**MSC/M/019/2011**
ADOPTED IN MSC-20

**Final Minutes**

# Minutes of the 19th Meeting of the Member State Committee (MSC-19)
# 20-23 September 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 19th 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

**a) Update from ECHA Secretariat on handling of conflicts of interest**

ECHA Secretariat (SECR) gave a short overview on ECHA's plans to introduce an overall policy on handling conflicts of interest of members of different ECHA bodies. A guidance document and a new declaration form with more detailed information will be used in the future. The guidance will include instructions how to fill in the form and how ECHA should handle these declarations. The Committees' Rules of Procedure will need to be modified in the near future to include the new declaration form. No questions or comments were raised by the meeting participants.

**b) Use of CIRCABC in MSC**

SECR gave a brief oral report on the experience gained since CIRCABC has been introduced. Also some new features of CIRCABC were presented. The members were requested to notify the SECR about any difficulties they may have faced with the use of CIRCACB. MSC took note of the report.

**c) Commission's Transparency Register for Stakeholders**

SECR informed that the Management Board of ECHA (MB) agreed at its meeting in June 2011 that one of the eligibility criteria for stakeholder organisations to participate in ECHA's work is the registration in the Register of Interest Representatives ('the transparency register') established by COM. Stakeholder observers participating in MSC's work were reminded to ensure their registration in the transparency register before the next MSC meeting. Missing registration may indicate that participation in MSC work would not any more be possible.

**d) Participation of Croatia in the work of MSC**

SECR reported that Croatia submitted a letter to ECHA expressing its wish to participate in the ECHA Committees' work. According to Article 106 of REACH, the MB of ECHA in agreement with the Committees can decide to invite third countries to participate in their work. Croatia as a candidate country closed all chapters for its EU Accession Treaty on the 30 June 2011 and its accession is expected for 1 July 2013. The Accession Treaty is currently to be signed by the end of 2011. When the Acces-

sion Treaty has been signed ECHA shall invite the Croatian representatives as observers to the Committees and when the Accession Treaty enters into force the Croatian representatives will become full members. SECR explained that it is normal practice to invite candidate countries to participate in the work of EU Committees. MSC took note of the report and unanimously agreed to invite Croatia to participate in its work.

## Item 5 – Adoption of the minutes of MSC-18

SECR explained that written comments on the draft minutes of MSC-18 received from one MSC member and one stakeholder observer had been taken into account and representatives of Registrants have been consulted for their respective parts of the draft minutes. The minutes were adopted with one minor further change. 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 a report on the written procedure of the five substances, *3-[2-(2-Hydroxyethoxy)ethylimino]-2,2-dimethylpropyl dodecanoate*, M-CDEA, vinyl neodecanoate, *A mixture of isomers of: 1,1'-[(3,5(or 2,4 or 4,6 or 2,6)-dihydroxy-o(or m or p)-phenylene)bis(azo-meta-phenyleneazo{1-[3-(dimethylamino)propyl]-1,2-dihydro-6-hydroxy-4-methyl-2-oxopyridine-5,3-diyl})]dipyridinium-dichloride-dihydrochloride; 1-(1-[3-(dimethylamino)propyl]-5-{3-[x-(4-{1-[3-(dimethylamino)propyl]-1,6-dihydro-2-hydroxy-4-methyl-6-oxo-5-pyridinio-3-pyridylazo}phenylazo)-2,4(or 2,6 or 3,5 or 4,6)-dihydroxyphenylazo]phenylazo}-1,2-dihydro-6-hydroxy-4-methyl-2-oxo-3-pyridyl)pyridinium-dichloride-dihydrochloride (where x is variable)* and m-phenylenebis (methylamine).

By the closing date 2 September 2011, responses were received from 22 MSC members with voting right and from the Norwegian MSC member. All responses were in favour and none was against the proposed decisions and agreements. It could be concluded that unanimous agreement on the draft decisions and respective agreement documents of these five substances has been reached by MSC on the 2 September 2011. ECHA will continue processing the agreements and decisions. The final documents will be made available on MSC CIRCABC. MSC took note of the report.

**b) Information to MSC on the state of play in the CARACAL Expert Group on the use of EOGRTS under REACH**

COM gave a brief report on the discussions of the Expert Group. The details of the presentation were provided to MSC on MSC CIRCABC.

COM clarified replying to questions that the discussions have not yet been concluded and after the Expert Group, also CARACAL and COM have to negotiate and take a stand on the topic. COM said that so far no legal analysis had been carried out by COM whether or not a Registrant can be requested to conduct an EOGRTS. The relevant cases may need to be handled case-by-case. It was reported that on the triggers for the second generation, the Expert Group had dissenting views and as no scientific hazard-based criteria were found, exposure criteria for triggering the second generation were looked for. COM stressed that the decision on possible postponing of compliance checks concerned is in ECHA's discretion. SECR highlighted that delays of testing proposal examinations are not possible. COM will report on further develop-

ments after the next CARACAL meeting (end of October 2011) in the MSC-20 meeting.

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

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

**TPE 007/2011 (2,3-epoxypropyl neodecanoate)**

***Session 1 (open)***

The representative of the Registrant did not participate in the initial discussion (Session 1). As no discussion on confidential issues was to be expected, an open session was held.

ECHA explained that the substance was registered in the tonnage band >1000 tonnes per year and proposals for amendment on ECHA's draft decision were submitted from three MSCAs. Two MSCAs proposed to use rat as test species instead of mouse in the sub-chronic toxicity study and the two-generation test as well as to consider the use of Extended One Generation Reproductive Toxicity Study (EOGRTS, OECD 443), rather than the two-generation protocol (OECD 416/EU B.35). Concerning reproductive toxicity testing, two MSCAs proposed a tiered testing strategy in order to first clarify carcinogenic/mutagenic properties with four tests before starting the two-generation reproductive toxicity study.

The Registrant in his written comments on the proposed amendments supported the proposal to use the rat as test animal instead of the mouse in 90-day and two-generation test but "somewhat disagreed" with the proposal to replace the two-generation test with EOGRTS. Regarding the proposal for tiered testing, the Registrant informed that negative results of an *in vitro* cytogenicity and an *in vivo* mutagenicity study have already been made available in the updated registration dossier. However, the Registrant agreed to carry out the remaining two first tier tests and proposed to apply a weight-of-evidence approach to the study data to evaluate classification and labelling for adverse target organ effects.

ECHA had modified the draft decision on the basis of the proposals for amendment regarding sequential testing and provided this modified draft decision for the meeting. MSC discussed the case based on ECHA's draft decision as provided for the meeting and on the proposed amendments of MSCAs, taking into account the Registrant's comments on the proposed amendments.

Concerning the test species for sub-chronic toxicity testing, ECHA had presented a written summary of arguments for and against the use of both species. Several MSC members supported the view that the alfa-2µ-microglobulin nephropathy in similar available tests with rats was not a dose-limiting factor and therefore the test species should be the rat. Some MSC members suggested that differential sensitivity of rat strains to this kind of nephropathy should be taken into account by the Registrant when selecting the strain of tests animals. One MSC member mentioned that due to the prolonged exposure durations for instance in chronic toxicity tests the nephropathy could interfere with other toxic effects, but in a 90-day study this is less likely. After some more discussion MSC concluded that the test species for sub-chronic toxicity testing (and for the possible two-generation test) should be the rat.

Concerning the issue of two-generation study versus EOGRTS, some MSC members were in favour of EOGRTS as specified by the OECD 443 guideline. Instead of requiring the two-generation study as had been proposed by the Registrant, they proposed to require the Registrant to perform the "highest tier" or "most appropriate" reproductive toxicity study to give the Registrant the chance to choose one of the two tests. They argued that 8.7.3 of Annex IX/X refers to a two-generation test without further specification. Some members considered that the Registrant could be required to perform the two-generation test either with the method OECD 416 (EU B.35) or EOGRTS to give the Registrant the chance to choose one of the two test methods. Some other members supported this argument but wanted to include as further specification the second generation in EOGRTS.

ECHA reemphasised that the Registrant preferred test method OECD 416 to OECD 443. However, requiring the Registrant to carry out the two-generation test either with the B.35 or OECD 443 test method with the second generation, recognised via Art. 13(3), was considered to be legally possible.

An industry observer supported the idea that decisions on this issue should be postponed until the relevant discussions in CARACAL and COM are closed.

***Session 2 (closed)***

In the vote, the majority of MSC members voted for and the minority against ECHA's draft decision as provided for the current MSC meeting by ECHA. The Chair explained that in this case of disagreement of MSC, the draft decision, the draft agreement, the RCOM, the result of the vote and the extract of the relevant part of the minutes with justification of (all) MSC members for their position will be submitted to the COM by ECHA, according to the procedure of Article 51(7) of REACH. COM will take the decision in accordance with the procedure of Article 133 of REACH.

**<u>CCH 022/2011</u> (Bis(5-amino-2-hydroxyphenyl)methane dihydrochloride)**

***Session 1 (open)***

Two representatives of the Registrant participated in the initial discussion (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.

ECHA explained that five proposals for amendment to ECHA's draft decision were submitted by two MSCAs. One CA had proposed the Registrant to update the registration dossier with all available relevant information including information from assessments carried out under other international programmes (Report of Scientific Committee on Consumer Products, SCCP[1]) and update the dossier as appropriate. The other CA had proposed ECHA to accept the information provided in the registration dossier with regard to the description of the analytical methods for the identification of the substance, due to the outcome of the notification of the substance under the New Chemicals Notification procedure. Furthermore, the same CA had also proposed ECHA to remove the request for data on vapour pressure, growth inhibition test on aquatic plants as well as for determination of the partition coefficient n-octanol/water from the draft decision.

[1] Since 2009 SCCS (Scientific Committee on Consumer Safety)

The Registrant had provided comments on the proposed amendments and agreed to update the dossier with the missing data taking into account the report of SCCP.

SECR had modified the draft decision based on the proposals concerning vapour pressure, growth inhibition test on aquatic plants and missing available relevant information from the report of SCCP. The modified draft decision had been provided to MSC as a meeting document for the current meeting.

The representatives of the Registrant confirmed in the meeting their agreement with the proposal to update the registration dossier with the conclusions of the SCCP report.

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 to the proposed amendments. In the discussion, MSC members from the two MSs that proposed amendments accepted how ECHA reacted to their proposals. No further discussion points were raised. SECR clarified some relevant procedural steps of the dossier evaluation process for the Registrant.

***Session 2 (closed)***
MSC found unanimous agreement on ECHA's draft decision as provided for the current meeting without further amending it, and adopted the formal agreement.

**<u>CCH 020/2011</u> (2,3-epoxypropyl neodecanoate)**

***Session 1 (open)***

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

Ten proposals for amendment to ECHA's draft decision were submitted by four MSCAs. One CA had proposed to amend the draft decision with regard to the estimated boiling point and the expression used for the estimated reliability of the study. This CA had also proposed to recommend a tiered testing approach to the Registrant in order to clarify carcinogenic/mutagenic properties before initiating the two-generation reproduction study (this proposal for amendment concerns more the draft decision on TPE-007/2011 on the same substance; please see the Registrant's comments under the discussion of TPE-007/2011).

Another CA had proposed not to specify the test for mutagenicity and to allow the Registrant to select the option of doing an *in vitro* cytogenicity (IVC) test (EU B.10) or an *in vitro* micronucleus study (OECD 487). They also did not agree with requesting an *in vivo* unscheduled DNA synthesis (UDS) test for genotoxicity and proposed to request a transgenic rodent assay (TGR) in accordance with the new OECD test guideline (OECD 488). In addition, they had proposed to request the Registrant to conduct a repeated algal inhibition study (once the water solubility test requested under the compliance check is completed) and to update the CSR on the basis of the physico-chemical and environmental fate data from the compliance check. A third CA had proposed also TGR assay instead of UDS.

The fourth CA had questioned the acceptability of waiving arguments concerning surface tension, stability in organic solvents and identity of relevant degradation products, dissociation constant and biodegradation.

The Registrant in his written comments on the proposed amendments had agreed to check the waiving arguments for the surface tension, stability in organic solvents/identity of the relevant degradation products and dissociation constant. Regarding biodegradation and persistency the Registrant had seemed to agree to carry out hydrolysis study and then to consider bioaccumulation testing. Regarding the proposal to repeat algal inhibition study the Registrant had agreed to conduct a new study. Furthermore, the Registrant had informed that cytogenicity study in mammalian cells has already been carried out in accordance with EU method B.10 to meet registration requirements in Asia. The Registrant had also informed that the *in vivo* mutagenicity test (UDS) had already been carried out to meet registration requirements in Asia. ECHA had modified the draft decision based on the proposals concerning the boiling point, the repeated algal inhibition study and biodegradation. The modified draft decision had been provided as a meeting document for the current meeting.

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 to the proposed amendments.

Concerning surface tension, the MSC member from the MS that proposed the amendment stressed that based on the chemical structure of the substance surface activity could be expected. MSC concluded that the test could be asked for.

Concerning stability in organic solvents, the same MSC member asked ECHA how the stability can be guaranteed taking into account the molecular structure of the substance. ECHA replied that the test can be required only when the surface tension is critical which was not considered to be so in this case. According to the guidance surface tension can be considered critical for technical reasons, but it does not refer to toxicity or ecotoxicity.

Concerning dissociation constant, the same MSC member repeated the relevant proposal for amendment and stated that waiving of the Registrant based on the functional groups was not acceptable and a new test or a better waiving argumentation should be requested. Supported by an observer of an NGO, MSC concluded that waiving may not be acceptable.

MSC also supported the proposal to request the algal inhibition test and the proposal to update the CSR based on the requested physico-chemical and environmental fate data, including bioaccumulation.

Regarding testing for *in vitro* mutagenicity in accordance with EU B.10, MSC concluded that as such the proposed amendment to leave the choice for the registrant to choose between the two test methods in accordance with Annex VIII, 8.4.2 is correct and suggested to introduce the two options for the tests in the draft decision. This would not harm the Registrant although the Registrant made the choice already.

Regarding *in vivo* mutagenicity, the Registrant has carried out an *in vivo* UDS test and not the TGR that was proposed by two CAs. At the time when the Registrant submitted the registration dossier, the guideline for TGR (OECD 488) was not yet adopted by the OECD. Some MSC members stressed that TGR is a more sensitive and modern test than UDS. MSC concluded that there may be a reason to ask for the TGR assay.

***Session 2 (closed)***

In the continued discussion on *in vivo* mutagenicity, several MSC members stressed that based on alerts from non-test results, there is a clear concern for mutagenicity.

UDS measures DNA repair caused by DNA damaging chemicals in liver while TGR measures mutations, is able to detect mutations in several organs and it was argued that it is a more sensitive test. Therefore, TGR is more sensitive to mutagenicity, allows analysis in multiple suspected target organs and gives higher level of proof so it is more appropriate in this case. Therefore it was concluded that sufficient scientific justification exists to request TGR instead of UDS test. COM also emphasised that good scientific justification is needed for asking another *in vivo* mutagenicity study.

ECHA replied that there is no reason to assume that the Registrant followed the draft decision when conducting the UDS test. At the time of issuing the draft decision ECHA was convinced that the most appropriate test was the UDS because it was the only available adopted test guideline for *in vivo* mutagenicity. ECHA considered that there are no legal obstacles to request TGR as it is at present an internationally accepted test method recognised as being appropriate. Annex IX 8.4 does not specify a test method to be used for *in vivo* mutagenicity test. However, UDS and recently also TGR are available test methods adopted by OECD for this endpoint. There are scientific arguments supporting the need for TGR so that in an overall perspective the request would appear to be proportionate. MSC agreed that a request for TGR test instead of UDS will be made, with request to investigate mutagenicity in liver, bone marrow, kidney and developing germ cells.

MSC also agreed that concerning degradation test in section II, the reference to exact test method is replaced with a general reference to the guidance (where the available test methods are cited). It was considered that reference to the guidance would give to the Registrant better understanding how the specific test methods should be applied for the persistency assessment. In the relevant part of the statement of reasons more detailed instructions on methodology for enhanced biodegradability is given.

As a conclusion, MSC agreed on the following changes of the draft decision: the request for data on stability in organic solvents was deleted, request for test on surface tension, dissociation constant, algal inhibition test was included, request for biodegradation and *in vitro* mutagenicity (i.e. the Registrant is given the choice to choose between the *in vitro* cytogenicity (IVC) test (EU B.10) or an *in vitro* micronucleus study (OECD 487)) was changed. For *in vivo* mutagenicity, TGR assay in mouse was requested instead of the UDS test. Statement of reasons was modified accordingly. Furthermore, as the phrase “to update the CSR accordingly” refers to more endpoints requested, a generic statement was inserted in section II.

MSC found unanimous agreement on ECHA’s draft decision with the above modifications and adopted the formal agreement.

SECR concluded that the case is a precedent: first, MSC considered that it cannot take into account in its agreement seeking an update of the dossier submitted to ECHA after the start of MSCA consultation and second, MSC recognised for this specific case that a test method can be imposed which has recently been adopted by the OECD but not yet included in the Test Method Regulation.

**<u>CCH017/2011</u> (CETIOL CC)**

***Session 1 (closed)***

Two representatives of the Registrant participated in the initial discussion (Session 1). Due to justified confidentiality concerns in the draft decision, the Registrant did not accept the presence of the stakeholder observers in the discussions in Session 1, there-

fore, a closed session was held. The Chair informed the representatives of the Registrant on the relevant practicalities during and after Session 1.

Three proposals for amendment on ECHA's draft decision were submitted by three MSCAs. One CA had proposed to request the Registrant to perform a step-wise testing for bioaccumulation. Another CA had proposed to include a recommendation for the Registrant to consider conducting a screening reproductive/developmental toxicity test (OECD 421) in addition to the pre-natal development toxicity study. The third CA had proposed that the Registrant should be encouraged to develop a sound read-across to the existing toxicokinetic information on structurally related substances, rather than conduct a pre-natal developmental toxicity study.

The Registrant in the written comments to the proposed amendments had agreed to use read-across for prenatal developmental toxicity instead of performing a study and proposed to provide some further justification for the read-across. Also, he had informed about a planned OECD 414 study for a structurally-related substance to be used as further justification for read-across. Concerning bioaccumulation (Flow-through fish test), the Registrant had provided further arguments in relation to the proposed amendment and disagreed to base argumentation on calculated low Kow data instead of available experimental data.

The representatives of the Registrant in the meeting repeated their written comments stating that the substance hydrolyses *in vivo* very rapidly thus no toxic effect can be caused by the parent substance. More specifically, due to the rapid hydrolysis, the parent substance can not reach the reproductive organs and therefore no reproductive toxicity study is needed.

SECR had not modified the draft decision in advance of the meeting based on the proposed amendments. 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.

Concerning bioaccumulation, the MSC member from the MS proposing the test agreed not to request the study.

Concerning pre-natal developmental toxicity study, the MSC member from the MS proposing the read across emphasised that the parent molecule is metabolised in the body very rapidly into $CO_2$ and octanol so the systemic effect is very likely to be dominated by octanol. Therefore, a read across to octanol should be justified. He said it is possible but extremely unlikely that the reactive parent substance or a reactive metabolite after metabolism in liver could reach the reproductive organs. The representatives of the Registrant agreed that in studies with substances structurally similar to octanol there was no hint for reprotoxic effects.

ECHA explained that it cannot be excluded that the parent substance can reach reproductive organs although the likelihood is low. In the toxicokinetic study, some radioactivity was found in reproductive organs and uncertainty remains on possible reproductive effects of the parent compound or metabolites other than octanol.

***Session 2 (closed)***

In the further discussion it became clear that negative results of the gene mutation study required in the draft decision would be sufficient in this particular case for the Registrant to waive the pre-natal developmental study. This is based on the assumption that (a) potential reactive metabolite(s) would give a positive mutagenicity result and therefore this potential reactive metabolite could lead also to developmental ef-

fects. If the mutagenicity study would be negative, it would deliver further indications that a reactive metabolite is not formed from the parent compound. If the results would be positive, ECHA would open a compliance check on the dossier and request the Registrant to consider further tests to clarify the positive results. Based on these considerations, MSC agreed that the pre-natal developmental toxicity test should not be required in the draft decision and as a consequence, the time period for the Registrant to provide an updated registration dossier should be shortened from 12 to nine months. Explanation to the Registrant for the reduced time period should be given in the cover letter.

MSC found unanimous agreement on ECHA's draft decision as modified in the current meeting, and adopted the formal agreement.

**TPE014/2011 (Mono- and/or di- and/or tri(1-phenylethyl)-m-cresol and p-cresol)**

***Session 1 (open)***

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

Nine proposals for amendment on ECHA's draft decision were submitted by two MSCAs. Five CAs had proposed to reject the request for a two-generation reproductive toxicity study at this tonnage level (100-1000 tonnes per year), due to misinterpretation of the results of the available 28-day and reproductive/developmental screening study. The CAs had emphasised that the two-generation study could be requested only based on results of a 90-day study. Furthermore, one CA had challenged the wording of the draft decision where reference is made to the OECD process for setting up the guideline for extended one-generation reproductive toxicity study (EOGRTS). Another CA had proposed to delete from section II (Testing required) of the draft decision requesting the Registrant to clarify the identity of one of the constituents of the registered substance.

The Registrant in his written comments on the proposed amendments had agreed with the proposals to reject the testing proposal for the two-generation study indicating that the need for two-generation study on reproductive toxicity would depend on the results of the 90-day study.

ECHA had modified the draft decision based on all proposals and the modified draft decision had been provided as a meeting document. MSC discussed the case based on ECHA's modified draft decision as provided for the meeting, the proposed amendments of MSCAs and the Registrant's comments to the proposed amendments.

Considering the request for the two-generation reproductive toxicity study, MSC members expressed different views suggesting to (conditionally) reject or to (conditionally) accept based on results of the 90-day study the two-generation study but ask for EOGRTS, or to leave the test method open.

ECHA emphasised that as the information requirement for the two-generation test in this case is not an absolute one but needs clear toxicological triggers (8.7.3 of Annex IX), there is a legal possibility to reject the test.

Concerning the two proposals on identity of the substance to be tested and wording regarding OECD development process for EOGRTS, MSC concluded that section IV on substance identity will be deleted from the draft decision and the wording on

EOGRTS as proposed by ECHA based on the amendment proposals would not be changed.

***Session 2 (closed)***
As a conclusion, MSC modified the draft decision that was provided for the meeting as follows: (1) the two-generation reproductive toxicity study was rejected but this was made conditional on the results of the 90-day repeated dose study. More specifically, if results of the 90-day study are not severe enough to induce classification of the substance, a new testing proposal for the two-generation study would have to be submitted to ECHA. However, the Registrant was reminded about the possibility to submit a testing proposal for the two-generation study if other available information would indicate a need for it; (2) the deadline for submitting the required tests was reduced from 36 to 18 months; (3) the statement of reasons was modified accordingly concerning the response to third party comments, the deadline and the tests required; (4) section IV on adequate identification of the composition of the material to be tested was deleted.

The Chair concluded that majority of the members present were in favour of the modified draft decision. Due to lack of quorum it was decided that unanimous agreement on the draft decision and the formal agreement will be sought in an urgent written procedure starting after the meeting on 23 September and closing on 30 September 2011.

**<u>TPE012/2011</u> (Reaction mass of disodium hydroxysulfinatoacetate and disodium hydroxysulfonatoacetate)**

***Session 1 (open)***
The representative of the Registrant did not participate in the initial discussion (Session 1) but accepted the presence of stakeholder observers in this discussion, therefore an open session was held.

SECR explained that two proposals for amendment on ECHA's draft decision were submitted by two MSCAs. One CA had proposed that the Registrant should either conduct the 90-day study or submit a robust argument for waiving the 90-day study. The other CA had proposed to include in the draft decision the recommendation to request the Registrant to consider also performing a screening study for reproductive/developmental toxicity (OECD TG 421) in accordance with Annex VIII.

The Registrant in his comments to the proposed amendments had supported ECHA's draft decision and disagreed with the proposed amendments.

SECR had not modified the draft decision based on the proposed amendments. MSC discussed the case based on ECHA's draft decision as referred to MSC, the proposed amendments of MSCAs and the Registrant's comments on the proposed amendments. SECR indicated that the Registrant will be informed in a notification letter to the decision that the screening study should be considered.

In the detailed discussion, the relevant MSC members of the proposing CAs accepted ECHA's proposal that the draft decision does not need to be modified. MSC also supported these views.

***Session 2 (closed)***
MSC reached unanimous agreement on ECHA's draft decision without any modification. MSC also adopted the formal agreement.

**<u>CCH018/2011</u> (Dipropylene glycol methyl ether acetate (DPMA))**

***Session 1 (open)***

Two representatives of the Registrant participated in the initial discussion (Session 1) and accepted the presence of stakeholder observers in this discussion, therefore an open session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

Proposals for amendment to ECHA's draft decision were submitted by two MSCAs. One MSCA had considered the case as borderline for read-across and suggested further discussion in relation to the requested 90-day repeated dose and the pre-natal developmental toxicity study. The other MSCA had not agreed to request the Registrant to conduct these studies and supported the Registrant's read-across arguments for these endpoints.

The Registrant in his written comments on the proposed amendments had agreed with the proposal for read-across and provided further arguments for read-across. The Registrant had argued based on available studies on similar substances that hydrolysis would be even more rapid *in vivo* than *in vitro* thus making the time when the substance would be available in the body very limited and justifying the read across argument based on hydrolysis products. The Registrant had disagreed with the other CA that further testing (i.e. 90-day repeated dose and the pre-natal developmental toxicity study) would be needed.

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

The representatives of the Registrant repeated their main argument in the written comments to the proposed amendments - the rapid hydrolysis - for read across. In their view, the *in vitro* half life of the parent substance is short and the substance hydrolyses already in the stomach and gut to dipropylene glycol methyl ether (DPM). Accumulation of the parent substance in the body is not likely due to low log Kow. 28-day studies are available for both DPM and DPMA indicating a very similar toxicity profile, and DPMA also demonstrates a lack of reactivity in the available genotoxicity studies, skin sensitising studies and irritation studies. Moreover, 90-day dermal and inhalation studies are available for DPM which demonstrate low toxicity. Therefore, read across from DPM to DPMA is justified. The Registrant clarified that although the beta isomer of monopropylene glycol ether (which is teratogenic) also is produced during the manufacturing of propylene glycol ethers, this isomer is eliminated as much as possible from commercial propylene glycol methyl ether (PM) so their level (<0.3%) does not reach the level at which the substance would need to be classified. In DPM and its corresponding acetate (DPMA), the beta-isomer of PM is not present at all. The Registrant also commented that the dermal penetration of DPMA is very low and as such, since the major route of exposure would be via the skin, human exposure through its uses would be very low, lending further confidence to the use of read-across to address the 90-day and pre-natal development endpoints.

One MSC member pointed out that QSAR screening showed some alerts for mutagenicity/carcinogenicity, however they confirmed that this QSAR information was provided for information only and that it was not to be considered further in the discussions. The same MSC indicated that *in vivo* data on hydrolysis of DPMA itself would make the read across case stronger. The MSC member of the MS proposing

read across agreed with the argumentation of the Registrant. ECHA highlighted that 10% of substance could be in the body from 30 min to some hours and toxic effects can not be excluded during this time. SECR also stressed that there is only limited data available on reprotoxicity of similar substances and that read across from a smaller substance (DPM) to a bigger one (DPMA) can sometimes be misleading because a single functional group like acetate in this case can lead to changes in the toxicity profile. The Registrant re-iterated their earlier comments that in this particular case, the additional functional group would not significantly alter the behaviour of the substance in the body and there is no evidence of any significant difference between the toxicity of the substance (DPMA) and the read-across substance (DPM).

***Session 2 (closed)***

ECHA proposed not to request the 90-day study but keep the request for the prenatal developmental toxicity study. Some MSC members argued that read across should be accepted for both tests.

ECHA explained that read across could be accepted for the 90-day repeated dose study based on the weight of evidence of the available negative results of the 28-day studies for the registered substance and on the category read across arguments.

After this explanation, MSC members supported ECHA's argumentation and agreed that the 90-day study will not be required from the Registrant in the draft decision and the statement of reasons will be modified accordingly. With these modifications on ECHA's draft decision that was referred to MSC, MSC found unanimous agreement on the draft decision and adopted the formal agreement.

**<u>CCH019/2011</u> ((trans(trans))-4'-Vinyl-4-(4-methylphenyl)bicyclohexyl (CCP-V-1))**

***Session 1 (open)***

Two representatives of the Registrant participated in the initial discussion (Session 1) and accepted the presence of stakeholder observers in this discussion, therefore an open session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

Five proposals for amendment to ECHA's draft decision were submitted by four MSCAs. One CA had expressed concerns with regard to the legal basis of the draft decision (a former new notified substance (NONs)) and proposed more detailed scientific argumentation to be provided in the draft decision for requesting of a new test for chromosomal aberrations as well as scientific grounds for non-acceptance of the mouse lymphoma assay for the mutagenicity endpoint. Furthermore, the same CA had proposed to remove the request for a combined 28-day/reproductive toxicity screening test from the draft decision because the CA considered the existing 28-day study valid and waivers based on "non-significant exposure" used by the Registrant sufficient to waive the reproductive toxicity study. A second CA had proposed to replace the request for the combined study (OECD 422) with the reproduction/developmental toxicity screening test (OECD 421) only as the information from 28-day repeat dose toxicity study is already available and in relation to animal welfare. The third CA had not agreed with the request for a repeated dose toxicity study (28-days) as the existing information would be sufficient for classification and risk assessment purposes. The fourth CA had proposed to include in the draft decision a request to the Registrant to provide more details in the robust study summary of the bioaccumulation study and to revise the PBT assessment, as well as to submit new testing proposals to further explore the potential PBT properties of the substance.

The Registrant in his written comments on the proposed amendments had agreed with the proposals considering the existing 28-day study valid and had not seen a need to repeat the test. The Registrant had supported the proposal that mouse lymphoma assay should be accepted and did not see another *in vitro* chromosome aberration study warranted. The Registrant had agreed that exposure based waiving requirements are met for waiving the screening study for reproductive/developmental toxicity. The Registrant had explained that a valid, guideline- and GLP-compliant BCF study is available that can be used for PBT assessment and agreed to update the robust study summary in the registration dossier.

ECHA Secretariat had modified the draft decision based on the following proposals for amendment: more details for robust study summary for bioaccumulation, revision of and new testing proposal for PBT assessment, improvement of the scientific argumentation for non-acceptance of the mouse lymphoma assay for the mutagenicity endpoint. The modified draft decision had been provided to the current meeting as a meeting document.

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.

The representatives of the Registrant generally repeated their written comments on the proposed amendments. They expressed their view that after the negative mouse lymphoma assay, a request for a chromosomal aberration test is not justified and usually not requested e.g. for pharmaceuticals. They were of the view that results of a chromosomal aberration test correlate very well with the findings in the mouse lymphoma assay. They also stressed that in their view the deaths in the 28-day study were not related to the effects of the substance but were treatment related and the only effect at low dose was increased liver weight which is a not adverse effect but an adaptive response. They also disagreed with that a BCF (bioconcentration factor) value based on a valid GLP-compliant OECD test would not be considered as sufficient and refinement of the PBT assessment based on QSAR would be requested.

Regarding the proposed amendment questioning the legal basis for the compliance check ECHA clarified that based on Article 24(2) of REACH ECHA is competent to perform a compliance check on a registration dossier following a tonnage band upgrade of a former NONS case. MSC supported ECHA's view.

Concerning mutagenicity, ECHA explained replying to the Registrant that the lymphoma assay is a valid test for detection of mutagenicity but generally not sufficient for detection of chromosomal aberrations, i.e. the scope of these two assays is different. More specifically, ECHA was of the view that the Registrant could not satisfactorily show that colony sizing information from the lymphoma assay is sufficient for detection of chromosomal aberrations. It was acknowledged that there may be discrepancies between the requirements of REACH and those of the legislation regulating pharmaceutical chemicals.

Concerning the request for a screening study or the combined 28-day/developmental toxicity screening test some MSC members and an observer of an animal welfare organisation supported the use of a simple screening study for animal welfare reasons. They argued that although the combined test would not require a higher number of animals it would require additional blood sampling and more handling of animals.

The representative of the Registrant agreed with their view. ECHA replied that for animal welfare reasons blood sampling can also be performed at termination.

MSC discussed the proposed amendment to accept the "exposure based waiving" argument of the Registrant for the combined 28 day/reproductive toxicity screening study. The definitions of "significant exposure" and "well below DNEL" under Annex XI, 3.2.(a)(i) and 3.2.(a)(iii), were considered respectively. MSC agreed that the exact definition of these phrases is missing and the guidance does not explain these concepts. Concerning PBT assessment, the MSC member of the MS that proposed the relevant amendment highlighted that the weight of evidence approach indicates the substance has a tendency to bioaccumulate. He did not suggest further tests as environmental exposure does not seem significant based on the Registrant's most recent data but proposed the Registrant to reassess the PBT properties of the registered substance and update the CSR accordingly. MSC supported the proposal. The representative of the Registrant stated that based on a valid BCF study, no significant environmental exposure and extremely low solubility, the environmental risk is very low.

***Session 2 (closed)***

MSC concluded that "exposure based waiving" arguments were not sufficient in this case.

MSC agreed that the draft decision should include (1) the combined 28 day/reproductive toxicity screening test with a request for terminal blood sampling in Section II and the statement of reasons should be changed accordingly (2) more explanation in Section III concerning *in vitro* cytogenetics why the lymphoma assay (with colony sizing) is not sufficient to detect chromosomal aberrations (3) refined explanation in Section III on PBT assessment.

MSC reached unanimous agreement on ECHA's draft decision after the modifications as listed above and adopted the formal agreement.

**<u>TPE016/2011</u> (1,2,3-Propanetricarboxylic acid, 2-hydroxy-, tri-C18-22 esters Tri-C18-22 (even numbered)-alkyl 2-hydroxypropane-1,2,3-tricarboxylate)**

***Session 1 (open)***

The representative of the Registrant did not participate in the initial discussion (Session 1) but accepted the presence of stakeholder observers in this discussion, therefore an open session was held.

ECHA explained that four proposals for amendment on ECHA's draft decision were submitted by three MSCAs. One CA had proposed that the Registrant should either conduct the 90-day study or submit a robust argument for waiving the 90-day study. A second CA had proposed to specify that the Registrant should perform first a limit test for both the 90-day repeated dose and pre-natal developmental toxicity study; in case of adverse effects observed in the limit test, the Registrant shall be requested to perform full studies. The third CA had proposed to include in the draft decision the recommendation to request the Registrant to consider also performing a screening study for reproductive/developmental toxicity (OECD 421) in accordance with Annex VIII.

In his written comments to the proposed amendments, the Registrant had agreed that the substance was likely to be of low toxicity but was still of the view that the 90-day study should be conducted. The Registrant had also shared the view that the limit test

would save animals, and expressed his intention to perform first a limit test for the 90-day study and, if no adverse effects would be observed in the 90-day limit study, also for the pre-natal developmental toxicity study. The Registrant had disagreed to perform a screening study for reproductive/developmental toxicity.

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

In the discussion, the relevant MSC members of the proposing CAs accepted ECHA's proposal that the draft decision does not need to be modified concerning the 90-day study and the recommendation to the Registrant to consider performing a screening study for reproductive/developmental toxicity (this will be included in the notification letter of the final decision). MSC supported these views.

MSC also concluded that for animal welfare reasons, although the limit test concept is part of the test guideline, the possibility of performing a limit test for both the 90-day and pre-natal developmental toxicity study should explicitly be mentioned in the statement of reasons of the draft decision in accordance with a proposal for amendment of a MSCA.

***Session 2 (closed)***
MSC modified the statement of reasons in the draft decision so that the Registrant is reminded that there is a possibility to perform a limit test for both the pre-natal developmental toxicity and the 90-day sub-chronic toxicity study.

MSC reached unanimous agreement on ECHA's draft decision after the above modification. MSC also adopted the formal agreement.

**e) Discussion of any further comments made by MSs during CA consultation (no agreement seeking necessary)**

With regard to a comment, SECR first gave a presentation on ECHA's approach on TPE cases where substance identity may not be fully clear in all respects, but the situation is clear enough to issue a draft decision on the testing proposal. ECHA in these cases uses a standard text in a separate section of the draft decision reminding the Registrants that they have a responsibility to ensure the sameness of (1) the registered substance and the tested substance and (2) the identity of the substance in dossiers of joint Registrants. MSC and also an industry observer supported ECHA's approach.

Concerning a second comment, ECHA clarified that if the adverse effects seen in a 90-day study are sufficient for classification of the substance, there is no need for a two-generation study to fulfil the requirement of 8.7.3 of Annex IX/X. If the adverse effects are not sufficient for classification, the two-generation reproduction toxicity study needs to be conducted.

Regarding a third comment, SECR pointed out that 3rd party comments and ECHA replies to them will be dealt in an annex of the draft decisions in the future, in order not to confuse and distract the Registrant from the core content of the decision. To repetitive comments standard answers will be developed and provided.

**f) Information on appeal process and one appeal case**

SECR gave a detailed presentation on the appeals process and on the details from an ongoing appeal case. SECR replied to a question that it needs further consideration whether an appeal would suspend the effect of all parts (e.g. other requests for information) of the decision appealed against or only the specific part of the decision that was appealed against.

**g) General topics:**

- **Status report on ongoing evaluation work**

SECR gave a summary report on the current situation and on future challenges of dossier evaluation work in ECHA. Estimates for the workload of the next MSC meetings were provided. With regard to MSCA consultations, SECR highlighted that comments with supporting argumentation and exact text proposals for amendment of draft decisions within the set deadlines are appreciated. Simple supporting comments should be avoided because they add to the workload. SECR informed that from 1 September 2011 onwards IUCLID files will not be provided on Evaluation CIRCA but only on MSC CIRCABC. Every effort will be taken to handle similar draft decisions in batches, simplify and rationalise the workflow and document handling. SECR will duly inform MSCAs when compliance check draft decisions are targeted on substance identity. The above information will be provided also to the CARACAL meeting.

- **Dossier Evaluation Workshop January/February 2012**

SECR announced the workshop to be held on 31 January-1 February 2012 (the week before MSC-22) and informed that nominations for the preparatory working group should be submitted to ECHA by 5 October 2011. Participation of stakeholder organisation will be further assessed. Main topics will be how to enhance collaboration between ECHA and MSCAs, how to reduce the number of draft decisions referred to MSC and how to gain efficiency in the decision making process.

## Item 7 – Proposals to tackle MSC workload

- **Discussion on how to increase efficiency of MSC work**

As the document was discussed at MSC-18 meeting, SECR presented only the changes of the document revised on the basis of the written comments of MSC members since the MSC-18 meeting.

MSC generally supported the document. However, one MSC member disagreed with some of the examples brought up by ECHA regarding policy issues which as such in ECHA's view should not be discussed by MSC but by CARACAL meetings. Another MSC member stated that some policy issues need to be dealt with by MSC and missed any appreciation for the several proposals made by MSCAs that improved the quality of ECHA's decisions. SECR replied that there is a fine line between policy and scientific technical matters which should not be crossed in MSC otherwise ECHA would loose credibility as an independent scientific and technical body. Keeping out policy issues would also help to reduce the number of the proposed amendments because currently many of them are based on policy related matters.

One MSC member suggested updating the paper with an extension of the purpose of compliance checks stating that compliance check draft decisions should also give an incentive to industry to improve registration dossiers by repeated updates. SECR proposed to discuss the suggestion in the dossier evaluation workshop end of January 2012.

Some other MSC members asked for a better communication between ECHA and MSCAs and asked if decision support documents (DSD) could be sent to MSCAs like it was the case in the pilot project. Others suggested technical improvements like using a reference to the specific MSC meeting on MSC documents while others asked for statistics on dossier evaluation cases showing how many proposals were submitted and based on them how many cases were modified by MSC/ECHA. Recommendations for phone conference instead of Webex and for workshop-type MSC sessions were also made. Some MSC members also pled ECHA to reply to MSCA comments made in the dossier evaluation process, to send RCOMs with ECHA responses to the proposed amendments back to MSCAs not only to MSC members and to avoid sending documents of different MSC meetings at the same time. Interest for a paper on document flow and meeting organisation and for possible invitation of stakeholders to ECHA/MSC workshops was expressed.

Some stakeholder representatives pointed out that increasing use of working groups and written procedures should not reduce transparency and asked for more information on outcomes of written procedures and working group meetings. They argued that based on this information they could provide better advice to their constituents and this could improve also the quality of dossiers coming to ECHA.

ECHA welcomed all the comments and highlighted that due to overlapping timelines of the dossier evaluation process it is not possible to avoid sending documents for different MSC meetings at the same time and that RCOMs with ECHA's responses are sent by default only to MSC members in order to keep the roles of MSCAs and MSC members separate. ECHA was of the view that DSDs would normally not be provided to MSCAs (very resource intensive for ECHA) but communication between ECHA and MSCAs needs to be further enhanced. Invitation of stakeholders to workshops should be decided by MSC, MSCAs and ECHA. Replying to stakeholders, SECR stressed that ECHA did and will also in the future do its best to ensure transparency.

COM particularly welcomed the clarification in the document concerning disagreement of MSC in written procedure and emphasised the relevance of any input from MSC discussions in these cases.

The Chair concluded that the statistics table of the document regarding the number of dossier evaluation cases will be updated with information on modified draft decisions due to the proposed amendments and slides with the conclusions of the current discussion be prepared. She also noted that the entire document would not be updated and its endorsement would not be necessary if the conclusions and action points are adopted.

## Item 8 – Substance evaluation (SEV)

### a) Update by ECHA on the work on CoRAP development

SECR in its presentation informed the meeting that the fifth revised version of the preliminary draft CoRAP with 95 substances (37, 25 and 33 substances for 2012, 2013 and 2014 respectively) has been uploaded to Evaluation CIRCA. All cases where substances were initially claimed for SEV by more than one MSCA have been sorted out. The draft CoRAP will be submitted to MSC and published on ECHA website (a public version) by end of October. Final opinion of MSC will be adopted at the MSC-22 meeting (beginning of February 2012) and the CoRAP will be published by end February 2012. The full presentation was made available to MSC members and stakeholders on MSC CIRCA.

ECHA clarified that payments to MSCAs based on the service contracts will be initiated when the draft decision and the evaluation report are submitted to ECHA. For the follow-up phase, there is no extra payment foreseen. SECR also pointed out that justification documents for SEV proposals will be provided for MSC. Also stakeholders will receive versions without confidential business information. One MSC member suggested a meeting between ECHA and MSCAs to clarify all remaining issues before the SEV work starts.

**b) Tasks of the Rapporteur and Co-Rapporteur in drafting the opinion of MSC**

SECR briefly introduced the draft mandate of the rapporteur. MSC adopted the mandate as proposed by SECR with one change specifically clarifying that the co-rapporteur is responsible for the tasks of the rapporteur if the rapporteur has a conflicting interest with tasks and vice versa. SECR explained that the template for the content of the opinion will be drafted after the justification documents have been received. SECR will make a proposal for the template for the next MSC meeting.

**c) Appointment of Rapporteur and Co-Rapporteur**

SECR introduced the process leading to the volunteering of one-one MSC member for the rapporteurship and co-rapporteurship. MSC appointed the volunteering members as rapporteur and co-rapporteur.

**d) Possible establishment of a Working Group to support the Rapporteur and Co-Rapporteur**

MSC decided to establish the Working Group (WG), adopted its mandate as proposed by SECR and agreed on its members (accepting as WG members four plus two MSC members who volunteered before and during the current meeting). Because of the potential high workload members were invited still to consider membership in the WG and inform the MSC-S about that by the next meeting.

**e) MSC working procedures - report of the written procedure**

SECR informed that since the MSC-18 meeting, the draft working procedure on providing the MSC opinion on CoRAP has been revised on the basis of the written comments of MSC members and the revised version has been adopted via written procedure. MSC took note of the report.

## Item 9 – SVHC identification - information about new SVHC proposals

SECR introduced the proposals in a brief presentation. The full presentation was made available to MSC members and stakeholders on MSC CIRCA.

## Item 10 – Preparations for the opinion on ECHA's 3rd draft recommendation of priority substances to be included in Annex XIV

**- Possible exchange of views on the draft recommendation and comments received**

SECR gave statistics on the comments received (all together 1382) and a brief overview on their content. The wide range of commented topics covered, e.g. views on whether certain uses are fulfilling the definition for intermediate use or can be regarded as wide dispersive use, proposals for exemptions (under Article 58(2)), views on the appropriateness of the suggested latest application dates and sunset dates as

well as comments related to the potential next phase of the authorisation process, e.g., impacts of authorisation requirement and whether suitable alternatives are available. Some comments stated that application dates for cobalt and chromium (VI) compounds are too close to each other. Many comments were repetitions from several different companies. Vast majority of comments were received from industry, mainly on chromium(VI) and cobalt compounds.

In the brief discussion an industry observer underlined that his organisation promotes very much the co-ordinated submissions of comments and the importance of factual evidence behind the comments.

MSC took note of the report.

- **Development of the MSC opinion on draft recommendation for Annex XIV - initial plan by the Rapporteur**

The Rapporteur reported that the working group (WG) started its work with the draft recommendation and around 1400 comments. Some possible discussion points have been identified. The preliminary opinion will be provided for the next MSC meeting in November (MSC-20). Concerning the working method of the WG, he explained that one person will be in charge of each group of chromium compounds, cobalt compounds and of trichloroethylene. MSC took note of the report.

Two MSC members highlighted that they were approached by chromate or cobalt industry. As a reply to a plea, SECR gave a brief update on the timeline of the recommendation process.

## Item 11 – Provisional work plan for 2012

- **Tentative meeting calendar for 2012**

SECR presented the meeting calendar highlighting the conclusion of the SECR that changing of the dates generally was in practice not possible (except possible extension/reduction of meeting days). In case of any changes, particularly for the MSC-23 meeting in April 2012 where a change would theoretically be still possibly, SECR will inform MSC in due time.

## Item 12 – Any other business

**a) PBT expert group**

Due to lack of time, no presentation was held. The slides will be available on MSC CIRCABC. SECR clarified that setting up of the PBT group will be discussed more in detail probably in October CARACAL meeting.

**b) ECHA involvement in new graduate training scheme**

Due to lack of time, no introduction to the topic was held. The relevant information was provided on MSC CIRCABC for MSC's consideration.

**c) Workshop announcement by Eurometaux and CEFIC**

The industry observers announced the meeting to be held in Brussels on 12 October 2011. More detailed information was provided on MSC CIRCABC for MSC's consideration.

## Item 13 - Adoption of conclusions and action points

The conclusions and action points of the meeting were proposed to be adopted in written procedure after the meeting (see Annex IV).

*Signed*

Anna-Liisa Sundquist
Chair of the Member State Committee

## II. List of attendees

| **Members/Alternate members** |
|---|
| BIWER, Arno (LU) |
| COCKSHOTT Amanda (UK) (alternate member)[1] |
| COSGRAVE, Majella (IE) |
| DEIM Szilvia (HU) |
| DRUGEON, Sylvie (FR) |
| DUNAUSKIENE, Lina (LT)[2] |
| FINDENEGG, Helene (DE)[2] |
| FLODSTRÖM, Sten (SE) |
| HEISKANEN, Jaana (FI) |
| HUMAR-JURIC, Tatjana (SI) |
| KORENROMP, Rene (NL)[1,3] |
| KULHANKOVA, Pavlina (CZ) |
| LUDBORZS, Arnis (LV) |
| LULEVA, Parvoleta Angelova (BG) |
| MARTIN, Esther (ES) |
| MARTINS, Ana Lilia (PT) (alternate member) |
| MIHALCEA-UDREA, Mariana (RO) |
| PISTOLESE, Pietro (IT) |
| REIERSON, Linda (NO) |
| RUSNAK, Peter (SK) |
| SPETSERIS, Nikolaos (GR) (alternate member) |
| STESSEL, Helmut (AT) |
| TYLE, Henrik (DK)[2] |
| VANDERSTEEN, Kelly (BE) |
| VESKIMÄE, Enda (EE) |
| |
| **Representatives of the Commission** |
| GARCIA JOHN, Enrique (DG ENTR) |
| KOBE, Andrej (DG ENV) |
| |
| **Observers** |
| ANNYS, Erwyn (CEFIC) |
| DMYTRASZ, Bohdan, (CONCAVE) |
| NAMIROFF, Natasha (ECETOC) (on 21-22/09/2011) |
| STAIRS, Kevin (Greenpeace) |
| TAYLOR, Katy (ECEAE) |
| VAN VLIET, Lisette (HEAL) |
| WAETERSCHOOT, Hugo (EUROMETAUX) |

| **ECHA staff** |
|---|
| BALDUYCK, Bo |
| BALOGH, Attila |
| BELL, David |
| BROERE, William |
| CARLON, Claudio |
| DE COEN, Wim |
| DE WATZE, Wolf |
| FEDTKE, Norbert |
| HEINONEN, Jari |
| HIRVONEN, Tero |
| HUUSKONEN, Hannele |
| KARHU, Elina |
| KNIGHT, Derek |
| KOULOUMPOS, Vasileios |
| KORJUS, Pia |
| LE CURIEUX, Frank |
| MALM, Jukka |
| NAUR, Liina |
| PELLIZZATO, Francesca |
| REUTER, Ulrike |
| RIALA, Riita |
| RÖCKE, Timo |
| RODRIGUEZ IGLESIAS, Pilar |
| RÖNTY, Kaisu |
| RUOSS, Juergen |
| SANDBERG, Eva |
| SUMREIN, Abdelqader |
| SUNDQUIST, Anna-Liisa |
| VAHTERISTO, Liisa |
| VASILEVA, Katya |
| VERSONNEN, Bram |
| YLÄ-MONONEN, Leena |
| |
| |
| |
| |
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| |

[1] Not present during agreement seeking on CCH-018/2011 (Item 6d)

[2] Not present during agreement seeking on TPE-007/2011 (Item 6d)

[3] Not present during agreement seeking on CCH-017/2011 (Item 6d)

**Proxy's**

- SPETSERIS, Nikolaos (EL) also acting as proxy of KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
- PISTOLESE, Pietro (IT) also acting as proxy of CAMILLERI, Tristan (MT)
- RUSNAK, Peter (SK) also acting as proxy of ANDRIJEWSKI, Michal (PL)

**Experts and advisers to MSC members**

ALMEIDA, Inês (PT) (expert to MARTINS, Ana Lilia)

ANDERSSON, Lars (expert to FLODSTRÖM, Sten)
ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BALCIUNIENE, Jurgita (LT) (expert to DUNAUSKIENE, Lina)
INDANS, Ian (UK) (expert to DOUGHERTY, Gary)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LØFSTEDT, Magnus (DK) (adviser to TYLE, Henrik)
MOELLER, Ruth (LU) (expert to BIWER, Arno)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
PECZKOWSKA, Beata (PL)
SCIMONELLI, Luigia (IT) (adviser to PISTOLESE, Pietro)
SULG, Helen (EE) (expert to VESKIMÄE, Enda)
TALASNIEMI, Petteri (FI) (adviser to HEISKANEN, Jaana)
TRAAS, Theo (NL) (expert to KORENROMP, Rene)

**By Webex-phone connection:**

- HAKKERT, Betty C. (NL) (expert to KORENROMP, Rene) for discussions on 20 September 2011, from agenda item 6b onwards
- HERZLER, Matthias (DE) (expert FINDENEGG, Helene) for discussions on CCH-019 (CCP-V-1)

**Case owners:**

A representative of the Registrant was attending under agenda item 6c for:
- CCH-017/2011 (CETIOL CC)
- CCH-018/2011 (Dipropylene glycol methyl ether acetate)
- CCH-019/2011 (CCP-V-1)
- CCH-022/2011 (Bis(5-amino-2-hydroxyphenyl)methane dihydrochloride)

- TPE 012/2011 (Reaction mass of disodium hydroxysulfinatoacetate and disodium hydroxysulfonatoacetate)

**Apologies:**

ANDRIJEWSKI, Michal (PL)
CAMILLERI, Tristan (MT)
DOUGHERTY, Gary (UK)
Dr KOUTSODIMOU, Aglaia (EL)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
CARMO PALMA, Maria do (PT)

## III. Final agenda

# Final Agenda
# 19th meeting of the Member State Committee

20-23 September 2011
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

20 September**: starts at 9:00**
23 September**: ends at 13:00**

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

MSC/A/019/2011
***For adoption***

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

**Item 4 –Administrative issues**

a. Update from secretariat on handling of conflicts of interest
b. Use of CIRCABC in MSC
c. Commission's Transparency Register for Stakeholders

***For information***

d. Participation of Croatia in the work of MSC

ECHA/MSC-19/2011/033
***For agreement***

**Item 5 –Adoption of draft minutes of the MSC-18**

- Draft minutes of MSC-18

MSC/M/18/2011
***For adoption***

**Item 6 – Dossier evaluation**

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

*For members only:* ECHA/MSC-19/2011/001

***For information***

**b. Information to MSC on the state of play in the CARACAL Expert Group on the use of EOGRTS under REACH**

***For information***

**c. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MS-CA reactions *(Session 1)*[2]**

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

ECHA/MSC-19/2011/030

***Open session***

TPE-007 2,3-epoxypropyl neodecanoate (EC 247-979-2)

ECHA/MSC-19/2011/005-006 & 008

CCH-022 Bis(5-amino-2-hydroxyphenyl)methane dihydrochloride (EC 440-850-3)

ECHA/MSC-19/2011/015-016

CCH-020 2,3-epoxypropyl neodecanoate (EC 247-979-2)

ECHA/MSC-19/2011/009-010

***Closed session***

CCH-017 CETIOL CC

ECHA/MSC-19/2011/002-003
ECHA/MSC-19/2011/037-039

***Open session***

TPE-014 Mono- and/or di- and/or tri(1-phenylethyl)-m-cresol and p-cresol (EC 700-427-9)

ECHA/MSC-19/2011/024-025

TPE-012 Reaction mass of disodium hydroxysulfinatoacetate and disodium hydroxysulfonatoacetate

ECHA/MSC-19/2011/012-013

**Day 2**

CCH-018 Dipropylene glycol methyl ether acetate (EC 406-880-6)

ECHA/MSC-19/2011/018-019

CCH-019 (trans(trans))-4'-Vinyl-4-(4-methylphenyl)bicyclohexyl (CCP-V-1) (EC 439-730-3)

ECHA/MSC-19/2011/021-022

[2] All documents for 6c and d are available for members only

TPE-016 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, tri-C18-22 esters Tri-C18-22 (even numbered)-alkyl 2-hydroxypropane-1,2,3-tricarboxylate (EC 700-316-5)

ECHA/MSC-19/2011/027-028

***For information and discussion***

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

TPE-014 Mono- and/or di- and/or tri(1-phenylethyl)-m-cresol and p-cresol (EC 700-427-9)

ECHA/MSC-19/2011/024-026

TPE-012 Reaction mass of disodium hydroxysulfinatoacetate and disodium hydroxysulfonatoacetate

ECHA/MSC-19/2011/012-014

CCH-022 Bis(5-amino-2-hydroxyphenyl)methane dihydrochloride (EC 440-850-3)

ECHA/MSC-19/2011/015-017

CCH-017 CETIOL CC

ECHA/MSC-19/2011/002-004

CCH-020 2,3-epoxypropyl neodecanoate (EC 247-979-2)

ECHA/MSC-19/2011/009-011

TPE-007 2,3-epoxypropyl neodecanoate (EC 247-979-2)

ECHA/MSC-19/2011/005-007

CCH-018 Dipropylene glycol methyl ether acetate (EC 406-880-6)

ECHA/MSC-19/2011/018-020

CCH-019 (trans(trans))-4'-Vinyl-4-(4-methylphenyl)bicyclohexyl (CCP-V-1) (EC 439-730-3)

ECHA/MSC-19/2011/021-023

TPE-016 1,2,3-Propanetricarboxylic acid, 2-hydroxy-, tri-C18-22 esters Tri-C18-22 (even numbered)-alkyl 2-hydroxypropane-1,2,3-tricarboxylate (EC 700-316-5)

ECHA/MSC-19/2011/027-029

***For agreement***

**e. Discussion of any further comments made by MSs during CA consultation (no agreement seeking necessary)**

***For discussion***

**f. Information on appeal process and one appeal case (*Closed session)***

***For information***

**g. General topics:**

- Status report on ongoing evaluation work

***For information***

- Dossier Evaluation Workshop January/February

***For information***

**Item 7 – Proposals to tackle MSC workload**

- Discussion on how to increase efficiency of MSC work

ECHA/MSC-19/2011/035

***For discussion & endorsement***

**Item 8 – Substance evaluation**

**a. Update by ECHA on the work on CoRAP development**

***For information***

**b. Tasks of the Rapporteur and Co-Rapporteur in drafting the opinion of MSC**

ECHA/MSC-19/2011/031

***For discussion & decision***

**c. Appointment of Rapporteur and Co-Rapporteur**

***For decision***

**d. Possible establishment of a Working Group to support the Rapporteur and Co-Rapporteur**

ECHA/MSC-19/2011/032

***For discussion and decision***

**e. MSC working procedures**

- Report of the written procedure

***For information***

**Item 9 – SVHC identification**

- Information about new SVHC proposals

***For information***

**Item 10 – Preparations for the opinion on ECHA's 3rd draft recommendation of priority substances to be included in Annex XIV**

- Possible exchange of views on the draft recommendation and comments received

- Development of the MSC opinion on draft recommendation for Annex XIV – Initial plan by the Rapporteur

***For discussion***

**Item 11 –Provisional work plan for 2012**

- Tentative meeting calendar for 2012

ECHA/MSC-19/2011/034
***For information***

**Item 12 – Any other business**

a) PBT expert group

***For information***

b) ECHA involvement in new graduate training scheme

ECHA/MSC-19/2011/036
***For information***

**Item 13 – Adoption of conclusions and action points**

- Table with conclusions and action points from MSC-19

***For adoption***

## IV. Main conclusions and action points


### Main conclusions and action points

**MSC-19, 20-23 September 2011**
(adopted at MSC-20 meeting)

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| **4. Administrative issues**<br>**d. Participation of Croatia in the work of MSC** | |
| MSC agreed on inviting Croatia to participate in their work as a third country observer. | MSC-S to communicate this MSC decision to the ECHA Management Board for its consideration at its meeting on 29-30 September 2011. |
| **5. Adoption of the minutes of MSC-18** | |
| Written editorial comments received from a member prior to the meeting had been taken into account. The confidential and non-confidential versions of the minutes were adopted without further changes proposed in the meeting. | MSC-S to upload the adopted versions on MSC CIRCABC IG and to publish the non-confidential version of the minutes on the ECHA website. |
| **Item 6 - Dossier evaluation**<br>**a. Written procedure report on seeking agreement on draft decisions on dossier evaluation** | |
| MSC took note of the report of ECHA SECR. | MSC-S to upload in MSC CIRCABC the final ECHA decisions and agreements on cases CCH-021/2011, CCH-024/2011, CCH-025/2011, CCH-026/2011 and TPE-015/2011. |
| **6c. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MSCA reactions (Session 1, closed session for CCH-017/2011 only)**<br>**6d. Seeking agreement on draft decisions on compliance checks when amendments were proposed by MSCA (Session 2, closed)** | |
| **<u>CCH 020/2011</u> (2,3-epoxypropyl neodecanoate)**<br>**Discussion (6c, Session 1)**<br>As regards to the Algae Inhibition study, MSC had the view that the registrant should be requested to repeat the algae test and provide the experimental data. Members also concluded that it is justified to request for information regarding the surface tension and dissociation constant. With regard to degradation endpoint, | SECR to prepare a discussion paper with comparison of in vivo unscheduled DNA synthesis (UDS) and transgenic rodent assay (TGR) for a further MSC discussion at some of the following Committee's plenary meetings |

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| members considered the appropriate analytical methods to be recommended to the registrant. Regarding *in vitro* mutagenicity, members suggested to include to the registrant the option of doing an IVC test or an *in vitro* micronucleus study. On the *in vivo* mutagenicity test, even though UDS test has been done, some members suggested to request TGR test, as it is considered more appropriate for this substance and had just recently been approved by the OECD. The revised draft decision (as modified at the meeting) is to be further discussed in Session 2 (agreement seeking).<br>**Agreement seeking (6d, Session 2)**<br>Following the discussion on the appropriateness of UDS versus TGR *in vivo* mutagenicity tests for this case, MSC concluded that from scientific point of view, it is appropriate to request the Registrant to carry out TGR test for *in vivo* mutagenicity endpoint. Other parts of the DD were agreed to be modified based on the suggestions of Session 1.<br>MSC reached unanimous agreement on the ECHA's draft decision (as modified at the meeting). MSC adopted the formal agreement.<br><br>**<u>TPE 007/2011</u> (2,3-epoxypropyl neodecanoate)**<br>**Discussion (6c, Session 1)**<br>MSC concluded that rat is the most appropriate test species in a sub-chronic toxicity study. Further, the issue whether the registrant should be requested to carry out Extended One Generation Reproductive Toxicity Study (EOGRTS) instead of 2-generation reproductive toxicity study was considered. This issue, as well as some further suggested modifications on the draft decision, are to be further considered and concluded in Session 2 (agreement seeking).<br>**Agreement seeking (6d, Session 2)**<br>Following a thorough and comprehensive discussion on all possible options, it was concluded that unanimous agreement on the ECHA's draft decision could not be reached and therefore a formal voting procedure was launched based on the draft decision as submitted to MSC. The outcome indicated positive votes of 21 members (also the Norwegian member supported ECHA's DD) and negative votes of two members. Four other members were not present. All voting members presented justifications for their positive and negative votes.<br><br>**<u>CCH-022/2011</u> (Bis(5-amino-2-hydroxyphenyl)** | Members to submit their positions with the grounds and the justification for their votes after the meeting.<br><br>Justification for positions of the members at the vote will be attached to the minutes: SECR to provide to COM further decision making a package of the documents (DD, MSC DA, RCOM, minutes, outcome of the vote, and justification for the position at the vote). |

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| **methane dihydrochloride)**<br>**Discussion (6c, Session 1)**<br>MSC concluded that waiving the new growth inhibition study on algae would be justified and requested the registrant to provide a study summary that is in accordance with Article 3 (29) of REACH Regulation.<br>**Agreement seeking (6d, Session 2)**<br>MSC reached unanimous agreement on ECHA's draft decision (as provided for the current meeting) without amendments at the meeting. MSC adopted the formal agreement.<br><br>**<u>CCH-017/2011</u> (CETIOL CC)**<br>**Discussion (6c, Session 1)**<br>During the discussion on pre-natal developmental toxicity study, different views were exchanged on whether the registrant should be recommended in the draft decision to develop a read-across approach or he should carry out the study. This issue was transferred for further discussion and conclusion in Session 2 (agreement seeking).<br>**Agreement seeking (6d, Session 2)**<br>Following the discussion, MSC agreed to modify the draft decision by removing the request for a pre-natal developmental toxicity study and to modify the deadline in the draft decision to 9 months for the registrant to submit the required information.<br>MSC reached unanimous agreement on the modified ECHA's draft decision. MSC adopted the formal agreement.<br><br>**<u>TPE-014/2011</u> (Mono- and/or di- and/or tri(1-phenylethyl)-m-cresol and p-cresol)**<br>**Discussion (6c, Session 1)**<br>A modified draft decision was provided for the meeting; however, different views were expressed on the need to conditionally accept the testing proposal and to refer to the sequential performance of 2-generation study as follow-up of the results from 90-day and pre-natal developmental toxicity studies (as proposed in DD for the meeting). As another option the proposal to conditionally reject the testing proposal for 2-generation study at this tonnage level was to be further discussed at Session 2 (agreement seeking) because 2-generation study is not a standard information requirement in Annex IX.<br>**Agreement seeking (6d, Session 2)**<br>MSC discussed modified ECHA's draft decision based | SECR to launch written procedure for |

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| on conditional rejection of the proposed 2-generation reproductive toxicity study for this particular dossier at this tonnage level and requesting a new testing proposal to be submitted on the basis of the results of 90 d study as appropriate. However, due to the absence of quorum, agreement will be sought by MSC in a written procedure after MSC-19 meeting. | agreement seeking immediately after MSC-19 using the draft decision as modified during the meeting. |
| **<u>TPE-012/2011</u> (Reaction mass of disodium hydroxysulfinatoacetate and disodium hydroxysulfonatoacetate)**<br>**Discussion (6c, Session 1)**<br>MSC concluded that there is no need for further modifications in the draft decision, but a recommendation to the registrant in the notification letter to consider performing a screening study for developmental/reproductive toxicity in accordance with OECD 421.<br>**Agreement seeking (6d, Session 2)**<br>MSC reached unanimous agreement on ECHA's draft decision without modifications. MSC adopted the formal agreement. | ECHA to include in the decision notification letter an explanation to the registrant why the request for pre-natal developmental study was deleted. |
| **<u>CCH-018/2011</u> (Dipropylene glycol methyl ether acetate)**<br>**Discussion (6c, Session 1)**<br>Following the discussion on the appropriateness of the read-across approach as regards to the 90-day repeated dose toxicity study and the pre-natal developmental toxicity study, MSC members concluded that there are arguments in favour and against the suggested approach. The final conclusion on the issue was to be made in Session 2.<br>**Agreement seeking (6d, Session 2)**<br>Following a discussion on whether to accept read-across approach for both 90-day repeated dose toxicity study and the pre-natal developmental toxicity study or just for the 90-day study MSC agreed that based on the results of the 28 d study and read-across arguments and applying weight of evidence approach the request for 90 d study can be removed. For reproductive toxicity endpoint, although some members were not completely convinced that there were uncertainties left, MSC concluded that read-across arguments left uncertainty that would justify asking for the test and MSC agreed that pre-natal developmental toxicity study should be requested; however, this case should not be seen as a precedence for future decisions on the possibilities for | ECHA to set up a kind of expert group on the issue of read-across. |

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| read across. MSC reached unanimous agreement on ECHA's draft decision, as modified at the meeting. MSC adopted the formal agreement.<br><br>**<u>CCH-019/2011</u> (CCP-V-1)**<br>**Discussion (6c, Session 1)**<br>Following the discussion, MSC concluded that on the requested testing on mutagenicity would be warranted and the requested update of the PBT assessment needed. As regards to the request for combined 28-day/reproductive toxicity screening testing, members came to conclusion that there is a need for further consideration and discussion on the issue in Session 2.<br>**Agreement seeking (6d, Session 2)**<br>Following the discussion, MSC agreed to make some further modifications in the text of DD, as regards blood sampling that was to be done only at the termination of the test, some further justification for mutagenicity testing and further clarification for the PBT assessment. MSC reached unanimous agreement on the modified ECHA's draft decision. MSC adopted the formal agreement.<br><br>**<u>TPE-016/2011</u> (1,2,3-Propanetricarboxylic acid, 2-hydroxy-, tri-C18-22 esters Tri-C18-22 (even numbered)-alkyl2-hydroxypropane-1,2,3-tricarboxylate)**<br>**Discussion (6c, Session 1)**<br>MSC concluded that a reference to the limit dose study for sub-chronic toxicity should be included in the statement of reasons in the draft decision. Further, a recommendation to the registrant in the notification letter to consider performing a screening study for developmental/reproductive study in accordance with OECD 421 test. No other issues were suggested for further discussion in Session 2 (agreement seeking).<br>**Agreement seeking (6d, Session 2)**<br>MSC reached unanimous agreement on ECHA's draft decision (as modified at the meeting). MSC adopted the formal agreement. | ECHA to include in the decision notification letter a recommendation to the registrant to consider performing a screening study for developmental/reproductive study in accordance with OECD 421 test.<br><br>MSC-S to upload in MSC CIRCABC the final ECHA decisions and agreements on cases CCH-017/2011, CCH-018/2011, CCH-019/2011, CCH-020/2011, CCH-022/2011, TPE-012/2011 and TPE-016/2011. |
| **6g. Status report on the ongoing dossier evaluation (DEV) work** | |
| | ECHA to inform MSCAs at CARACAL meeting of the observations made on the increased dossier evaluation workload and its impact on the |

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| | ECHA Secretariat. |
| **Item 7 – Proposals to tackle MSC workload** | |
| MSC considered document ECHA/MSC-19/2011/035 and made several general comments and suggestions. Instead of endorsement of the document it was agreed that conclusions and action points based on the discussion will be drafted for adoption. | • SECR to revise the meeting document by deleting the 'policy arguments' part and updating Table 5 to provide information about the draft decision process in terms of number of cases that a PfA or MSC discussion led to a change<br>• SECR to draft and circulate some actions and conclusions from the discussion and the document via CIRCABC<br>• SECR to identify generic issues outside the specific dossier discussions and consider a workshop-type sessions for more general MSC discussion.<br>• SECR to reconsider and modify the current dossier evaluation document-naming convention<br>• ECHA to more clearly indicate to CAs when the DD (CCH) is targeted<br>• SECR to explore how MSC Stakeholder Observers could better be informed in advance of the meeting about the nature of topics to be discussed under dossier evaluation |
| **8. Substance evaluation**<br>**a. Update by ECHA on the work on the first draft Community Rolling Action Plan (Co RAP) development** | |
| Work on preliminary draft CoRAP is progressing and draft CoRAP will be made available to MSC by end of October.<br>MSs could already now provide proposals for new substances in the update of the CoRAP. | Members to provide ideas to ECHA SECR on how to prevent overlapping wishes for the same substance in the draft CoRAP. |
| **8. Substance evaluation**<br>**b. Mandate and tasks of the Rapporteur and Co-Rapporteur in drafting the opinion of MSC on the first draft Community Rolling Action Plan (Co RAP)** | |
| MSC adopted the mandate and tasks of the rapporteur and co-rapporteur in the process of providing an opinion of MSC on the 1st draft CoRAP (document ECHA/MSC-19/2011/031) with a minor modification. | • SECR to upload the agreed revised document to MSC CIRCABC IG after the meeting<br>• SECR to prepare and present the MSC opinion template at the forthcoming MSC-20 meeting |

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| **8c. Appointment of Rapporteur and Co-Rapporteur** | |
| MSC appointed the two volunteering members as a rapporteur and a co-rapporteur for developing of a MSC opinion on 1st draft CoRAP. | SECR to finalise the appointment procedure providing the newly-appointed (co-) rapporteurs with their letters of appointment after the meeting. |
| **8d. Possible establishment of a Working Group to support the Rapporteur and Co-Rapporteur** | |
| MSC agreed to establish a working group to support the (co-)rapporteurs in drafting the MSC opinion on the 1st draft CoRAP (document ECHA/MSC-19/2011/032). MSC agreed to appoint the volunteering MSC members and their experts as members of the working group supporting the (co-)rapporteurs. | MSC members are invited to reconsider their potential participation in this WG and to express their interest by MSC-20 |
| **13. Adoption of conclusions and action points** | |
| Due to the lack of quorum, the draft conclusions and action points from this meeting will be proposed for adoption by written procedure or at the next MSC meeting. | MSC-S to upload the presentations delivered at the meeting on MSC CIRCABC IG and the MSC-19 conclusions and action points when adopted |