to make a final conclusion on these endpoints.

Following the above considerations, MSC unanimously agreed on this SEV DD as modified at the meeting.

SEV-NL-024/2012 Hexyl salicylate (EC No. 228-408-6)
Session 1 (open)

One representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.
eMSCA presented the outcome of SEV of the above mentioned substance performed by NL-CA on the basis of the initial grounds for concern, human health/suspected CMR, exposure/wide dispersive use, consumer use, high aggregated tonnage, and risk characterisation ratios close to 1 (human health). An additional concern was identified during the evaluation regarding the local toxicity via the inhalation route. Five PfAs were submitted to DD. The first PfA proposed to amend the DD to clarify that whether the initial concern for substance evaluation was only reproduction toxicity exclusively and not carcinogenicity or mutagenicity. The CA proposed to include a request that a substance specific justification should be used in the CSR if using other than default assessment factors in the estimation of the DNELs. Another PfA was to amend the DD by redrafting the reasoning for or deleting the requirement of *in vitro* dermal absorption

study suggesting to apply the default dermal absorption values in accordance with the ECHA Guidance. Regarding the need for a 28-day repeated dose toxicity study in the rat by inhalation a PfA proposed to redraft the reasoning or delete the need for this test. Finally a general PfA was submitted to reflect the registrants' comments in Section III of the DD.

eMSCA explained that DD has been amended based on the first PfA by stating clearly that only the reproductive endpoint was meant to be evaluated, enabling further evaluation of carcinogenicity and/or mutagenicity later if concern for these exists, and asking for substance specific justification on using other than default assessment factors for DNEL derivation. Based on the PfA by ECHA, eMSCA also agrees to amend DD to better reflect in DD the comments from the Registrant and the reflections of eMSCA. DD was not amended based on PfAs on dermal absorption and 28-day repeated dose toxicity study in rat by inhalation because information beyond REACH standard information requirements can be asked in the SEV process, using default skin absorption values according to ECHA Guidance would lead to RCRs>1, and since local effects in airways cannot be considered negligible based on the uses of the substance and local effects by inhalation cannot be excluded based results available from studies not directly addressing this specific concern.

Registrant's comments on PfAs of CAs and discussion

The Registrants provided written comments on the PfAs and on the DD itself. The Registrants stated that they still believed the available dermal absorption studies and the computer model were reliable but noted that using default values according to ECHA Guidance would not be correct either, and that the *in vitro* test should not be required. As for the 28-day inhalation repeated dose study, the Registrants noted that no reasons had been given as to why the justifications of the Registrants, which are based on read-across approach on isoamylsalicylate (tests not via inhalation route), that the study was not needed were not considered valid. The Registrants feel that in their replies to the Registrants' comments eMSCA did not sufficiently justify the extrapolation from skin irritation/sensitisation to respiratory irritation/skin sensitisation; did not here address the absence of eye irritation in relation to respiratory irritation; and did not agree that the respiratory route exposure will be low in view of the vapour pressure of the substance and the used concentrations in the product and thus indicate minimal inhalation exposure, as eMSCA also considered spraying might result in inhalation exposure. Regarding worker exposure (for which no PfAs were launched) the Registrants agreed to carry out the assessments except for the decision point 3(b) (Perform enquiry for quality control employees to provide realistic exposure assessment).

The representative of the Registrants gave an overview of the Registrants' concerns at the meeting, restating the arguments of the written comments and emphasized that the 28-day study would not reveal respiratory sensitivity in light of existing information and because no animal study can be used for testing of respiratory sensitisation.

The expert of eMSCA further explained that the proposed read-across to isoamylsalicylate is not acceptable because no inhalation testing results are available (route-to-route extrapolation not possible) and because isoamylsalicylate is not an irritant. It was explained that the aim for the 28-day study is to obtain a local inhalation DNEL protective for workers and consumers, noting that this would not be requested for classification purposes, and justifying the study on observing irritation or sensitisation causing certain inflammation effects triggered by the immune system.

Session 2 (closed)

eMSCA explained regarding the 28-day inhalation study that there was a data gap for such information on any of the salicylates as argued in the response to comments and that the read-across to isoamylsalicylate is not justified as explained in DD, which

justifies to carry out this study. The representative of the MSCA, which had provided in its PfAs supporting argumentation against the requested studies accepted the provided arguments of eMSCA for the *in vitro* skin absorption and 28-day inhalation study. SECR encouraged to cover all concerns in SEV where possible and acknowledged that in this SEV the initial concern on reproduction toxicity has been addressed as initially there was no intention to cover carcinogenicity or mutagenicity concerns in this evaluation. Based on the above considerations, MSC agreed unanimously not to further amend the DD. MSC found unanimous agreement on SEV DD on hexyl salicylate as provided for the meeting.

SEV-UK-032/2012 Alkanes, C14-17, chloro (MCCPs) (EC No. 287-477-0)
Session 1 (open)

One representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.
eMSCA expert from UK CA presented the outcome of SEV of the above-mentioned substance performed by UK CA on the basis of the initial grounds for concern, i.e. relating to the need to check current exposure scenarios for the environment to ensure that the risk characterization ratios are all below one, and to review the registrants' persistence, bioaccumulation and toxicity (PBT) assessment.

One PfA was submitted. It proposes the eMSCA to reflect the registrants' comments on the DD in Section III, paying particular attention to the choice of constituents selected for bioaccumulation and persistence tests and to the need for multiple tests for the same endpoint.

The eMSCA has responded to the PfA (RCOM) and amended the DD as suggested prior to MSC meeting.

Registrant's comments on PfAs of CAs and discussion

The Registrants provided comments on the DD and they seem to focus in the comments on those parts of the DD where amendments were introduced based on the comments of the Registrants on the initial DD and not on the PfA. However, part of the comments concern the choice of the substance(s) required to be tested and the need for multiple tests for one endpoint for the same substance, as pointed out in the PfA. The Registrants commented that the proposed approach of testing "representative" individual carbon length chloroalkanes for the assessment of MCCPs is fundamentally inappropriate because one cannot determine what is a representative chloroalkane of MCCP, there are no means of selectively making a single representative test chemical of MCCP (any such test material would also be a mixture), and the proposed approach would require the testing of (non-commercial) UVCB substances to represent the actual (commercial) UVCB substance.

Instead, the Registrants stressed that testing the UVCB substance placed on the market would be a preferable approach. When performing the tests with the substances as presented in this DD knowing the precise reason for a given experimental observation would be very difficult and the conclusion will never be known absolutely. They even stressed that there are better ways to test the hydrophobic chloroalkanes than the ones being proposed. In their view the costs of the proposed tests are quite high with questions raised on the applicability of the OECD TG 308 test. However, the Registrants agree with other areas of the DD.

The expert of the eMSCA stated that because the evaluation has identified several carbon chain length and chlorine content combinations present in commercial products that meet the PBT screening criteria, it is therefore important to generate further information on these constituents to clarify this concern.

Although there was no PfA provided by the CAs two members brought up a concern for further testing and felt that the substance could have been considered as PBT/vPvB without a need for further testing.

Session 2 (closed)

MSC concluded to keep the relevant argumentation in Section III that was added by the eMSCA before the MSC meeting on the rationale for the choice of the test substances to generate information for comparison with the Annex XIII criteria, since a single product type does not exist. Also in response to the Registrants comments, the word 'representative' was removed from the naming of the test substance to avoid unintentional ambiguity about the meaning of this term.

Based on the above considerations, MSC agreed unanimously not to amend DD. MSC found unanimous agreement on SEV DD on Alkanes, C14-17, chloro as provided for the meeting. The member from DE abstained from the vote.

SEV-FI-014/2012 Decahydronaphtalene (EC No. 202-046-9)
Session 2 (closed)
This SEV case was returned from the written procedure as mentioned in item 6a above because one member pointed out that the DD made a reference to the draft SEV report and raised a need for a general discussion whether such reference in a decision was appropriate. The expert from the Finnish CA introduced the case by explaining that since for this substance there was only one registrant there were no confidentiality matters, so they shared the SEV report with the Registrant in the beginning of the decision making process. This proved to be quite useful and therefore they did not see a problem to make a reference to the draft SEV report in the DD. However, it was concluded by MSC (based also on conclusions of one of the substance evaluation workshops) that because the decision should be a self-standing document with full justification to all information requirements any reference to the draft SEV report as providing explanation to the information requirements should be removed from the DD. It was also noted that the report at the time of the decision will be only a draft and therefore confusion may arise later when further modifications may be introduced to the report to finalise it.

Following the above considerations, MSC unanimously agreed on this SEV DD by deleting the reference to the draft SEV report and by introducing the corresponding reasoning in Section III of DD itself.

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 three dossier evaluation cases (see Section VI for more detailed identification of the cases). WP was launched on 14 November 2013 and closed on 25 November 2013. By the closing date, responses to WP were received from 25 members with voting rights and from the Norwegian member. Unanimous agreement was reached on all three DDs.

b. Update on appeal cases (closed session)

SECR provided MSC with feedback from the appeal cases on dossier evaluation decisions. As no information on the latest appeal cases had yet been published at the time of the meeting, a closed session was organised.

c. General topics

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

Item 8 – Community Rolling Action Plan (CoRAP) update

- **Preparations for the MSC opinion on the draft Community Rolling Action Plan (CoRAP)** Report by the Rapporteur and discussion on the first draft opinion of MSC followed by exchange of views on the draft opinion

The Rapporteur introduced the working group (WG) members and explained how they worked in order to come up with the draft opinion. The documents as a basis for their opinion were the draft CoRAP Update 2014-2016, the 2011 selection criteria and the justification documents prepared by the evaluating MSCA on each substance found in the draft CoRAP Update. The WG and the rapporteur were of the opinion that for all substances on the draft CoRAP there are sufficient grounds to consider that the substance may constitute a risk for the environment and/or human health, thus the draft opinion supports the draft CoRAP.

Whilst going through the justification documents and filling in the Annex to the opinion, the WG came up with a list of questions which were then discussed at the meeting. The discussion focused mostly on two main issues.

Firstly, on whether a reference to a decision/ selection by an (ECHA) expert group is considered as sufficient justification. It was agreed that the full justification as given by an expert group has to be part of the justification and not just a reference to a fact sheet or a document that belongs to the expert group since such documentation are not available to the public. This would enhance clarity and transparency. Furthermore, MSC also discussed this issue of substances which had been subject to EU risk assessments before work under REACH started. For these substances in particular it is of importance that in the justification documents the reasoning for the inclusion of these substances in the CoRAP is sufficiently elaborated.

Secondly, it was mentioned that some substances fulfil only hazard related selection criteria and not exposure or based on potential risk selection criteria, consequently the initial grounds for concern are hazard based. MSC discussed whether this is considered sufficient to support their inclusion under CoRAP. It was mentioned that the legal text says that SEv should be based on potential risk. Thus for inclusion under CoRAP exposure of a substance might not be the critical factor however, it should be the contributing factor to make the final selection based on potential risk. Regarding the substances where this was an issue the member from the MS responsible for the justification promised to update the justification documents of the relevant substances in order to improve the risk based justification. SECR explained that with regards to intermediates, they are trying to understand whether the definitions of transported isolated intermediate and strictly controlled conditions are met. If there are doubts or if they are not met, ECHA would place the substances for other processes, like subject to Article 36 measures or for dossier evaluation, meaning that SEV is not the preferred first step.

MSC was invited to send comments to the Rapporteur on the Annex and draft opinion by 7 January 2013 and to remind their evaluating CA to update the justification documents of the substances they are evaluating latest by end of January 2014 and preferably by 7 January 2014.

Item 9 – SVHC identification
Written procedure report on seeking agreement on identification of SVHCs

SECR gave a brief report on the outcome of the written procedure for SVHC agreement seeking on the identification of two substances, as follows: dihexyl phthalate proposed to be identified as SVHC based on Article 57 (c) due to its reproductive toxicity and cadmium sulphide proposed to be identified as SVHC based on Article 57 (a) and (f) as carcinogenic and as a substance of equivalent concern (kidney and bone effects) to the substances identified as SVHCs under Article 57 (a)-(e) of the REACH Regulation. It was explained that MSC agreed unanimously on identification of cadmium sulphide and dihexyl phthalate as SVHCs in the written procedure launched on 18 November and closed on 28 November 2013. The member from NL wanted to include in the minutes their view regarding cadmium sulphide: NL can support identification of cadmium sulphide as SVHC but according to their view inclusion of cadmium sulphide in the authorisation list could be debatable due to the importance of the substance for PV panel production. SECR indicated that the final documents have already been made available on MSC CIRCABC and on the ECHA website and the substances will be shortly be included in the Candidate List of SVHCs.

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

- **Update of the Priority Setting Approach for recommending substances for inclusion in Annex XIV**

SECR presented the changes that had been introduced to the draft document since the last meeting.

MSC welcomed the paper saying that it was providing a good reflection of the previous discussions and that the scoring and wide dispersive use-aspects have improved. In the following discussion several industry stakeholders took the floor to indicate their clear disappointment on how the information from industry has been used until now. In their view the use of information from the registration dossiers has been inconsistent, and it has been unpredictable/ not transparent whether the data submitted during public consultation versus the data in the registration dossiers is finally used. One industry stakeholder also indicated that it is very difficult to motivate various industry representatives to submit data in the public consultation when such submissions seem to be in vain. The same representative then continued on commenting on a few more technical details, among other things asking clarifications for scoring of substances that are present in capsulated forms or in a matrix. MSC members together with SECR responded to reiterate that all relevant information should be in the registration dossiers. SECR also explained that in responding to the comments one aim has been to clarify the type of information that could be taken into account but acknowledged that improving the transparency still further on the factors which are relevant for the prioritisation would be useful to all actors and that the new prioritisation approach aims also to improve the predictability. Addressing the further comment, it was noted that information on the form of the substance is often not available.

After few minor modifications MSC endorsed the updated draft priority setting approach which will then be applied when assessing the substances for prioritisation in the next recommendation by ECHA for inclusion in Annex XIV in 2014.

Item 11 – ECHA's draft recommendation of priority substances to be included in Annex XIV

- **Introduction of any changes to the draft recommendation documentation following the consultation**

SECR made an overview of latest updates made (as specified in documents ECHA/MSC-33/2013/027 and ECHA/MSC-33/2013/029) in the *draft recommendation*, *RCOMs* and

Background documents(BDs) for bringing further clarification on issues raised in MSC-32 meeting and during the MSC consultation on the 1st draft opinion (DO).

Item 12 – Opinion on the draft recommendation of priority substances to be included in Annex XIV

a. Discussion on the draft opinion based on the draft recommendation of priority substances to be included in Annex XIV

MSC rapporteur presented to the Committee the main modifications made in the revised draft opinion based on the oral and written MSC comments on the 1st DO and the updated recommendation documentation (RCOMs and BDs), as well as for consistency with the previous MSC recommendation opinions. Some general explanations were introduced in the introductory part of the opinion seeking to improve clarity regarding the objective of the opinion on one hand and on the other hand providing an opportunity to raise other issues, identified by members in the opinion-development process but not relevant for ECHA's recommendation process as such, i.e. not related to application of the prioritisation criteria or of the priority setting approach or specification of the parameters for the recommendation. Such matters were also presented and addressed in the draft opinion under 'Other issues' sections giving a possibility to list things that may be relevant for the later political decision making process at the Commission level but which cannot be taken up by ECHA when finalising the recommendation for submission to the Commission.

The draft opinion reflected upon ECHA's draft 5th recommendation on priority substances to be included in Annex XIV, of the following five substances: N,N-Dimethylformamide (DMF), Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA), Aluminosilicate Refractory Ceramic Fibres (Al-RCF), Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF) and 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO).

In the general discussion MSC supported the opinion as drafted by the Rapporteur jointly with the Working Group. The following specific issues were discussed and the outcome of the discussion included either in the opinion or in the minutes (see also the Annexes) of the meeting.

With regard to DMF, MSC was informed of the recently submitted intention by the Italian CA to prepare a restriction proposal for this substance in 2014. It was concluded that this late submission of a restriction intention (not yet published in the public Registry of Intentions) does not influence the MSC opinion as such at this stage of the recommendation process but depending on the scope of the envisaged restriction might have an impact when considering regulating the substance under REACH. SECR and several members noted that there are political, procedural and technical issues that would need to be further discussed by the appropriate fora (e.g. RiME, CARACAL, REACH committee) in this regard. However, as this is perceived not to be a task for MSC, the Committee concluded that a notation for the restriction intention could be made in the opinion under 'Other issues' section for this substance. Several MSC members highlighted the importance of having a consistent approach to address the aprotic solvents (DMF, DMAC, NMP) that should be consistently applied to all of them and encouraged ECHA and COM to work in this direction.

Further, seven members made a joint statement to the minutes (Annex V) with regard to the recommendation of DMF.

Based on the concerns expressed in MSC-32 meeting, seven members formulated and submitted a minority position to the MSC opinion with regard to the prioritisation of ADCA due to disagreement with ECHA on whether the prioritisation criteria are met. These members indicate that the scores for wide dispersive use should be lower and in their view, SECR has not considered sufficiently the information on risk management

measures in place provided by the concerned industry in their comments in public consultation. SECR provided response to these views and disagreed with these conclusions giving clarification on the ADCA scoring and the type of information taken into account in accordance with the legal criteria within the remit of the recommendation process. SECR provided further explanation on the comparative aim of the assessment made for different substances and the need, accordingly, to follow the same methodology for all substances, including ADCA. SECR explained that using 'other' criteria and methodology for ADCA prioritisation would challenge the comparative assessment between the substances.

Three other members, recognising that some of the concerns raised are either not relevant for this stage of the authorisation process, or not for MSC consideration, made statements on their concerns about recommendation of ADCA which are annexed to these minutes (Annex V).

In the discussion on RCFs, an STO asked for further clarification on the indicated volumes for Al- and Zr- RCFs (combining the volumes of RCFs used as substances and as substances in articles), as well as on how the new information provided in the public consultation and in the updated registration dossiers was considered in these substances' prioritisation assessment. SECR explained how registration information for RCFs was used and reminded that it is the responsibility of industry to identify whether a substance is used on its own or in an article when making the substance registration, further underlining that the basis for the prioritisation and the further decision-making process is the substance information provided in the registration dossiers; thus, it is essential that industry keeps their registration dossiers up-to-date.

A member expressed concern regarding the clarity of the substance definitions for RCFs that may lead to enforcement problems at a later stage. Four members sharing the same concern made a joint statement to the minutes (Annex V) with regard to RCFs' recommendation.

In response to an ASO observer's remark on the RCFs manufacturing and finishing under strictly controlled conditions and the lack of exposure to the workers, SECR explained that only part of the processes involved are closed, gave examples of steps where there is potential for exposure, and in addition noted that the whole substance lifecycle needs to be considered in the substance's prioritisation process.

No issues were raised with regard to 4-tert-OPnEO.

Following a member's request for clarification as regards SECR's response to requests for PPORD exemptions in draft Annex XIV entries, SECR noted that PPORD uses may be included in the authorisation applications if intended to occur after the sunset date of an Annex XIV substance; SECR expressed the view that PPORD uses for substances included in Annex XIV could be justified, e.g., in cases where they aim to improve the control of the risks subject to the authorisation process or to developing alternatives, clarifying that any PPORD uses can be applied for and can continue after the sunset date as long as the Commission grants an authorisation.

b. Adoption of the MSC opinion

MSC adopted the opinion on ECHA's draft 5th recommendation as presented by the rapporteur and further modified at the meeting.

In conclusion, SECR thanked MSC for the opinion including the minority view on ADCA on the 5th draft recommendation and the statements made to the minutes (Annex V) and promised to carefully consider them when finalising the recommendation for submission to COM. It was noted that several of the aspects included in the statements were already

addressed in the feedback provided for the meeting (e.g. RCOMs). the MSC opinion and the extract of the minutes with the statements will be provided to COM. Further, the COM indicated that further political discussion on the critical points of the authorisation process will be needed at the COM level. Recognising that some policy aspects play a major role in this process, SECR agreed on the need to increase common understanding on the implementation of the 3-step authorisation process in a more effective way.

Item 13 – Any other business

No suggestions were received from the members under this agenda item, however on request of a member the Chair allowed discussion on some specific issues related to substance evaluation. One topic concerned a delay after MSC agreement/no PfAs on the DEv DD in sending out the final decisions to the Registrants. A long delay in submission of the final decision can lead to a time problem for the eMSCA that is performing a substance evaluation on the same substance. SECR responded that finalisation and practical sending out of decisions does take some time, but can be improved, and also includes steps related to the publication of decisions. As regards substance evaluation SECR explained that those decisions would be on a different website from the compliance check and testing proposal decisions. In the context of the discussion about the possibility to share the draft SEV reports with the registrants MSC was reminded that a paper about informal interaction with the evaluating MS and registrants during SEV has been produced and endorsed by CARACAL giving some recommendations in that regard.

MSC was informed that a Workshop planned for February on Authorisation and SVHC has been post-poned due to the large number of SEV and DEV DDs on the agenda of the February meeting.

One member asked if categories and e.g QSARs can be discussed prior to agreement seeking so as to simplify the discussion during the agreement seeking phase. SECR responded by promising to organise a webex or teleconference to provide an opportunity for such discussion.

Item 14– Adoption of conclusions and action points
The conclusions and action points of the meeting were adopted at the end of the meeting (see Annex IV).

[*signed*]

Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
BASTIJANCIC-KOKIC, Biserka (HR)
BIWER, Arno (LU)
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
GAIDUKOVS, Sergejs (LV)
HUMAR-JURIC, Tatjana (SI)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina(CZ)
LULEVA, Parvoleta (BG)
MARTÍN, Esther (ES)
MIHALCEA UDREA Mariana (RO)
PALEOMILITOU, Maria (CY)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
WIJMENGA, Jan (NL)
Representatives of the Commission
BERTATO, Valentina (DG ENTR)
BINTEIN, Sylvain (DG ENV)
Observers
AIRES DO AMARAL, Maria José (HCWH)
ANNYS, Erwin (CEFIC)
MCIVOR, Emily (HIS)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
BROERE, William
CARLON, Claudio
DE WOLF, Watze
FEEHAN, Margaret
HALLING, Katrin
HUUSKONEN, Hannele
JOHANSSON, Matti
KARHU, Elina
KORJUS, Pia
KOULOUMPOS, Vasileios
KREUZER, Paul
MELZER, Kai
MÜLLER, Birgit
NAUR, Liina
O'FARRELL, Norah
PELLIZZATO, Francesca
RUOSS, Jürgen
RÖCKE, Timo
RÖNTY, Kaisu
SOBANSKA, Marta
SUNDQUIST, Anna-Liisa
VALENTINI, Marco
VAHTERISTO, Liisa
VASILEVA, Katya
WALKER, Lee
ZANDER, Joakim

Proxies

- MARTÍN, Esther (ES) also acting as proxy of DRUGEON, Sylvie (FR)
- PISTOLESE, Pietro (IT) also acting as proxy of CAMILLERI, Tristan (MT)
- RUSNAK, Peter (SK) also acting as proxy of ANDRIJEWSKI, Michal (PL)
- KOUTSODIMOU, Aglaia (EL) also acting as proxy of PALEOMILITOU, Maria (CY) on Friday
- STESSEL, Helmut (AT) also acting as proxy of HUMAR JURIC, Tatjana (SL) on Friday latter morning
- LULEVA, Parvoleta (BG) also acting as proxy of KOUTSODIMOU, Aglaia (EL) on Friday latter morning

Experts and advisers to MSC members

ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BRACQ, Elise (FR) (expert to DRUGEON, Sylvie)
CIESLA, Jacek (PL) (expert to ANRIJEWSKI, Michal)
GARCÍA, Patricia (ES) (expert to MARTíN, Esther)

HOLMEN TVERMYR, Marianne (NO) (adviser to REIERSON, Linda)
INDANS, Ian (UK) (expert to DOUGHERTY, Gary)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
LUNDBREGH, Ivar (SE) (expert to FLODSTRÖM, Sten)
NIEDERSTRASSER, Berndt (DE) (expert to FINDENEGG, Helene)
NEISEL Friederike (DE) (adviser to FINDENEGG, Helene)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
PEDERSEN, Finn (DK) (expert to TYLE, Henrik)
TRAAS, Theo (NL) (expert to WIJMENGA, Jan)
VILNISKE, Lina (LT) (expert to DUNAUSKIENE, Lina)
WAGENER, Alex (LU) (expert to BIWER, Arno)
WODLI, Jordane (FR) (adviser to DRUGEON, Sylvie)
ZELJEZIC, Davor (HR) (expert to BASTIJANCIC-KOKIC, Biserka)

MSCA Experts for SEV cases
DOYLE, Ian (UK)
FERNÁNDEZ SÁNCHEZ, Raquel (ES)
HAMMERSCHMIDT, Thea (DE)
MALKIEWICZ, Katarzyna (SE)
ROUSSEAU, Cécile (FR)

By WEBEX-phone connection:
During agenda item 6b: Betty Hakkert (NL), Wouter ter Burg (NL), Steve Dungey (UK), Thomas Schultz (DE) and Rosemarie Eppler (DE).
From the Commission during agenda items 1-12: Enrique García-John, Andrej Kobe, Mariana Fernandes de Barros, Georg Streck, Giuseppina Luvarà, Jacek Rozwadowski, Anna Borras Herrero, Barbara Heinrich-Hirsch and Katarina Pirselova.

Case owners:
Representatives of the Registrants were attending under agenda item 6b for SEV-SE-029/2012, SEV-ES-012/2013, SEV-DE-008/2012, SEV-FR-016/2012, SEV-NL-024/2012 and SEV-UK-032/2012.

Apologies:
ANDRIJEWSKI, Michal (PL)
CAMILLERI, Tristan (MT)
DRUGEON, Sylvie (FR)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)

III. Final Agenda

ECHA/MSC-33/2013/A/33

Agenda
33rd meeting of the Member State Committee

10-13 December 2013
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

10 December: **starts at 10:00**
13 December: **ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/033/2013
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-32

- Adoption of draft minutes of MSC-32

MSC/M/32/2013
For adoption

Item 6 – Substance evaluation decision-making

Closed session for 6c
Indicative time plan for 6b is Day 1&2

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

ECHA/MSC-33/2013/013
For information

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

ECHA/MSC-33/2013/014

- **SEV-SE-029/2012** 2-(4-tert-butylbenzyl) propionaldehyde (EC No. 201-289-8)
  ECHA/MSC-33/2013/009-010
- **SEV-ES-012/2012** 2-Ethylhexanoic acid (EC No. 205-743-6)
  ECHA/MSC-33/2013/003-004
- **SEV-DE-008/2012** 2,2'-Iminodiethanol (EC No. 203-868-0)
  ECHA/MSC-33/2013/001-002
- **SEV-FR-016/2012** 1,3-diphenylguanidine (EC No. 203-002-1)
  ECHA/MSC-33/2013/005-006
- **SEV-NL-024/2012** Hexyl salicylate (EC No. 228-408-6)
  ECHA/MSC-33/2013/007-008
- **SEV-UK-032/2012** Alkanes, C14-17, chloro (EC No. 287-477-0)
  ECHA/MSC-33/2013/011-012

For information and discussion

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

As listed above and the case returned from written procedure

- **SEV-FI-014/2012** Decahydronaphtalene (EC No. 202-046-9)[2]

For agreement

Item 7 – Dossier evaluation

Partly closed session for 7b

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

ECHA/MSC-33/2013/015

For information

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

For information

c. General topics

- Status report on on-going evaluation work

For information

Item 8 – Community Rolling Action Plan (CoRAP) update

Preparations for the MSC opinion on the draft Community Rolling Action Plan (CoRAP)

- Report by the Rapporteur and discussion on the first draft opinion of MSC followed by exchange of views on the draft opinion

[2] Documents available in substance specific folders

ECHA/MSC-33/2013/016
For discussion

Item 9 – SVHC identification

- **Written procedure report on seeking agreement on identification of SVHC**

ECHA/MSC-33/2013/33
For information

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

- **Update of the Priority Setting Approach for recommending substances for inclusion in Annex XIV**

ECHA/MSC-33/2013/030
For endorsement

ECHA/MSC-33/2013/031
For information

Item 11 – ECHA's draft recommendation of priority substances to be included in Annex XIV

- **Introduction of any changes to the draft recommendation documentation following the consultation**

ECHA/MSC-33/2013/017-029
For information and discussion

Item 12 – Opinion on the draft recommendation of priority substances to be included in Annex XIV

c. Discussion on the draft opinion based on the draft recommendation of priority substances to be included in Annex XIV

d. Adoption of the MSC opinion

ECHA/MSC-33/2013/032
For discussion and adoption

Item 13 – Any other business

- Suggestions from members

For information

Item 14 – Adoption of conclusions and action points

- Table with conclusions and action points from MSC-33

For adoption

Main conclusions and action points
MSC-33, 10-13 December 2013
(adopted at MSC-33)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 5 – Adoption of minutes of the MSC-32	
	MSC-S to upload final version of the minutes on MSC CIRCABC by 17 December 2013.
Item 6 - Substance evaluation decision-making **b. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CAs/ECHA reactions *(Session 1, tentatively open session)*** **c. Seeking agreement on draft decisions when amendments were proposed by MS-CAs/ECHA *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting (where appropriate): **SEV-SE-029/2012** 2-(4-tert-butylbenzyl) propionaldehyde (EC No. 201-289-8) **SEV-ES-012/2012** 2-Ethylhexanoic acid (EC No. 205-743-6) **SEV-DE-008/2012** 2,2'-Iminodiethanol (EC No. 203-868-0) **SEV-FR-016/2012** 1,3-diphenylguanidine (EC No. 203-002-1) **SEV-NL-024/2012** Hexyl salicylate (EC No. 228-408-6) **SEV-UK-032/2012** Alkanes, C14-17, chloro (EC No. 287-477-0) **SEV-FI-014/2012** Decahydronaphtalene (EC No. 202-046-9)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions/cover letters of the agreed cases.
Item 7 – Dossier evaluation **7 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 that were agreed in written procedure, as indicated in document ECHA/MSC-33/2013/015.
Item 8 – Community Rolling Action Plan (CoRAP) update **Preparations for the MSC opinion on the draft Community Rolling Action Plan (CoRAP)**	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Report by the Rapporteur and discussion on the first draft opinion of MSC followed by exchange of views on the draft opinion	
MSC took note of the update.	**MSC members** to send comments to Rapporteur on the CoRAP opinion by 7 January 2014. **MSC members** to inform their CAs to update the justification documents of the substances they are going to evaluate to further substantiate the justification for proposing the substance for CoRAP, latest by end January 2014 but preferably by 7 January 2014.
Item 10 – Prioritisation of Candidate List substances for inclusion in Annex XIV **Update of the Priority Setting Approach for recommending substances for inclusion in Annex XIV**	
MSC endorsed the updated draft priority setting approach with minor modifications.	**MSC-S** to upload on CIRCABC the updated Priority Setting Approach after its finalisation. **SECR** to follow the new approach when assessing the substances for prioritisation in the next ECHA's recommendations for inclusion in Annex XIV.
Item 12 – Opinion on the draft recommendation of priority substances to be included in Annex XIV **a. Discussion on the draft opinion based on the draft recommendation of priority substances to be included in Annex XIV** **b. Adoption of the MSC opinion**	
MSC noted the 5th ECHA's draft recommendation for inclusion of priority substances in Annex XIV. Several members did not consider the prioritisation of ADCA as appropriate and provided minority view to the opinion for this substance. Statements to the minutes were introduced by several members on DMF, by some members on RCFs and by some members on ADCA. The opinion on draft recommendation covers the following substances: – N,N-Dimethylformamide (DMF); – Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA); – Aluminosilicate Refractory Ceramic Fibres (Al-RCF), [*fibres covered by Index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of*	**SECR** to take into account the MSC opinion when finalising the 5th ECHA's recommendation for inclusion of substances in Annex XIV and to submit it to the Commission in January 2014. **MSC-S** to publish the final MSC opinion on MSC CIRCABC and on ECHA website after the meeting.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
aluminium and silicon are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm) c) alkaline oxide and alkali earth oxide ($Na_2O+K_2O+CaO+MgO+BaO$) content less or equal to 18% by weight]; – Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF), [*fibres covered by Index number 650-017-00-8 in Annex VI, part 3, table 3.1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions: a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm). c) alkaline oxide and alkali earth oxide ($Na_2O+K_2O+CaO+MgO+BaO$) content less or equal to 18% by weight*]; – 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated *[covering well-defined substances and UVCB substances, polymers and homologues]* (4-tert-OPnEO). MSC adopted the opinion on ECHA's 5th draft recommendation.	
Item 14 – Adoption of conclusions and action points	
MSC adopted the conclusions and action points of MSC-33.	MSC-S to upload the conclusions and action points on MSC CIRCABC by 16 December 2013.

V. Statements from the Member States to the minutes on the opinion on the draft recommendation of priority substances to be included in Annex XIV

FR Statement for Azodicarbonamide (ADCA)

FR is of the opinion that the recommendation for Azodicarbonamide (ADCA) to be taken forward to Annex XIV may not be appropriate as regards of the prioritization performed by ECHA.
FR is of the opinion that the tonnage taken into account in the exercise of prioritization by ECHA for this substance need to be reassessed. Indeed, as the concern is associated with respiratory effects, the tonnage corresponding to the (allegedly low) proportion of this substance used in powder form seems to be more relevant than full tonnage covering all physical forms. The consequence could be that the calculation of score used by ECHA could have been reassessed accordingly.
However, FR agrees that even if a new score could be reconsidered about the prioritization of this substance, a possible lower score for this substance does not necessary imply that ADCA prioritization in the recommendation would in all case be challenged, depending on the comparison with the score of the others substances considered in the prioritization exercise.
More generally, FR reminds its reservation with regard to the criteria used for prioritization. Although FR acknowledges that the prioritization performed by ECHA relies on the criteria as defined in the regulation, it seems necessary, especially in the framework of the 2020 roadmap for SVHC, to take also into account conclusions of best RMO analysis at the stage of proposals for regulatory measures, including prioritization for annex XIV. FR notes that there remains some doubts about the most appropriate risk management measure for ADCA.

UK statement for Diazene-1,2-dicarboxamide (ADCA)

The UK are of the opinion that the recommendation for Diazene-1,2-dicarboxamide [C,C'-Azodi(formamide)] (henceforth referred to as ADCA) to be taken forward for addition to Annex XIV may be flawed. In line with the themes in the 'Roadmap for 2020', we would encourage the Commission to investigate whether alternative risk management options may be more effective.
During the public consultation on the ECHA recommendation, various stakeholders observed that in those countries which have set national exposure limits, the incidence of occupational asthma caused by ADCA has been reduced to a very low level. Indeed, the data used in the original RMOA for ADCA shows a significant drop in cases which coincides with the introduction of an exposure limit in the UK. Whilst the RMOA did explore setting a Binding Occupational Exposure Level Value, this route was dismissed as it was considered too difficult. However, despite these difficulties, it would appear that such a measure is effective and more focussed on reducing the actual risks posed by the use of this substance. We would encourage the Commission to consider this option.
In addition to the apparent efficacy of an exposure limit, we believe that adding ADCA to Annex XIV could be a problem for other reasons. Information from national sources (e.g., inspection reports, health surveillance) indicates that, although ADCA is widely used throughout Europe in different supply chains, in many cases the number of workers at risk of respiratory sensitization is limited. In particular:

- Not all sites use ADCA in powder form and in those that do, only a small number of workers may potentially be exposed. The existing classification triggers the need for rigorous exposure control for those workers potentially exposed.
- Whilst the ADCA is in a powder form when initially imported, much of the onward supply of formulations containing it are in a form in which inhalation exposure is unlikely or even impossible. For example, non-dusty forms, granules, polymer 'master-batch' or liquid dispersions or pastes.

- Registration dossiers now clearly advise against professional use and consumer use

This means that for a large number of companies the only potential for exposure is to forms that do not carry the potential to induce or elicit an asthmatic response. However, these same companies may need to apply for authorisation. This creates a disproportionate burden for both authorities and industry, without any significant added benefits.
Also, authorisation could have unintended consequences due to the drive for substitution. Two of the alternative substances identified in the original RMOA have hazard profiles that could be considered as more severe. One is classified with Carcinogen Category 1B and another with Mutagenic Category 2. Neither of these substances is included on the Candidate List and one does not meet the criteria (but should still be controlled as a non-threshold level substance). Substitution to these more hazardous substances would allow companies to avoid the need to apply for authorisation and could lead to an increased risk. These increased risks are more likely to occur for the very users who currently have poor exposure control. Setting an exposure limit would allow action to be taken against those who have poor control, without placing any additional burden on those who already apply adequate controls.

PT statement for ADCA prioritisation

The ECHA's 5th Annex XIV recommendation includes the substance Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA). ADCA was identified as a Substance of Very High Concern (SVHC) according to art. 57 (f) due to its classification as Resp. Sens. 1 (Annex VI, part 3, Table 3.1 of CLP Regulation) and included in the candidate List on 19/12/2012.
Background information:
Tonnage*:* 10,000 – 100,000 t/y
Uses: mainly used in downstream user sectors (e.g. automotive, construction, electrical application; main uses as blowing agent in rubber and plastics industry.
Prioritisation:
The substance is used in "very high" volumes in the scope of authorization; therefore the high volume criterion for prioritization is met.
The use of the substance in Europe is confined to industrial sites, no use by professional users or consumers is identified and there is no indication of releases from articles during service life. Therefore PT is of the opinion that release of this substance is limited and, consequently the use should not be considered wide dispersive.
Scoring approach:
In the scoring approach the scores for inherent properties (1) and volume (9) are appropriate. Regarding wide depressiveness the factor "number of sites" (3) is also considered appropriate, however for the "releases" considering that the use is on industrial sites, no use by professional users is identified and there is no indication of releases from articles during service life the score should be 1 (WDU =3*1=3). Therefore the total score should be 13 (1+9+3).
As a result, it may be the case that other substances could be more important to prioritise in comparison with ADCA, presently.

Joint statement of the UK, Ireland, Italy, Hungary, Cyprus, Greece and Malta on the prioritisation of Dimethylformamide

The Member State Committee representatives from UK, Ireland, Italy, Hungary, Cyprus, Greece and Malta are of the opinion that the recommendation for Dimethylformamide (DMF) to be taken forward for addition to Annex XIV may not be appropriate. In line with the emerging themes in the roadmap for 2020, we would encourage the Commission to investigate whether alternative risk management options may be more effective.

During the public consultation on the ECHA recommendation, various stakeholders suggested that other risk management options (including restriction) could be better risk management options than authorisation. This is supported by one of the conclusions from the original risk management options analysis (RMOA) for DMF in which authorisation was identified as not being an appropriate option. This conclusion was widely agreed by a number of member state authorities. In addition, we would encourage the Commission to consider handling all the aprotic solvents currently being considered for regulatory action (DMAc, DMF & NMP) in a consistent and proportionate way.
In particular, the use of authorisation as a driver for substitution seems to be undermined for DMF as suitable alternatives (with a lower hazard profile) are unlikely to exist. DMF is one of a handful of 'aprotic polar solvents' and substitution of these could be very difficult. The aprotic polar solvents all have the advantage of being able to dissolve a wide range of substances, but do not have the acidic proton that most highly polar solvents have. For many reactions, the acidic proton can lead to complications in the reactions. Thus, as industrial solvents they are ideal for certain reaction types. For example, in second order nucleophilic substitution reactions (a very commonly used reaction in chemical synthesis) aprotic polar solvents allow for faster reaction times and help to minimise side reactions such as E2 eliminations reactions. The problem for substitution is that the other aprotic polar solvents with similar physico-chemical properties tend to have the same reproductive hazards. Thus, true substitution for a less hazardous substance cannot be achieved.
In addition, should DMF be added to Annex XIV, then there is a high likelihood for multiple applications. As a threshold for the reproductive hazard may exist, these applications could proceed along the adequate control route and would require only those controls that are already in place. Thus, authorisation could be burdensome for both authorities and industry, without any significant added benefits.

Statement of the UK, Hungary, Austria and the Czech Republic on the prioritisation of Aluminosilicate Refractory Ceramic Fibres (Al-RCF) and Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)

The representatives on the Member State Committee for the countries named above are of the opinion that the recommendation for Al-RCF & Zr-RCF to be taken forward for addition to Annex XIV may be flawed for the following reasons:

- The definitions of these substances currently included in the background documents are confusing and create difficulties for duty holders and enforcement authorities. In particular, there are two RCF definitions for materials that have a single entry in Annex VI of the CLP Regulations. This makes it difficult to know to which RCF type a particular material would belong and consequently whether the use of the correct material had been authorised. This would become increasingly difficult to determine as materials/products move further down supply chains.
- Whilst it has been claimed that the definitions cover other RCF types, e.g., those containing chromium oxides, it is not clear if this is the case. The background documents do mention that other oxides can be present and gives example oxides; however, in each document a limit value is given for each oxide and these limits are different for each RCF. As different limits are set for each RCF type, it must be assumed that RCF materials containing oxides outside these limits are not included in the definitions. This could provide a mechanism for suppliers to easily bypass authorisation by making simple changes to the RCF composition.
- This is directly relevant for the "Chromia-RCF". The limits for chromium oxide cited in both documents (<0.01% for Zr-RCF & <0.03% for Al-RCF) are below the typical level of chromium oxide present in "Chromia-RCF" (typically 3%). This means that this RCF, which has the same dangerous properties, is not covered by the current entries.
- During the consultation, comments were received that claimed that the fibres themselves (as produced) meet the definition of an article used in REACH. Whilst

the fibres have been regulated previously under the Dangerous Substances Directive, there was not an article definition in that Directive; therefore, this in itself does not mean that the fibres are substances. Logical and cogent arguments can be made to support a decision that the fibres are articles as defined in REACH.

- This means that it is difficult to know where or when the authorisation requirement would apply. A supplier who decides the fibres are articles would not be covered by authorisation, whereas one who decides they are substances is covered. This is both unfair and difficult to enforce.
- In addition, should the RCFs be added to Annex XIV, then there is a high likelihood for multiple applications. It is known that the bulk of the material supplied is used in furnace production and maintenance. In this use, the RCF make a significant contribution to lowering energy consumption and reducing carbon footprints. There are few, if any, effective alternatives for this use and a high level of control already is in place at sites where this use occurs. This means that authorisation could be burdensome for both authorities and industry, without any significant added benefit.

In summary, we urge the Commission to consider if addition to Annex XIV is appropriate at this time. In particular, without clarification of the above mentioned issues on the exact scope of the proposed authorisation it would be difficult for all stake-holders to comply with the requirements of REACH.

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

Draft decisions unanimously agreed by MSC in WP:

MSC ID number	Substance name used in draft decision	EC No
CCH 132/2013	4-hydroxy-2,2,6,6-tetramethylpiperidine-1-ethanol	258-132-1
CCH 141/2013	1,4-dioxacyclohexadecane-5,16-dione	259-423-6
CCH 148/2013	1,3,5-triazine-2,4,6(1H,3H,5H)-trione, compound with 1,3,5-triazine-2,4,6-triamine (1:1)	253-575-7