MSC/M/020/2011
ADOPTED IN MSC-21

Final Minutes

Minutes of the 20th Meeting of the Member State Committee (MSC-20)
2-4 November 2011

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 20th 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 proposed by the MSC Secretariat. The final Agenda is attached to these minutes.

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

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

Item 4 - Administrative issues

- **Satisfaction survey 2011**

SECR announced the Committee of the forthcoming annual satisfaction survey 2011. It was explained that the survey will be limited to several relevant questions. It will be launched on 23 November 2011 and responses are expected within the following 3 weeks. SECR is expected to report on the survey outcome at a MSC meeting in the beginning of 2012.

Item 5 – Adoption of the minutes of MSC-19

SECR presented to MSC the draft MSC-19 minutes focusing on the written comments received and taken into account on the part of the minutes on TPE-007/2011 and on draft MSC-19 Main conclusions and Action Points. Representatives of Registrants who had participated in the meeting have been also consulted for their respective parts of the draft minutes. As regards to TPE-007/2011, members were informed that the dossier evaluation case was duly documented and sent out to the Commission for their further decision-making in accordance with Article 51 (7) of REACH Regulation. The minutes were adopted without any further changes. The MSC Secretariat will upload the minutes on MSC CIRCABC and on the ECHA website (public minutes).

Item 6 – Dossier evaluation

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

SECR gave report on the written procedures of the five substances Mono- and/or di- and/or tri(1-phenylethyl)-m-cresol and p-cresol; B-TTEGME, Cellcore QX, 2,2'-(Ethylenedioxy)diethanol and 3-[(diisoalkyloxyphosphorothioyl) thio]-2-methylalkanoic acid.

MSC agreement was sought via written procedure on the draft decision and respective draft agreement on mono- and/or di- and/or tri(1-phenylethyl)-m-cresol and p-cresol, due to lack of quorum at the end of the meeting of MSC-19 preventing seeking unanimous agreement of MSC. Therefore, MSC agreement was sought via written

procedure launched on 23 September 2011 and closed on 30 September 2011. Responses were received from 23 members with voting right and from the Norwegian member. All responses to the case were in favour and none was against the proposed decision and agreement. Thus unanimous agreement on the draft decision and respective agreement document has been reached by MSC in written procedure on 30 September 2011.

Further, MSC agreement was sought via written procedure on the draft decisions and respective draft agreements for B-TTEGME, Cellcore QX, 2,2'-(Ethylenedioxy)diethanol and 3-[(diisoalkyloxyphosphorothioyl) thio]-2-methylalkanoic acid that was launched on 3 October 2011 and closed on 14 October 2011. Responses were received from 24 members with voting right and from the Norwegian member. All responses were in favour and none were against the proposed decisions and agreements. Therefore, unanimous agreement on these four draft decisions and respective agreement documents has been reached by MSC in written procedure on 14 October 2011.

MSC stakeholder observers (STOs) expressed concerns of the lack of full transparency on the written procedures for agreement seeking during and immediately after the procedures, as the outcomes are communicated only at the following plenary meeting without documents.

b) Topics for discussion related to cases under 6c

- **In vivo genotoxicity testing – Unscheduled DNA Synthesis (UDS) test method and Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays (TGRA)**

SECR gave a presentation on *in vivo* genotoxicity testing focusing on the key characteristics of UDS and TGRA methods and their comparison. It was also pointed out that although three methods on genotoxicity testing are available, adopted guidelines are available only for UDS and TGRA. TGRA test guideline was adopted by OECD in July 2011. Both methods are now valid for the purpose of *in vivo* genotoxicity testing. ECHA together with the MSCAs and MSC would be able to recognise the new OECD 488 test method on TGRA on a case by case basis when the specific criteria for its use set by the guidance are fulfilled; however, only the UDS was available at the time when testing proposals for the phase-in substances in the context of the first registrations in REACH were made.

Several members expressed their opinions on the different guidelines, sharing the view that the testing strategy on carcinogenicity (including genotoxicity) in REACH is not well-developed and needs further update to be in line with the internationally recognised OECD test guideline programmes and other recently published scientific monographs. Each of these test methods has advantages and drawbacks and when positive results appear, there is a need to look further into the mechanisms of action and test sensitivity, and to optimise the selection on *in vivo* tests. It was also indicated that recent scientific development in particular in the area of *in vitro* testing, possibly affecting the need for *in vivo* testing, should be considered for REACH implementation.

It was agreed that careful consideration is needed on case-by-case basis on whether it would be justified to request TGRA test method instead of the UDS if the registrant has proposed the UDS test to be carried out. Furthermore, it was agreed that ECHA

should consider a possible need to review the REACH Guidance concerning genotoxicity testing to take into account the recent scientific development.

It was also proposed by a member that SECR should consider potential involvement of MSC members in the ECHA guidance reviews, as appropriate.

One STO reminded that although the issues of human health and environmental protection are important, cost issue is also essential for many companies and MSC should also take into account these aspects when considering the way forward for each testing proposal.

- **A comparison between EU test method B.35 Two-generation reproductive toxicity study (OECD 416) and OECD TG 443 Extended One-Generation Reproductive Toxicity Study (EOGRTS)**

Prior to the presentation prepared on this topic, the COM provided MSC with a brief report from last CARACAL discussion on the use of EOGRTS under REACH. It was explained that CARACAL decided to extend the mandate of the expert group on the use of EOGRTS under REACH (EOGRTS EG) until the next CARACAL meeting for further continuation of their work. The preliminary conclusions of the EOGRTS EG indicated that EOGRTS would be preferred to be used under REACH. This conclusion was supported by CARACAL. However, a need was identified for gathering further knowledge of and analysing it, as regards to the possible triggers for the second generation study (such as e.g. based on exposure). A review was planned to be carried out considering the outcome of the cases where the second generation was included in the test on one hand and where only the extended one generation test was performed on the other hand. It should also be clarified under which conditions the cohorts on developmental neurotoxicity and on developmental immunotoxicity could be waived. It was mentioned that legal, procedural or financial analysis on the application of this test guideline are still pending by COM and were not covered by the mandate of the EOGRTS EG. Although the OECD 443 received general support at the last CARACAL meeting as a preferred method for testing for reproductive toxicity, it was mentioned at CARACAL that for the sake of compromise the second generation test could performed for certain number of cases. The Commission was urged to initiate inclusion of OECD TG 443 in the Test Method Regulation and to modify accordingly the relevant REACH Annexes for providing clarification to the registrants on the information requirements and the way to address them. Therefore, for the time being MSC has to continue considering the draft decisions on testing proposal examinations involving two-generation study on a case-by-case basis.

Referring to the report, several members of MSC pointed out that the provisional outcomes of CARACAL discussion are not helpful for the ongoing MSC work.

Further, SECR gave a specific presentation focusing on similarities and difference between the two test methods - OECD 416 and OECD TG 443.

Several members expressed their satisfaction for the intention of giving such presentation and for its distribution prior to the meeting. However, the time was still insufficient for thorough scrutiny of the slides and for providing comments on them. These members notified SECR of the expected submission of further written comments expressing their observations or views on the presentation after the meeting.

In conclusion, the MSC Chair reminded the members that choosing between OECD 416 and OECD 443 is a complex issue, due to the clear differences between the two methods such as EOGRTS does not produce second generation results unless trig-

gered and several optionalities included in EOGRTS which use should be specified by different jurisdictions.

- **Legal and procedural questions for the testing proposal examinations in addressing the information requirements for two-generation reproductive toxicity study - implementation of EOGRTS (CLOSED SESSION)**

SECR gave a presentation (that had been provided to MSC via CIRCABC) on legal considerations and procedural aspects for the testing proposal examinations in addressing the information requirements (IRs) for two-generation reproductive toxicity study (Annex IX/X, 8.7.3). MSC was informed that in accordance with Article 13(3) of REACH Regulation, in principle, ECHA can recognise OECD TG 443 as appropriate study guideline to produce information on intrinsic properties. However, as regards its applicability to meet the REACH IRs in Annex IX/X, 8.7.3 and possible use of EOGRTS, there are legal considerations that need to be taken into account. SECR pointed out that in cases where MSC fails to reach unanimous agreement the draft decision could be split and only the part where agreement failed for the highest tier reproductive toxicity study would be referred to the Commission for decision making.

SECR reminded on the need to prepare a decision on each testing proposal for registered phase-in substances by 1 December 2012.

SECR pointed out on the need to encourage the registrants to consider the waiving possibilities for the second generation testing using weight of evidence approach as specified by Annex XI and providing well-based substance-specific argumentation on low toxicity of the substance.

In conclusion, the Chair summarised the way forward that ECHA sees legally sound in recognising the OECD test guideline 443 (EOGRTS):

The responsibility in making testing proposals and using waiving arguments must remain with the registrant. ECHA together with the MSCAs and MSC would be able to recognise OECD 443 on a case by case basis for generation of information on intrinsic properties. If OECD 443 is proposed by the registrant it still has to fulfil the information requirements for the two-generation study (under Annex IX/X, 8.7.3). If the registrant has proposed the two-generation study (EU B.35) ECHA would give two options for the registrant: either to use EU B.35 or to carry out EOGRTS with the second generation. The registrants would be reminded about the possibility to waive the second generation based on options available in Annex XI. ECHA would inform the registrants about the possibility to update their registration dossiers with EOGRTS. ECHA appreciates that the disagreement regarding EOGRTS may persist at MSC in certain cases. If MSC fails to find agreement the draft decision would be split at MSC. The part of the draft decision where unanimous agreement can be reached would be finalised by MSC and addressed to the registrant by ECHA. The part of the draft decision where agreement failed would be referred to the Commission.

The Chair invited the members to provide their written comments on the suggested approach by 16 November 2011.

- **Possibilities and limitations in rejection of testing proposals (CLOSED SESSION)**

SECR gave a presentation (that had been provided to MSC via CIRCABC) focussing on the legal context of testing proposals for vertebrate and non-vertebrate testing and the decision-making options according to Article 40 (3) of REACH Regulation. Different possibilities for rejecting testing proposals on the basis of e.g. available infor-

mation, existing harmonised classification of the substance, availability of alternative methods were also covered and a practical example for read-across waiving was presented and briefly commented by the MSC members. One observation was that the registrant is expected to provide an explanation if it proposes tests that go beyond the standard information requirements. It was suggested that any explanation would be relevant and should not be questioned by SECR or MSC. If an explanation is missing it is proposed that SECR would explore the reason for the testing proposal with the registrant during the decision making process.

The MSC Chair encouraged the members to provide their comments (if any) on the presentation during the Session 2 discussions under 6c&d.

c) Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MSCA reactions and

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

CCH 027/2011 (Camphene)

Session 1 (open)

The Registrant has not indicated interest to participate in the MSC-20 meeting but informed ECHA that he accepts the presence of stakeholder observers during the initial discussions in Session 1. Therefore, an open session was held.

ECHA informed that five proposals for amendment to ECHA's draft decision were submitted by three MSCAs. Two proposals expressed only support to ECHA's line and no changes had been proposed to the draft decision. Two other proposals suggested ECHA not to accept the waiving arguments based on available fish study for an adequate *Daphnia magna* study (OECD 202). The Registrant has provided results of *Daphnia magna* study that are indicated as not reliable. The Registrant has self-classified the substance based on the fish study as Aquatic acute 1, H400 /Aquatic chronic 1, H410. The fifth proposal regarding substance identity and high pressure liquid chromatogram (HPLC) requested to leave an option to the Registrant to use any other valid and appropriate method than HPLC to confirm the substance identity for camphene, low tricyclene.

ECHA had modified the draft decision on the basis of the proposal regarding substance identity and HPLC and provided this modified draft decision for the meeting. ECHA was of the view that the draft decision did not need modification concerning request for a new *Daphnia* study. The Registrant had not provided comments on the proposed amendments.

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

MSC concluded that the M-factor is essential information for the classification and labelling of mixtures but has to be specified in the context of classification of substances. As an adequate study on aquatic invertebrates that is potentially more sensitive than fish as a test species is missing and the result of this study might impact the M-factor or the PNEC value, the Registrant should be requested to submit a valid *Daphnia magna* test. Recognising that the substance might be difficult to test, the Registrant should alternatively be given the possibility to submit a valid QSAR esti-

mation which may be used as basis for adapting the standard information requirement for this endpoint.

Session 2 (closed)
MSC reached unanimous agreement on ECHA's draft decision as provided for and modified in the meeting, including the statement or reasons, on the basis of the above conclusions. MSC also adopted the formal agreement.

CCH 032/2011 (Allyl alcohol)

Session 1 (open)
The Registrant had indicated that two of his representatives would participate in the initial discussions (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the Registrant's representatives of practicalities during and after the meeting.

SECR explained that nine proposals for amendment to ECHA's draft decision were submitted by three MSCAs. Regarding *in vitro* gene mutation study in bacteria two proposals pointed out that the *in vitro* gene mutation study in bacteria with additional fifth strain is available to the Registrant. Regarding *in vivo* genotoxicity (somatic cell test) two CAs proposed to request the Transgenic Rodent Somatic and Germ Cell Gene Mutation Assay (TGR, OECD 488) instead of the unscheduled DNA synthesis (UDS) test.

Regarding the two-generation reproductive toxicity study, one CA was of the view that the Registrant should be required first to pursue tests for genotoxicity that may lead to classification as carcinogenic and consequent implementation of appropriate risk management measures. If so, the two-generation test might become unnecessary. Similarly, another CA did not agree with the requirement for a two-generation study and considered a decision on further reproductive testing at Annex X level as premature as reproductive testing according to Annex X is not required for germ cell mutagens (8.7, column 2) for which testing would be required by the current decision. These two CAs also suggested that if a two-generation test is required, the Registrant should perform the extended one generation reproductive toxicity study (EOGRTS). A third CA supported the Registrant to address this endpoint with a combined read-across/weight of evidence (WoE) approach using the results of a reproductive toxicity screening test (OECD 421) and a OECD 416 equivalent two-generation study with the read-across substance acrolein.

Regarding the pre-natal developmental toxicity one CA proposed to postpone the decision on this test on the same grounds as for the two-generation study (see above). Another CA did not agree with the requirement of a pre-natal developmental toxicity study in a second species because the decision would be premature for the same grounds as indicated for two-generation study (see above). A third CA supported the use of acrolein as read-across substance for this endpoint as well and pointed out that therefore an additional pre-natal developmental toxicity study in another species may not be necessary.

The Registrant in his written comments on the proposed amendments had indicated that the IUCLID dossier has been updated with data on an *in vitro* gene mutation study on fifth bacterial strain and a UDS study for *in vivo* mutagenicity since the MSCA consultation on the draft decision started. The Registrant also stressed that the UDS test (OECD 486) is not an outdated test method. The Registrant had also provided a genotoxicity discussion document covering all available *in vitro* and *in vivo*

genotoxicity tests and concluded that no further genotoxicty testing would be necessary. The Registrant also drew attention to scientific papers describing limitations of TGRA. Furthermore, the Registrant had informed of an update of the registration dossier providing further justification for read across from acrolein concerning two-generation reproductive toxicity and pre-natal developmental toxicity studies.

ECHA was of the view that the draft decision does not need to be amended based on the proposed amendments and Registrant's comments on them.

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

In the discussion, the representatives of the Registrant re-emphasised the main points of their written comments. They explained that although the results of the *in vivo* and *in vitro* genotoxicity studies were available to the Registrant, due to data ownership issues certain studies could be included in the registration dossier only after ownership of these data could be clarified. The updated dossier includes in addition to the liver UDS test a recent study showing no micronucleus induction in livers of ally alcohol treated juvenile rats: these investigations in the principal target organ for systemic toxicity provide a suitable follow-up to the mouse lymphoma study, addressing the biological endpoints of clastogenicity and DNA repair *in vivo*. They also noted that the UDS test has been recognised by an international expert group as an appropriate follow up to in vitro mammalian cell mutation testing, and concluded that another *in vivo* test (i.e. TGRA) should not be requested instead.

The representatives of the Registrant mainly repeated their written comments for the read across arguments for two-generation reproductive toxicity and pre-natal developmental toxicity. They stated that consideration of all available toxicity data indicates that the target organ toxicity of allyl alcohol is a consequence of localised metabolism to acrolein within the liver with little or no indication of other systemic effect. The high reactivity of acrolein causes local effects at the site of primary contact, but repeat-dose test data again show little indication of systemic toxicity. It is therefore reasonable to suppose that allyl alcohol, like acrolein will not cause any adverse reprotoxic effects.

Concerning the read across approach, the MSC member representing the CA that in their proposals for amendment supported the Registrant's read-across approach revised his position and expressed his concerns to use read-across with acrolein. He pointed out that the registered substance and the read-across substance show some differences in repeated dose toxicity, in particular allyl alcohol is hepatotoxic in rats, but the read across substance is not hepatotoxic when administered to rats at the same dose levels. Furthermore, bioavailability of the read-across substance is high at low doses (80-90% at a dose of 2.5 mg/kg), but at a higher dose of 15 mg/kg bioavailability is limited (around 40-60%) due to the tendency of the substance to polymerise in the gastrointestinal tract. Thus, for the majority of the longer term studies on the read-across substance bioavailability of the substance will probably be limited by the tendency to polymerise. For the registered substance, systemic uptake is likely to be higher and this will serve as a mechanism to deliver the read-across substance to the internal organs at higher doses than could be achieved by dosing the read-across substance itself. He also pointed out that liver toxicity has already been seen for the read-across substance at relatively low systemic-doses and the possibility of toxicity to other organs at higher doses cannot be excluded.

The Registrant's representatives replied that in their view, due to its high reactivity, no systemic transport of acrolein would be likely within the body therefore no systemic effects distal from the administration site can be expected. They also stressed that the doses in the quoted studies with the read across substance were indeed low but still high enough for acrolein to have its effect if there would have been any.

Concerning *in vitro* and *in vivo* gene mutation, some MSC members questioned whether the main *in vitro* mutagenic effect of the registered substance is chromosome breakage (clastogenic effect) since this effect is not expressed in any of the *in vivo* studies provided by the Registrant. The Registrant's representatives responded that the clastogenicity seen in vitro was specifically investigated by a number of studies *in vivo*, where no such activity was detected. If the equivocal indications of gene mutation seen in certain (less reliable) *in vitro* tests indicated real activity, available data suggests this would lead to excision repair: however this too was not seen *in vivo* (in the UDS assay).Concerning reprotoxicity and developmental toxicity, some MSC members were of the view that if read across is not accepted, instead of two-generation reproductive toxicity test an EOGRTS should be requested. The Registrant's representatives repeated their argument based on read across and WoE approach that none of these two tests is necessary as available studies show no evidence of reprotoxic effects of allyl alcohol.

ECHA reminded the Registrant that ECHA's final decision might contain requirements to the Registrant which might already be fulfilled in the registration dossier, if the dossier had been updated with the data after the start of the MSCA consultation.

Session 2 (closed)

MSC concluded that the information requirements for *in vitro* and *in vivo* genotoxicity would not need to be modified in the draft decision. Furthermore, read across/WoE approach for the two-generation reproductive and pre-natal developmental toxicity study is not justified and should not be accepted. The request for two-generation reproductive toxicity study should be deleted from the draft decision and the reasons to do so (i.e. the process to incorporate EOGRTS under REACH) be explained to the Registrant in the cover letter of the draft decision. MSC also agreed that the reasoning for not-acceptance of read across for the developmental toxicity study shall be amended with arguments discussed in Session 1. Also, the deadline for the Registrant to submit the information required was modified to 12 from 24 months and the statement of reasons changed accordingly.

MSC reached unanimous agreement on ECHA's draft decision as provided for and modified in the meeting, including the statement or reasons, on the basis of the above conclusions. MSC also adopted the formal agreement.

TPE-017 (4,4'-Methylenebis[N,N-bis(2,3-epoxypropyl)aniline])

Session 1 (open)

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

Six proposals for amendment on ECHA's draft decision were submitted from three MSCAs. One CA supported ECHA's line on pre-natal developmental toxicity and proposed to reject the testing proposal for the two-generation reproductive toxicity study due to insufficient information currently available to determine whether this study is required. Regarding the 90-day repeated dose toxicity study, the same CA

suggested to request the Registrant to make a testing proposal for the 2-generation study only based on the results of the 90-day study later, as necessary. Another CA proposed the Registrant to consider a sequential testing strategy: if the results of the 90-day study, *in vitro* and *in vivo* mutagenicity studies as well as QSAR predictions lead to a conclusion that the substance should be classified as mutagen 1B or carcinogen 1B and appropriate risk management measures are implemented accordingly then the Registrant could avoid further testing for reproduction including pre-natal developmental toxicity and two-generation study. The same CA also asked discussion on EOGRTS vs. two-generation study. A third CA proposed to request EOGRTS instead of the two-generation study.

The Registrant had not provided any comments on the proposals for amendment.

MSC discussed the case based on ECHA's draft decision as referred to MSC and the proposed amendments of MSCAs.

In the discussion, the main consideration was whether the two-generation reproductive toxicity test proposed by the Registrant should be rejected or accepted, depending on the results of the 90-day study. Several members noted the similarity of the current case to a recently completed TPE case. SECR pointed out that although the two cases look similar as both were Annex IX dossiers where the Registrant proposed a two-generation study, there are also significant differences: in the earlier case, the Registrant submitted results of a 28-day study and responded to the proposed amendments of the CAs indicating that the two-generation study would not be necessary, whilst in this case no 28-day study was available and the registrant had not provided any explanation why the two-generation study would be necessary. Some members highlighted that the current substance is classified by the Registrant as genotoxic mutagen (muta 2) and several QSAR predictions indicate also carcinogenicity so the 90-day study could reveal possible reproductive effects. One member suggested, to recommend the Registrant to consider based on the results of the repeat dose toxicity study classification as carcinogen/mutagen category 1 and implementation of appropriate risk management methods and thus to avoid further testing. Only after these considerations, if necessary, the Registrant should submit a new testing proposal for the two-generation study.

Session 2 (closed)

In the continued discussion it was specified that there are neither standard information requirements for two-generation study for this tonnage level, nor explicit explanation provided by the Registrant for the proposed two-generation study in the dossier. MSC concluded that the testing proposal for the two-generation reproductive toxicity study should be currently rejected on the condition that if the 90-day study would indicate any adverse effect for reproductive organs or tissues, the Registrant should submit a testing proposal to cover the endpoint of Annex IX 8.7.3. The Registrant should also be reminded that if relevant, on the basis of other considerations, he may also submit a testing proposal for this endpoint at an earlier stage with indications of the reasons for testing. MSC also agreed that the draft decision should be modified by removing the requirement for two-generation study, adjusting the deadline accordingly to 24 from 36 months for submission of the required information, reminding the Registrant that it is at his discretion to determine the sequence of sub-chronic and pre-natal developmental toxicity studies and to consider the possibilities for adaptations of standard information requirements for the two-generation study (as explained above).

MSC reached unanimous agreement on ECHA's draft decision as modified on the basis of the above conclusions and adopted the formal agreement.

TPE-019 (2,2-Dimethylpropane-1,3-diol)

Session 1 (open)

The Registrant had indicated that one of his representatives would participate in the initial discussions (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

Three proposals for amendment on ECHA's draft decision were submitted by two MSCAs. Both CAs expressed sympathy for the Registrant's proposal to combine the sub-chronic toxicity study (90-day) and two-generation reproductive toxicity study because combination would give a possibility to reduce the number of test animals. However, the two CAs indicated that OECD TG 443 (EOGRTS) should be carried out instead of the two-generation study. One CA requested ECHA to provide the rationale why the combined 90-day and two-generation study was not accepted.

The Registrant in his written comments to the proposed amendments regarding the combined 90-day and two-generation study had appreciated the support of the CAs on the combined study. However, the Registrant did not see necessary a two-generation study as the substance is of low toxicity and no effects had been seen in the reproductive screening study (OECD 422). Therefore the Registrant had proposed to include additional fertility parameters (sperm mobility etc.) in the 90-day study and considered the 90-day study together with other available information sufficient to conclude on reprotoxicity. The Registrant had considered the requested two-generation reproductive toxicity study as scientifically unjustified and not providing any new information concerning the fertility endpoint.

Furthermore the Registrant had considered that EOGRTS (OECD 443) would provide only minimal additional information because most of the endpoints covered by this test are already covered by the existing screening study (OECD 422), the proposed pre-natal developmental toxicity study (OECD 414) and the proposed extended 90-day study.

SECR had not modified the draft decision in advance of the meeting based on the proposed amendments. Thus, MSC discussed the case based on ECHA's draft decision as referred to MSC, the proposed amendments of MSCAs and the Registrant's comments to the proposed amendments.

In the discussion, the representative of the Registrant mainly repeated their written comments and clarified that a two-generation study was not proposed in the submitted dossier. He made clear that the Registrant's intention was to propose only an extended sub-chronic toxicity study (90-day) with additional parameters covering reproductive toxicity. He did not support the request for an EOGRTS based on the unclear trigger for a two-generation study and the indicated low toxicity profile with no neurotoxic or reprotoxic effects. Concerning developmental toxicity, in his view there were no effects observed in the parent generation in most of the studies carried out and no further concerns could be assumed on F1 and F2 generations either; however, as the data gap for developmental toxicity exists, the Registrant proposed OECD 414.

Concerning the proposed combined sub-chronic toxicity (90-day) and two-generation reproductive toxicity study, one MSC member informed the participants of a recently

finished assessment report for a structurally similar substance and suggested that the Registrant should investigate the possibility for read-across to this substance instead of testing. This assessment report was only available to the CA represented by the member, and thus information was not available earlier to the registrant and ECHA.

SECR explained that a proposal for two-generation study was first not recognised by ECHA as such and thus, was not either addressed in the 3rd party consultation on this case. The registration dossier was not very clear in this respect. The Registrant's representative agreed to this clarification and highlighted that developmental toxicity should be further investigated if adverse effects were seen in other studies and a new testing proposal for the two-generation endpoint would be submitted.

MSC concluded that the two-generation reproductive toxicity study was not proposed by the Registrant but the requirement for a 90-day sub-chronic toxicity study with additional examinations concerning reproductive toxicity should be seen as the testing proposal. However, the Registrant should be reminded that the intended additional examinations for the 90-day study may not fulfil the standard information requirements for reproductive toxicity as set out in Annex X, 8.7.3.

Session 2 (closed)
ECHA further clarified that based on the results of a 90-day study a substance can be classified only for fertility while results of a pre-natal developmental study can be a basis only for classification for developmental toxicity. Therefore, as these two studies are necessary to fulfil the relevant endpoints and the results of any of them cannot be used as a waiver for the other study the sequence of performing these two studies is irrelevant.

MSC also concluded that the deadline for the Registrant to submit the required information should be shortened to 18 from 24 months, due to the removed requirement for two-generation reprotoxicity study and the statement of reasons should also be modified accordingly. MSC agreed that the Registrant should also be reminded in the notification letter to the draft decision that studies on a similar substance exist that the current substance can possibly be read across to. MSC reached unanimous agreement on ECHA's draft decision as modified on the basis of the above conclusions in the current meeting, and adopted the formal agreement.

e) General topics

- **Status report on ongoing evaluation work**

SECR updated MSC on the state of play of the dossier evaluation work and on future challenges for ECHA. Some estimates for the workload of the following four MSC meetings were provided.

SECR proposed to send for MSCA an extra batch of draft decisions for substance identity (SID) targeted compliance checks on dossiers where testing proposals have been made but cannot be further examined because of deficiencies in SIDs. To be able to buy more time for testing proposal examination the decisions on targeted compliance checks on SIDs need to be finalised as soon as possible. Therefore SECR proposes to organise the MSCA consultation on these draft decisions outside the framework of the MSC meeting dates. This arrangement is based on the assumption that no proposals for amendments would be introduced on the draft decisions and there would not be any need to address these cases in any of the MSC meetings. The MSCA con-

sultation for this extra batch of the draft decisions would be started on 19 December 2011 and would end on 19 January 2012.

To increase the efficiency and transparency of the dossier evaluation work and thereby to reduce the number of the MSCA proposals for amendment organisation of a workshop was announced. It was clarified that if workshops will be organised, possibilities for STO participation in such workshops or in workshop sessions with STO involvement will be explored for transparency reasons.

- **ECHA's approach in the evaluation of read-across and the development of a Read-Across Assessment Framework (RAAF)**

SECR gave a presentation on evaluation of read-across proposals based on, category and analogue approach. Information was provided on development of a tool called Read-Across Assessment Framework (RAAF). The tool will support achieving a consistent, streamlined and transparent evaluation at a high level of expertise required by read-across. SECR informed the committee that more specific read-across points are expected to be addressed with the further discussion on the implementation of the RAAF tool at a workshop with MSC, MSCA and STO in 2012.

MSC generally supported the presented ECHA's approach in read-across evaluation and appreciated the structured framework to be used when assessing read-across cases.

Several issues of scientific nature were raised regarding the read-across approaches, use of QSARS in support of read-across and how to take into consideration different uncertainty factors. It was concluded that further discussion on these relevant topics should take place in the workshop that will be organised in 2012.

Two MSC observers expressed an interest in participation in the workshop and suggested to SECR to consider whether the existing overarching read-across programmes of different industry sectors could be also of use for the development of Tier 2 of RAAF tool.

SECR responded that transparency is considered as a core of the procedure and agreed that the reasons for acceptance or rejection of a read-across should be clearly communicated and well-documented.

MSC was invited to contribute to the RAAF development process by submitting relevant information to SECR.

Item 7 – Substance evaluation (SEV)

a) Introduction to the draft Community Rolling Action Plan (CoRAP)

SECR in its presentation informed the meeting participants that the final draft CoRAP containing 91 substances (36 substances planned for 2012, 24 - for 2013 and 31 - for 2014) was submitted to MSC and MSs as preliminary envisaged. The public draft CoRAP version was published on the ECHA website on 20 October 2011, as it was clarified that non-confidential versions of the substance-specific justification documents were provided to STOs only for the 2012 year substances by the time of the meeting. Remaining non-confidential justification documents for 2013- and 2014-year substances would be made available to STOs shortly after MSC-20.

A preliminary overview on the initial concern is provided in the justification documents and justification for selection of the substance for the draft CoRAP. Some further estimates on the expected workload for the MSCAs in the coming years and the

capacity needed for the number of substances were given. MSC was reminded on the procedural steps and timelines under the SEV process and some additional information was provided on the future activities and the planned workshops in January 2012 on dossier evaluation (with a session on SEV) and in June 2012 on SEV only. The full presentation was made available to MSC members and stakeholders on MSC CIRCABC.

Several members welcomed the idea of having technical workshops with MSs and raised the need for improving the cooperation and coordination between MSs and ECHA in the pre-selection stage of the candidate-substances, in order to avoid the overlapping in the work, possible errors and misunderstandings. SECR shared the view that earlier collaboration with MSCA in the substance identification could be improved and further criteria needed to be able to avoid overlaps on substances between MSCAs. All kind of sharing of information in a systematic and structured way would be helpful as early in the screening process as possible.

Following a question of a STO observer, ECHA clarified that currently there are no considerations as regards possible engagement of registrants in the SEV process, as if needed, this should happen at a MS level where the evaluation work is expected to be done.

b) First exchange of views on the draft CoRAP and items to include in the MSC opinion

SECR briefly introduced the draft template for the MSC opinion on the 1st draft CoRAP (presented as a meeting document). Several members requested for clarification on the scope of the MSC opinion and the nature the rapporteurs and the CoRAP WG work in the SEV process.

SECR explained that the MSC opinion should contain the conclusions on whether risk-based approach had been followed in justification documents of a CoRAP substance; therefore, the objective of CoRAP rapporteurs and WG members is to develop an MSC opinion on the basis of substance documentation, as submitted, and not to in-depth test the grounds of concerns provided in justification documents for identification of a substance as a candidate for CoRAP.

A member was interested in whether further improvement of justification documents should be expected as an outcome of rapporteur's scrutiny, in particular for those substances other than risk-based grounds of concern had been provided, as this might require full evaluation to be done.

The Chair of MSC further clarified that when proposal for inclusion of a substance in CoRAP is made, it should follow the legal criteria in REACH and the rapporteur's task is to verify this in justification documents. If in particular cases a specific need for improvement of justification documents is identified, such update could be made by the MS before the adoption of the final CoRAP by ECHA.

Another member requested for clarification on the compliance check triggers under SEV. SECR confirmed that as SEV process is a flexible tool, compliance check could be required as a part of major SEV issues going behind the standard REACH IRs, or SEV process could follow a dossier evaluation process where the compliance check has been already completed. In addition, SECR also requested MSC and MSCAs to notify ECHA when a need for compliance check of registration dossiers is recognised during SEV activities carried out by MSCAs.

Two observers asked for ECHA's considerations in potential involvement of the registrants for contributing in SEV and in the opinion-development processes. The way of dealing with substances subject to CoRAP and other overlapping legislative programmes also required clarification.

SECR responded that as the in-depth SEV is expected to be done at a MS level, no legal expectations or considerations were made in ECHA on the potential industry involvement/consultation in SEV process. However, the issue of informing the Registrants of any relevant concern encountered during the SEV process would be further considered. An additional column was suggested to be included in the opinion template to indicate when a substance is addressed in some other regulatory programmes.

The MSC Chair concluded that the proposed opinion template was supported by MSC and the main objective for the rapporteurs and WG is to verify whether risk-based approach had been followed for CoRAP substances and not to explore the information behind the proposals. When further justification improvement is needed, this should be recorded in the opinion.

Item 8 – SVHC identification

- **Information about the progress on SVHC identification**

SECR presented the outcomes of the public consultation for the 20 substances proposed for identification as SVHC, as well as a brief overview on type and the nature of the comments received. Members were also introduced with the preliminary Secretariat's conclusions on the number of the dossiers to be referred to MSC and the possibilities and the practicalities for their agreement seeking, as specified in the distributed room document (Room document ECHA/MSC-20/2011/025).

It was further clarified that the candidate list would be updated at the end of the current process in December. The issue of possible merging of entries with the same index and EC numbers (the case of RCFs) is not currently relevant. It was noted that the current entries of RCF in the Candidate List (CL) would need to be maintained for at least 6 months in the Candidate List (CL) after potential inclusion of the new proposed RCFs with a broader substance composition definition (covering the "old " entries) because the obligation for producers and importers of articles containing the substances already apply for the "old" RCF entries whereas for the potential "new" entries this obligation only apply 6 months after inclusion in the CL.

- **Information about the court cases**

SECR briefly presented outcomes of recently completed court cases (T-268/10, T-343/10 and T-346/10) on MSC agreements on identification of SVHC. The cases were concluded to be inadmissible by the Court. Few other cases (T-93 to T96/10) concerning the identification as PBT or vPvB substances are still under consideration by the Court. The full presentation was made available to MSC members and stakeholders on MSC CIRCABC.

Item 9 – Draft recommendation for inclusion of priority substances in Annex XIV

a) Progress report after closure of the public consultation on ECHA's Draft Recommendation and Draft Annex XIV entries for prioritised substances

SECR presented the approach used for RCOM development due to the huge number of comments received (about 1400) during the public consultation on the 3rd draft recommendation. It was further clarified that the identified generic and specific issues in identified categories of comments would be responded in substance group specific RCOMs. MSC was also reminded on the procedural steps currently ongoing and the expected ones by the end of the 3rd recommendation process.

High appreciation was given to SECR of the work done under this process.

One observer indicated that the message for group comment submission was communicated to the industry and the SECR approach focusing on nature of comments was considered as the best possible approach also from the MSC industry observers' point of view. However, it was mentioned that some of the submitted comments, as ECHA's draft responses indicate, were obviously not clear enough or have been misunderstood by ECHA, which has led to misinterpretation. Thus, SECR requested the MSC STO observers to check and indicate the comments where obvious errors were spotted or which might have been misunderstood.

b) Preparations for the opinion on the draft recommendation of priority substances to be included in Annex XIV

- **Report by the rapporteur and discussion of the first draft opinion (DO)**

The rapporteur introduced to MSC the first DO and its support document prepared by WG and distributed as a room document. It was clarified that DO should be considered as preliminary, as the final RCOM were not yet completed (due to the high number of comments received) and the responses might require further DO modifications to be made. Further, the rapporteur stressed on the big number of comments received during the public consultation that needs attention. Later on three MSC members provided comments on cobalt acetate and their inclusion in Annex XIV inviting MSC to consider the prioritisation criteria in this case. It was also explained that at the prioritisation step no risk assessment is carried out. The prioritisation exercise is based on the parameters listed in Article 58(3) and further elaborated in the document *General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to Authorisation.* This document was agreed by MSC and introduces for prioritisation the so-called scoring method and the verbal argumentation method. Regulatory effectiveness criteria may be applied on top of the other criteria and may lead e.g. to application of a grouping approach of similar substances to be addressed at the same time for authorisation, thus avoiding replacement of one substance with a similar hazardous substitute. Some other issues for members' consideration were indicated, such as e.g. the setting of transitional arrangements and proposed exemptions.

- **Exchange of views on comments received including transitional arrangements**

Prioritisation of substances from the candidate list to Annex XIV

Many comments regarding prioritisation and how the prioritisation criteria were applied were raised in the public consultation. The indicated volumes, the consideration of uses as wide dispersive, the grouping approach as well as assigned scores were challenged. Some MSC members had in particular concerns regarding the prioritisation of (some) cobalt-compounds for inclusion in Annex XIV, the application of the grouping approach for these compounds and considering their uses as wide dispersive.

In response, SECR presented detailed explanation related to the prioritisation process for the cobalt compounds, assuring that all information has been considered. Based on the presented data, it became clear that the industry information regarding volumes for two out of the five compounds and wide dispersiveness of uses did not change significantly the original scoring towards lower priority. Furthermore, the issue of compatibility of Co-salts was also extensively discussed.

Some MSC industry observers stressed that some uses are considered as being intermediate uses contrary to ECHA's view and challenged the ECHA's analysis on compatibility of cobalt salts. With regard to the interchangeability of the cobalt salts a remark was made that not only the technical feasibility but also the costs should be considered when the potential for replacement of the salts by one another is made.

Some of the previously concerned MSC members, however, informed the committee that following the explanation given, they accepted the presented recalculations and agreed with the conclusions as regards these substances' prioritisation.

In conclusion, SECR reminded that the prioritisation is not based on a risk-assessment and that, the in-depth consideration of the comments received, and on updated registrations is still ongoing. The information on risks posed by the different uses of the substances and the control of these risks would be thoroughly considered in the authorisation granting phase provided the substances would be included in Annex XIV.

Exemptions

Referring to the big number of comments proposing exemptions from the authorisation submitted during the public consultation, one industry observer expressed concerns as regards the ECHA's responses to industries' requests to use Article 58(2) of REACH as a basis of exemptions referred to that in the draft recommendation no exemptions had been suggested. A MSC member also requested for the SECR's view on the application of the Community-wide measures in case a substance is produced by one company only and has only one single use.

SECR promised to continue analysing of the comments when developing a comprehensive picture on all different pieces of legislation proposed to be used as basis for exemptions. It was noted that the exemption on the uses of phthalates in the immediate packaging of medicinal products under Regulation (EC) No 726/2004, Directive 2001/82/EC and/or Directive 2011/83/EC included in the current Annex XIV provides an example of the exemption case. It was noted that no new aspects have been brought forward e.g. concerning the conclusion on under which conditions occupational health legislation would be considered to fulfil the conditions set out in Article 58(2). It was also clarified that not the prioritisation, but the authorisation process looks more in-depth into such issues like "one company-one substance-one use".

Transitional arrangements

Several members and a STO observer highlighted on the big number of public consultation comments requesting longer transitional periods for preparation for authorisation applications and longer periods for sun-set dates to be considered. In most of the cases this has been justified by complex vertical and horizontal supply chains, no EU manufacture of the substances used (applications would be for the downstream users) and small and medium size enterprises (SME) using the substances. Some MSC members feel that these comments should be thoroughly considered and pondered

against criteria that would be used for setting the application dates and sun-set dates and mentioned in ECHA guidance document.

Although some members recognised the benefits of having application dates as close as possible to entry into force of the update to Annex XIV, several MSC members were of a view that realistic transitional arrangements need to be established for some of the substances in accordance with the existing assessment criteria.

The MSC Chair made the following conclusions: Regarding the prioritisation, the most commented group was the one of cobalt compounds with suggestions for reducing the priority scores. However, so far no justified reason for de-prioritising these substances has been identified. Regarding the exemptions, the SECR review of the comments was not completed and their responses are to be prepared and sent to the rapporteur and WG shortly. Regarding the transitional arrangements, the suggested periods in the comments should be checked against the criteria and the rapporteur jointly with the WG should consider the need for revision of the transitional arrangements. Furthermore, the rapporteur and the WG assisting him were requested to take into account the outcome of discussions when preparing the draft MSC opinion for adoption at MSC-21.

Finally, the members were invited to provide their written comments on the draft recommendation and the draft opinion to the rapporteur and the WG members by 10 November 2011 for consideration during further elaboration of the draft MSC opinion.

Item 10 – Follow-up from MSC-19 on actions to increase efficiency of MSC work

- **Discussion and adoption of actions to increase efficiency of MSC work**

SECR introduced to MSC draft action points to increase the efficiency of MSC work and the members' comments received on some of them. Members were also provided with some statistical information (in a room document) regarding the number of dossier evaluation cases with modified draft decisions due to the MS proposed amendments.

Regarding the provision of clear text proposals for amendment by MSCA to be suggested directly to the text of the draft decisions, concerns were raised for possible legal implications or ambiguity when debatable issues are identified. SECR noted that providing clear message to the registrant is essential element in this regulatory process. From efficiency point of view it is essential that all contributors in the process, including MSCAs consider all necessary elements for a modification of a draft decision: legal basis, modification regarding the requested information and the statement of reasons. It was recognised that naturally uncertainties will remain regarding how the text of a draft decision should be formulated. However, SECR can help in finalisation of such text for the final draft decision. If such practice were adopted it would help greatly other members as well as SECR in preparation for the meetings/written procedures. If a more generic issue or concept needed further discussion it could be raised in a workshop or workshop-type of sessions of MSC. In response to a STO observer's query, SECR clarified that MSC observers' participation in such workshops or workshop-type sessions during the MSC plenary meetings would depend on the type of the expected discussions, confidentiality issues and the legal character of the topics for the session.

Following a comment from a member regarding the outcome of a written procedure with negative votes, the MSC Chair clarified that all cases proposed for agreement seeking by written procedure are selected by SECR on the basis of analyses on the content of the comments received (also visible in RCOMs). The Committee was reminded that in accordance with the MSC rules of procedure, the written procedure is an equally valid instrument for agreement seeking to the meeting one with the same consequences (i.e. transferring the case to the Commission for further decision-making by committology procedure). Therefore, members were encouraged to carefully consider the draft decisions/MSC agreements under written procedure and in case of concerns, to immediately contact the MSC SECR for clarification or termination of the written procedure. SECR would then terminate the written procedure and raise the case for agreement seeking at a meeting instead. In case of a negative vote, the member should provide his justification for the vote independently of the chosen instrument for agreement seeking.

MSC agreed with the draft Action points as presented by MSC SECR.

Item 11 – Manual of Decisions (MoD)

- **Discussion on next topics for MoD**

SECR introduced MSC with a topic proposed for inclusion in MoD of MSC on the based on the recent work in MSC on dossier evaluation, as indicated in document ECHA/MSC-20/2011/024. Furthermore, MSC was invited to establish a small group of members to identify potential issues for inclusion in MoD with the SECR support.

In the following brief discussion, members agreed in general to the proposed topic and supported the inclusion of the topic in the MSC MoD for improving the procedural understanding. However, it was suggested that on top of specification of the version of updates to the registration dossiers to be taken into account in draft decisions the process should be explained a bit more extensively to give the background to the limitations regarding updates. Thus, SECR was requested to prepare a text proposal of the agreed topic for the MSC-21 meeting.

MSC also supported establishment of a working group to be in charge of proposing new topics for MoD in the future. Therefore, SECR will prepare a mandate for the group, to organise a call for expression of interest among the MSC members and their experts and to inform the MSC on all the practicalities at the next MSC meeting in December 2011.

Item 12 – Report from other ECHA bodies and activities

- **Report from MB on topics relevant to MSC**

SECR gave report from the last MB meeting on the MSC relevant issues. Following the ECHA committees' unanimous agreements to invite Croatia to participate in their work, MB also agreed Croatia to be invited as an observer to the ECHA bodies' work. Thus, SECR would contact the Croatian CA and invite them to designate a person to take part as an observer in the MSC meetings.

SECR informed MSC of the new conflict of interest (CoI) policy (adopted on 30 Sept 2011) and its main elements, such us: the enlarged scope, the new definition provided of a "conflict of interest", the clearer responsibilities for handling the potential conflicts of interest, the newly developed more detailed declaration template, etc. It was

highlighted that the new CoI policy would influence the whole ECHA, including the Committees and the Secretariat's staff, as they need to fill-in annually more detailed declarations, following the newly-developed template in accordance with the guidance, the implementing procedure and a Code of conduct for ECHA bodies that would be provided in the forthcoming weeks.

Therefore, a revision process of the MSC Rules of procedure is expected to be initiated by the MSC Secretariat for the inclusion of the new declaration templates and further update of members' annual declarations using the new templates.

Item 13 – Any other business

- **Report from EUROMETAUX and CEFIC workshop**

The EUROMETAUX observer reported to MSC some feedback from the industry workshop on the status of raw materials use for the manufacturing of glass, frits, ceramics and enamels, held in Brussels on 12 October 2011. As many of the topics discussed there might be of interest of the MSC members in their work, it was suggested the report (under preparation by the organisers) and presentations given at the workshop to be provided to the MSC secretariat for distribution among the MSC members.

Item 14 - Adoption of conclusions and action points

The conclusions and action points of MSC-20 were adopted at the meeting (see Annex IV).

Signed

Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
ANASTASI Audrey Anne (alternate member)
ANDRIJEWSKI, Michal (PL)[1]
BIWER, Arno (LU)
COSGRAVE, Majella (IE)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
HUMAR-JURIC, Tatjana (SI)
KORENROMP, Rene (NL)
KULHANKOVA, Pavlina (CZ)
LUDBORZS, Arnis (LV)
LULEVA, Parvoleta Angelova (BG)
MARTIN, Esther (ES)
MIHALCEA-UDREA, Mariana (RO)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
SPETSERIS, Nikolaos (EL) (alternate member)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI) (alternate member)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
Representatives of the Commission
GARCIA JOHN, Enrique (DG ENTR)
KOBE, Andrej (DG ENV)
Observers
ANNYS, Erwin (CEFIC)
DMYTRASZ, Bohdan (CONCAWE)
LIGHTART, Jerker (HEAL)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (EUROMETAUX)

ECHA staff
AJAO, Charmaine
ANDERSSON, Niklas
BALDUYCK, Bo
BALOGH, Attila
BROERE, William
CARLON, Claudio
DE COEN, Wim
DE RAAT, Karel
DE WATZE, Wolf
FEDTKE, Norbert
HIRVONEN, Tero
HUUSKONEN, Hannele
KNIGHT, Derek
KARHU, Elina
KORJUS, Pia
KREUZER, Paul
KUITTINEN, Marko
LE CURIEUX, Frank
LEPPER, Peter
MALM, Jukka
NAUR, Liina
REUTER, Ulrike
RÖCKE, Timo
RODRIGUEZ IGLESIAS, Pilar
RÖNTY, Kaisu
RUOSS, Juergen
SUNDQUIST, Anna-Liisa
VAHTERISTO, Liisa
VASILEVA, Katya

[1] Present only on 4 November 2011

Proxies

- COSGRAVE, Majella (IE) also acting as proxy of DOUGHERTY, Gary (UK) and DEIM, Szilvia (HU)
- SPETSERIS, Nikolaos (EL) also acting as proxy of KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
- PISTOLESE, Pietro (IT) also acting as proxy of ANASTASI, Audrey Anne (MT) (for Friday afternoon)
- VASKIMAE, Enda (EE) also acting as proxy of LUDBORZS, Arnis (LV) (Friday from 10 a.m. onwards)

Experts and advisers to MSC members
ANDERSSON, Lars (expert to FLODSTRÖM, Sten)
ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BALCIUNIENE, Jurgita (LT) (expert to DUNAUSKIENE, Lina)
CSENGŐDY Krisztina (HU) (replacing DEIM, Szilvia)
GOMEZ, Jeannette (NL) (adviser to KORENROMP, Rene)
INDANS Ian (UK) (replacing DOUGHERTY, Gary)
JONGENEEL Rob (NL) (expert to KORENROMP, Rene)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
MOELLER, Ruth (LU) (expert to BIWER, Arno)
SULG, Helen (EE) (expert to VESKIMÄE, Enda)
SCHWÄGLER, Mark (DE) (expert to FINDENEGG, Helene)
SCIMONELLI, Luigia (IT) (adviser to PISTOLESE, Pietro)

By WEBEX-phone connection:
DOUGHERTY, Gary (UK) for discussions on 2-3 November 2011, for agenda items 6b-d, RAAF under 6e and items 8 and 9
GRACZYK Anna (PL) (expert to ANDRIJEWSKI, Michal) for discussions on 3 November 2011, for agenda item 9
HAKKERT, Betty (NL) (expert to KORENROMP, Rene) for discussion on agenda item 6b
TRAAS, Theo (NL) (expert to KORENROMP, Rene) for discussion on agenda item 6b, 6c and 6e)

Case owners:
A representative of the Registrant was attending under agenda item 6c for:
-CCH-032 (Allyl alcohol)
-TPE-019 (126-30-7_master_2,2-dimethylpropane-1,3-diol)

Apologies:
CAMILLERI, Tristan (MT)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
Dr KOUTSODIMOU, Aglaia (EL)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
CARMO PALMA, Maria do (PT)

III. Final agenda

Final Agenda

20th meeting of the Member State Committee

2-4 November 2011
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

2 November**: starts at 9:00**
4 November**: ends at 17:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/020/2011
For adoption

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

Item 4 –Administrative issues

- Satisfaction survey 2011

For information

Item 5 –Draft minutes of the MSC-19

- Adoption of the draft minutes of MSC-19

MSC/M/19/2011
For adoption

Item 6 –Dossier evaluation

Closed session for 6d
Indicative time plan for 6c is Day 1, for 6d Day 2&3

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

For members only: ECHA/MSC-20/2011/001
For information

b. Topics for discussion related to cases under 6c

a. In vivo genotoxicity testing – Unscheduled DNA Synthesis (UDS) test method and Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays

b. A comparison between EU test method B.35 Two-generation reproductive toxicity study (OECD 416) and OECD TG 443 Extended One-Generation Reproductive Toxicity Study (EOGRTS)

c. Legal and procedural questions for the testing proposal examinations in addressing the information requirements for two-generation reproductive toxicity study - implementation of EOGRTS

d. Possibilities and limitations in rejection of testing proposals

For information and discussion

c. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MS-CA reactions *(Session 1)*

For discussion followed by agreement seeking under 6d:

ECHA/MSC-20/2011/014
ECHA/MSC-20/2011/021

Tentatively open session

- CCH-027 Camphene (EC 201-234-8)

ECHA/MSC-20/2011/002-003

- CCH-032 Allyl alcohol (EC 203-470-7)

ECHA/MSC-20/2011/005-006

- TPE-017 4,4'-Methylenebis[N,N-bis(2,3-epoxypropyl)aniline] (EC 249-204-3)

ECHA/MSC-20/2011/008-009

- TPE-019 2,2-Dimethylpropane-1,3-diol (EC 204-781-0)

ECHA/MSC-20/2011/011-012

For information and discussion

6d. Seeking agreement on draft decisions on compliance checks and testing proposals when amendments were proposed by MS's *(Session 2, closed)*

- CCH-027 Camphene (EC 201-234-8)

ECHA/MSC-20/2011/002-004

- CCH-032 Allyl alcohol (EC 203-470-7)

ECHA/MSC-20/2011/005-007

- TPE-017 4,4'-Methylenebis[N,N-bis(2,3-epoxypropyl)aniline] (EC 249-204-3)

ECHA/MSC-20/2011/008-010

- TPE-019 2,2-Dimethylpropane-1,3-diol (EC 204-781-0)

ECHA/MSC-20/2011/011-013

For agreement

6 e. General topics

- Status report on ongoing evaluation work
- ECHA's approach in the evaluation of read-across and the development of a Read-Across Assessment Framework (RAAF)

For information

Item 7 – Substance evaluation

a. Introduction of the draft CoRAP by ECHA

ECHA/MSC-20/2011/015-017
ECHA/MSC-20/2011/022-023
For information

b. First exchange of views on the draft CoRAP and items to include in the MSC opinion

ECHA/MSC-20/2011/018 with Annex
For discussion and decision

Item 8 – SVHC identification

a. Information about the progress on SVHC identification

ECHA/MSC-20/2011/025 (Room document)

b. Information about the court cases

For information

Item 9 – Draft recommendation for inclusion of priority substances in Annex XIV

a) Progress report after closure of the public consultation on ECHA's Draft Recommendation and Draft Annex XIV entries for prioritised substances

ECHA/MSC-20/2011/020
For information

b) Preparations for the opinion on the draft recommendation of priority substances to be included in Annex XIV

- Report by the rapporteur and discussion of the first draft opinion
  - Exchange of views on comments received including transitional arrangements

ECHA/MSC-20/2011/027 (Room document)
ECHA/MSC-20/2011/028 (Room document)
For information and discussion

Item 10 – Follow-up from MSC-19 on actions to increase efficiency of MSC work

- Discussion and adoption of actions to increase efficiency of MSC work

ECHA/MSC-20/2011/019
ECHA/MSC-20/2011/026 (Room document)
For adoption

Item 11 – Manual of Decisions (MoD)

- Discussion on next topics for MoD

ECHA/MSC-20/2011/024
For discussion & decision

Item 12 – Report from other ECHA bodies and activities

- Report from MB on topics relevant to MSC

For information

Item 13 – Any other business

- Report from the Workshop of EUROMETAUX and CEFIC on the status of raw materials use for the manufacturing of glass, frits, ceramics and enamels

For information

Item 14 – Adoption of conclusions and action points

- Table with conclusions and action points from MSC-20

For adoption

IV. Main conclusions and action points

MSC-20, 2-4 November 2011
(adopted in the MSC-20 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
5. Adoption of the minutes of MSC-19	
Written comments received from meeting participants on the main conclusions and action points and on the sections discussing TPE 007/2011 and CCH 018/2011 had been taken into account. The confidential and non-confidential versions of the minutes were adopted without any further changes proposed in the meeting.	MSC-S to upload the adopted minutes on MSC CIRCABC and to publish the non-confidential version of the minutes on the ECHA website.
6. Dossier evaluation **6a) Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the report of ECHA.	MSC-S to upload on MSC CIRCABC the final ECHA decisions and agreements on cases CCH028/2011, CCH029/2011, CCH 030/2011 and TPE 018/2011 (documents for TPE 014/2011 are already on CIRCABC).
6b) Topics for discussion related to cases under 6c	
- (a) *In vivo* genotoxicity testing – Unscheduled DNA Synthesis (UDS) test method and Transgenic Rodent Somatic and Germ Cell Gene Mutation Assays (TGRA)	
Based on the current text of REACH guidance both UDS and TGRA are considered as appropriate to fulfil the requirements of the endpoint *in vivo* genotoxicity. For the time being, MSC has to decide on a case-by-case basis which one of these tests to use.	ECHA to consider a possible need to review the REACH Guidance concerning genotoxicity testing to take into account the recent scientific developments.
- (b) A comparison between EU test method B.35 Two-generation reproductive toxicity study (OECD 416) and OECD TG 443 Extended One-Generation Reproductive Toxicity Study (EOGRTS)	
MSC took note of the report of COM from the CARACAL expert group meeting, and ECHA's presentation. MSC acknowledged that currently MSC has to consider all cases, where EOGRTS/two-generation reproductive toxicity study is of a concern, on a case-by-case basis. So far no legal/financial analysis has been carried out by COM on implication of EOGRTS. Based on the outcome of this analysis, MSC urges COM to include EOGRTS in the Test Method Regulation and to amend the REACH Annexes as soon as possible.	By 16 November 2011, MSC members to provide comments (if any) on the presentation in writing.
- (c) Legal and procedural questions for the testing proposal examinations in addressing the information requirements for two-generation reproductive toxicity study - implementation of EOGRTS	
MSC took note of the report of ECHA and ECHA's	By 16 November 2011, MSC members

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
line how to deal with EOGRTS under REACH and in particular in dossier evaluation work before final decisions of COM are taken.	to provide comments (if any) on the presentation in writing.
6c) Introduction to and preliminary discussion on draft decisions on compliance checks after MSCAs' reactions *(Session 1, open)* **6d) Seeking agreement on draft decisions on compliance checks when amendments were proposed by MSCAs *(Session 2, closed)***	
<u>CCH 032/2011 (Allyl alcohol)</u> **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's draft decision, the proposed amendments of MSCAs and the Registrant's comments on the proposed amendments. MSC did not support the read across proposed by the Registrant for the two-generation reproductive toxicity study and for the prenatal developmental toxicity study on a second species. **Agreement seeking (6d, Session 2)** MSC concluded that the request for two-generation reproductive toxicity study should be deleted from the draft decision and the reasons to do so (i.e. the process to incorporate EOGRTS under REACH) be explained to the Registrant in the cover letter of the draft decision. MSC also agreed that the reasoning for not-acceptance of read across for the developmental toxicity study shall be amended. MSC reached unanimous agreement on ECHA's draft decision as referred to MSC and amended in the meeting based on the above conclusions. Also, the deadline for the Registrant to submit the information required was modified to 12 from 24 months and the statement of reasons changed accordingly. Otherwise the draft decision as referred to MSC has not been changed. MSC adopted the formal agreement. **<u>TPE-019/2011 (2,2-Dimethylpropane-1,3-diol)</u>** **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's draft decision, the proposed amendments of MSCAs and the registrant's comments on the proposed amendments. The Registrant sufficiently convinced MSC that his intention was to propose only the 90-day sub-chronic toxicity study with some additional examinations concerning reproductive toxicity. Therefore, MSC concluded that the two-generation reproductive toxicity study should not be required from the Registrant. However, the Registrant should be reminded that the intended additional examinations for the 90-day study may not fulfil the standard information requirements for reproductive toxicity as set out in Annex X, 8.7.3.	

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No other changes on the draft decision as referred to MSC were suggested by MSC members for further discussion in Session 2 (agreement seeking). **Agreement seeking (6d, Session 2)** MSC agreed that the Registrant should also be reminded in the cover letter of the draft decision that studies on a similar substance exist that the current substance can possibly be read across to. MSC reached unanimous agreement on ECHA's draft decision as referred to MSC and modified in the current meeting on the basis of the above conclusions. Also, the deadline for the Registrant to submit the information required has been modified to 18 from 24 months and the statement of reasons changed accordingly. MSC adopted the formal agreement. **TPE-017/2011 4,4'-Methylenebis[N,N-bis(2,3-epoxypropyl) aniline]** **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's draft decision and the proposed amendments of MSCAs. The main consideration of MSC was whether the two-generation reproductive toxicity test proposed by the Registrant should be rejected or accepted, conditioned on the results of the 90-day study. **Agreement seeking (6d, Session 2)** MSC concluded that the two-generation reproductive toxicity test should currently be rejected on the condition that if the 90-day study will indicate any adverse effect for reproductive toxicity, the Registrant should submit a testing proposal to cover the endpoint of Annex IX 8.7.3. The Registrant should be reminded that on the basis of other considerations he may also submit a testing proposal for this end-point at an earlier stage with indications of the reasons for testing. MSC also agreed to include in the draft decision that the Registrant should determine the sequence of sub-chronic and pre-natal developmental toxicity studies and consider the possibilities for adaptations of standard information requirements. MSC also concluded that the deadline for the Registrant to submit the information required should be modified to 24 from 36 months and the statement of reasons should be changed accordingly. MSC reached unanimous agreement on ECHA's draft decision as referred to MSC and modified in the meeting based on the above conclusions. MSC adopted the formal agreement. **CCH-027/2011 Camphene**	

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Discussion (6c, Session 1) MSC discussed the case based on ECHA's draft decision, the proposed amendments of MSCAs and the registrant's comments on the proposed amendments. MSC concluded that the M-factor is essential information for the classification and labelling of mixtures. As an adequate study on aquatic invertebrates is missing and this species can be potentially more sensitive than fish, the Registrant should be requested to submit a valid *Daphnia magna* test as the result of this study can have an impact on the M-factor or the PNEC value. Alternatively, the Registrant should be given the possibility to submit a valid QSAR estimation which may be used as basis for adapting the standard information requirement. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on ECHA's draft decision as provided to MSC and amended based on the above conclusion in the current meeting. MSC adopted the formal agreement.	MSC-S to upload in MSC CIRCABC the final ECHA decisions and agreements on cases CCH 027/2011, CCH032/2011, TPE017/2011 and TPE019/2011.
ECHA's approach in the evaluation of read-across and the development of a Read-Across Assessment Framework (RAAF)	
MSC took note of ECHA's report and generally supported ECHA's presented approach.	MSC to contribute to the development of RAAF by submitting any possibly relevant information to ECHA. ECHA to organise a Workshop in 2012 where a more detailed/advanced plan on how to implement RAAF is to be presented and discussed with MSC/MSCAs/StOs.
7. Substance evaluation **7a) Introduction of the draft CoRAP by ECHA**	
MSC took note of the report of ECHA.	ECHA to organise the next Workshop on Substance Evaluation in June 2012. Substance evaluation issues also to be discussed on the Evaluation Workshop in January 2012.
7b) First exchange of views on the draft CoRAP and items to include in the MSC opinion	
MSC took note of and generally supported the template for the opinion of MSC on the draft CoRAP. MSC agreed that the rapporteur and the opinion of MSC should focus on whether the risk based approach in the prioritisation for substance evaluation had been fol-	MSC and MSCAs to inform ECHA when a need for compliance check of registration dossiers is recognised during substance evaluation activities carried out by MSCAs.

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lowed. However, the opinion should not address whether the information to be required in or the prioritisation for substance evaluation of a given substance is justified.	ECHA to consider how to inform the Registrants of any relevant concern encountered during the process of substance evaluation.
8. SVHC identification **8a) Information about the progress on SVHC identification**	
MSC took note of ECHA's approach and selection of substances planned to be referred to MSC for identification as SVHC in an MSC meeting/written procedure.	For agreement seeking on their identification as SVHC in an MSC meeting and written procedure, ECHA to refer to MSC three and nine substances, respectively, as indicated in the relevant room document. ECHA to place eight substances, as indicated in the relevant room document, on the Candidate List of SVHC without involvement of MSC.
9. Draft recommendation for inclusion of priority substances in Annex XIV **9a) Progress report after closure of the public consultation on ECHA's Draft Recommendation and Draft Annex XIV entries for prioritised substances**	
MSC took note of the report of ECHA.	Industry stakeholders to indicate obvious errors in RCOMs to ECHA by 10 November 2011.
9b) Preparations for the opinion on the draft recommendation of priority substances to be included in Annex XIV **- Report by the rapporteur and discussion of the first draft opinion** **- Exchange of views on comments received including transitional arrangements**	
MSC took note of the report of the rapporteur.	MSC members and stakeholders to submit their written comments on the draft recommendation to the rapporteur by 10 November 2011. ECHA to finalise the responses to the comments received in the public consultation. Rapporteur to prepare the draft MSC opinion for the MSC-21 meeting.
10. Follow-up from MSC-19 on actions to increase efficiency of MSC work – Discussion and adoption of actions to increase efficiency of MSC work	
MSC took note of and adopted the actions points as presented by ECHA.	
11. Manual of Decisions (MoD) - Discussion on next topics for the MoD	
MSC supported the proposed topic and the proposal of ECHA to establish an MSC working group that will be in charge of proposing topics for the MoD of MSC.	ECHA to invite MSC members to volunteer for the membership in the working group, and to present the terms of reference of the working group and the text proposal of the agreed topic for the MSC-21 meeting.
12. Report from other ECHA bodies and activities – Report from MB on topics relevant to	

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MSC	
	Based on the new ECHA policy for managing potential conflicts of interest, ECHA to include the new template of the annual declarations in the RoP of MSC.
14. Adoption of conclusions and action points	
The conclusions and action points were adopted.	MSC-S to upload the main conclusions and action points on MSC CIRCABC by 7 November 2011.