MSC/M/018/2011
ADOPTED IN MSC-19

FINAL Minutes

Minutes of the 18th Meeting of the Member State Committee (MSC-18)
25-27 May 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 18th 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

No administrative issues were raised by the ECHA Secretariat (SECR).

Item 5 – Adoption of the minutes of MSC-17

SECR explained that written comments on the draft minutes of MSC-17 received from three meeting participants had been taken into account. The minutes were adopted with some further changes proposed in the meeting. The MSC Secretariat will upload the minutes on MSC CIRCA and on the ECHA website.

Item 6 – Dossier evaluation

a) General topics

1. Continued discussion about possibilities for waiving repeat dose studies for low-toxicity substances

An invited expert presented the main written comments of MSC members to the thought starter concerning possibilities for waiving repeat dose studies for low-toxicity substances that had been discussed in MSC-16 meeting, and his responses to them. The main idea of the thought starter was that in cases of low toxicity substances where the NOAEL is >1000mg/kg/day in the 28-day study, the 90-day study could be waived based on the Weight of Evidence (WoE) approach according to 1.2 of Annex XI of REACH. This approach could potentially significantly reduce the need for animal testing. The main written comments received were related to the legal basis, the low number of substances analysed, the definition of low toxicity and differences of the endpoints in 28-day and 90-day studies. The invited expert and the respective MSC member proposed ECHA to carry out analysis on the database of the substances registered by the 2010 registration deadline so that more conclusive results could be obtained. They also proposed ECHA to give more precise guidance to the industry on how to apply the WoE approach in similar cases if agreement of the Member States (MSs) on the issue could be reached during continued discussions in a proper forum.

In the discussion, several MSC members expressed some sympathy for the initiative presented in the thought starter emphasising at the same time the need for further discussions on the topic in a proper forum. It was mentioned that industry should not start carrying out 28-day studies to waive 90-day studies; the current discussions refer only to cases where 28-day studies are already available.

It was also pointed out that no general rules should be established for this kind of waiving but the substances should be discussed on a case-by-case basis (as required in WoE approach), taking into account the route of application, absorption, bioaccumulation and structural properties of the substance.

An observer noted that the general discussions on the topic should continue as soon as possible because the preparations for the 2013 registration deadline are already ongoing. He also confirmed that industry does not intend to start 28-day studies with the aim of waiving 90-day studies.

Another observer expressed her wish to participate in the continued discussions.

The Chair concluded that the WoE approach according to 1.2 of Annex XI on a case by case basis which is the starting point for the thought starter is available in REACH for the registrants already now. Some further assistance could be given to the registrants on how to properly apply this approach. However, conclusive arguments for this approach could not be presented by the proposing MSC expert. Therefore, taking into account the positive reactions of MSC members to the initiative, the topic should be further studied and discussed. ECHA can not commit to detailed analysis of dossiers registered by 2010. As ECHA Secretariat was not in a position to indicate on the spot any suitable forum for continuing the discussion on the initiative, it was suggested that the MSC member or the competent authority of that Member State could ask ECHA in writing to organise a forum for continuation of the discussion.

2. 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.

SECR gave feedback about the third party consultations on vertebrate animal testing proposals. In most of these consultations, only alternative hypothetic testing strategies were provided which could not be considered as relevant, scientifically valid information related to the hazard properties of the substance. Therefore, third party comments so far did not affect the draft decisions on testing proposals. Responding to a question from an animal welfare organisation, SECR clarified that registrants always receive third party comments with the first draft decision so they have a chance to update their dossier based on them if they consider it appropriate. Moreover, ECHA refers the registrants also to the relevant guidance documents where more detailed information is given on how to avoid animal testing.

SECR gave a short report on the two pilot projects concerning the communication between Member State Competent Authorities (MSCAs) and ECHA. On the project of sending to MSCAs detailed background information and rationale to draft decisions by ECHA a generally positive feedback was received. The other project of providing to MSCAs the possibility to directly communicate with ECHA (e.g. by phone calls) to receive more detailed information on draft decisions was not considered by MSCAs as useful and transparent. SECR is still analysing MSCAs' contributions to the pro-

jects and will soon decide on the way ahead. In any case, the approach would be case specific and the current experience shows that different tools may be necessary for individual cases.

SECR also informed about the pilot project regarding the informal interaction via teleconference with the registrants after the first draft decision is sent to the registrant.

These teleconferences do not replace the (possible) formal written comments of the registrants and during them ECHA does not give advice on how to improve the dossier but rather refers to the guidance documents that would help the registrant in updating the dossier with the relevant information. The project was received very positively by the industry. As result of the teleconferences, registration dossiers were successfully updated and as consequence some dossier evaluations could be terminated or some draft decisions were reformulated. Based on the positive results of the pilot project, SECR applies the possibility for a teleconference with registrants as a standard procedure from now on.

In response to a question of an observer SECR explained that testing proposal examinations can be terminated by ECHA when e.g. an appropriately documented tonnage downgrade or the cease of manufacture makes a testing requirement unnecessary, or if a testing proposal was successfully replaced by other appropriate available information.

MSC took note of the report.

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

SECR gave a short report on the written procedure of the seven substances, Polysantol, Magnesium hydroxide sulphate trihydrate (MOS-HIGE), Chlorobenzene, Vulcuren (1,6-Bis((dibenzylthiocarbamoyl)disulfanyl)hexane), 4-hydroxy-3,5-dimethoxybenzonitrile, UB 2740/50 and BDP (1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate).

By the closing date 10 May 2011, responses were received from 26 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 for Polysantol, Magnesium hydroxide sulphate trihydrate (MOS-HIGE), Chlorobenzene and Vulcuren (1,6-Bis((dibenzylthiocarbamoyl)disulfanyl)hexane). It could be concluded that unanimous agreement on the draft decisions and respective agreement documents of these four substances has been reached by MSC on the 10 May 2011. ECHA will continue processing the agreements and decisions. The final documents will be made available on MSC CIRCA.

For 4-hydroxy-3,5-dimethoxybenzonitrile, UB 2740/50 and BDP (1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate) the written procedure was terminated by the Member State Committee Secretariat on 10 May 2010 as one MSC member requested meeting discussion on the three cases at MSC-18. For UB 2740/50, 25 members with voting right and the Norwegian member responded. Before termination all MSC members, except for the MSC member that requested discussion at the meeting, voted in favour of the proposed decisions and agreements. The Member State Committee will seek unanimous agreement on the above three draft decisions and respective agreement documents of these three substances in the current MSC-18 meeting.

MSC took note of the report.

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 007/2011 (4-hydroxy-3,5-dimethoxybenzonitrile)

Session 1 (open)

SECR explained that the written procedure on the draft decision was terminated after one MSC member had requested plenary discussion on the case. The representative of the registrant did not participate in the initial discussion (Session 1) but agreed to the presence of stakeholders, therefore an open session was held.

MSC discussed the case based on ECHA's draft decision and the concerns raised in the written procedure by the MSC member who requested the plenary discussion.

In this MSC member's view, the way the concentration of the test substance should be measured in the test solution depended on the solubility of the substance, because depending on its hydrophobic properties the substance could be absorbed and accumulated in the algae during the test. Data provided on the solubility of the substance should be clarified first. SECR replied that a repeated algae test was requested because the study report provided in the registration dossier did not indicate the performance of any analytical measurement and only referred to nominal amounts of test substance added to synthetic freshwater. Moreover, the study report mentions problems encountered when solubilising the test substance. According to the C3 EC test guideline, in case of substances that are poorly soluble in the test medium, measurements shall be made during the test to confirm the actual exposure concentration. Therefore the registrant should be required to repeat the algae test according to C3 EC (OECD 201) guidelines. In the statement of reasons the registrant was also advised to review and adequately consider the solubility prior performing the study in order to avoid an inaccurate result.

Furthermore, the MSC member questioned on how ECHA could conclude that algae are the most sensitive species and why a repeated Daphnia test should not be required from the registrant. SECR replied that although the concentration data for the Daphnia test provided by the registrant were not absolutely clear, available QSAR data indicated that algae maybe the most sensitive species and therefore only the algae test was required to be repeated.

The concerned MSC member accepted ECHA's replies.

Session 2 (closed)

MSC concluded that the algae test should be repeated with measurement of the test substance concentration according to EU C3 (OECD 201) guidelines. The Daphnia test should not be repeated because based on QSAR estimations, algae may be considered as the most sensitive species.

MSC found unanimous agreement on ECHA's draft decision as provided for MSC for the written procedure and the current meeting without further amending it, and adopted the formal agreement.

TPE 006/2011 (11-aminoundecanoic acid)

Session 1 (open)

A representative of the registrant participated in the initial discussion (Session 1). As there were no confidentiality concerns in the draft decision, an open session could be held. The Chair informed the representative of the registrant on the relevant practicalities during and after Session 1.

SECR explained that proposals for amendment on ECHA's draft decision were submitted from two MSCAs. One MSCA proposed ECHA to consider requesting also a two-generation reproductive toxicity study according to 8.7.3 of Annexes IX and X, and not only the test proposed by the registrant according to 8.7.2. The other MSCA proposed to reformulate the statement of reasons regarding the weight of evidence approach and applicability of results of *in vitro* studies for reproductive/developmental toxicity. SECR amended the draft decision according to the second proposal for amendment and reformulated the statement of reasons while expressed its willingness to discuss with MSC the approach raised in the other proposal for amendment when not all related information requirements for a toxicity endpoint (e.g. reproductive toxicity) are covered by tests proposed by the registrant.

In its written comments on the MSCAs' proposals for amendment, the registrant supported the proposal to amend the statement of the reasons as proposed. Concerning the other proposal for amendment, the registrant provided waiving arguments (i.e. arguments to adapt the standard information requirements) for the information gaps for reproductive toxicity; some of these arguments are included in the registration dossier as well.

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 members expressed views on how the data gap under 8.7.3 of Annex IX and X, for which the registrant submitted waiving arguments, should be handled in the draft decision on examination of a testing proposal. SECR agreed that the waiving arguments for the two-generation reproductive toxicity study proposed by the registrant may not be sufficient and that this issue had been recognised in screening of the dossier in the context of the testing proposal examination. However, SECR explained that a compliance check should not automatically be opened when a testing proposal is examined.

MSC also concluded that in this particular case currently no further studies for reproductive toxicity would be required from the registrant. SECR recommended to the representative of the registrant to update the registration dossier with improved waiving arguments in accordance with the relevant guidance documents.

Session 2 (closed)

MSC found unanimous agreement on ECHA's draft decision as provided for the MSC-18 meeting without further amending it, and adopted the formal agreement.

CCH 008/2011 (UB 2740/50)

Session 1 (closed)

SECR explained that the written procedure on the draft decision was terminated as one MSC member requested meeting discussion on the case. A representative of the registrant participated in this session (Session 1). A closed session was held. The Chair informed the representative of the registrant on the relevant practicalities during and after Session 1.

MSC discussed the case based on ECHA's draft decision and the concerns raised in the written procedure by the MSC member who requested the meeting discussion.

SECR replied to the concerns that in the cover letter of the final decision not only the fertility but also the perinatal effects will be referred to where the prenatal developmental toxicity study is recommended to be performed by the registrant.

The representative of the registrant confirmed the position that the registrant presented in the written comments to the proposed amendments and did not support inclusion of the information requirements on fertility/perinatal effect in the draft decision.

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

TPE005/2011 (BDP (1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate))

Session 1 (closed)

SECR explained that the written procedure on the draft decision was terminated as one MSC member requested meeting discussion on the case. The representative of the registrant did not participate in the initial discussion (Session 1) and did not agree to the presence of stakeholders, therefore a closed session was held.

The MSC member proposing the meeting discussion withdrew his discussion proposal, therefore, no detailed discussion was held.

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

TPE003/2011 (DPF)

Session 1 (closed)

The representative of the registrant participated in the initial discussion (Session 1). The registrant had informed the MSC Secretariat that stakeholder observers can not be present at the same discussions. Therefore a closed session was held. The Chair informed the representative of the registrant on the relevant practicalities during and after Session 1.

SECR explained that the substance was a substance of *Unkown or Variable composition, Complex reaction products, or Biological materials* (UVCB). In addition, the dossier was originally a notified substance under Directive 67/548/EEC (NONS). The registrant submitted testing proposals for four studies. For testing long term toxicity on plants, the registrant submitted two options to perform the test: either in accordance with ISO 22030 or with OECD 208 test guideline. In ECHA's view ISO 22030 would produce true results on long term toxicity on plants whereas OECD 208 would not.

Two proposals for amendment on ECHA's draft decision were submitted by two MSCAs. Both are questioning the need to perform the test according to the ISO 22030 test method instead of OECD 208 test method. SECR considered that the draft deci-

sion as presented to the MSCAs did not need to be amended. The Secretariat also provided a Room Document (ECHA/MSC-18/2011/024) where further explanation for the use of ISO 22030 instead of OECD 208 was given.

The registrant submitted written comments on the proposed amendments and agreed with the proposals for amendments.

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 representative of the registrant explained that in acute terrestrial tests, the substance showed no potential for terrestrial ecotoxicity up to the highest doses used according to the relevant guidelines. With regard to ISO 22030 which also covers reproductive endpoints he mentioned analysing these endpoints is not useful as after adding nutrients to the soil, there is always an increase in the vegetative growth of plants and a delay in plant maturation. In such a case it is questionable whether the effects are adverse or just a delay in maturation, which is a normal phenomenon in nature. The registrant therefore stated that performance of the study and interpretation of the results can be difficult. The registrant pointed out that these expected effects are described in the ISO 22030 guideline. Thus, he stated his preference for the OECD 208 test method from scientific point of view.

In the discussion ECHA explained, that the registrant in the registration dossier left it up to ECHA to decide which of the two test guidelines should be used. However, the key aim of the registrant was to derive a lower PNEC level using a chronic assessment factor (AF) of 10, and therefore to obtain a low PEC/PNEC ratio. SECR pointed out that according to the guidance, three chronic toxicity tests would be required in order to use AF of 10. Because the OECD 208 test can not be considered as a chronic test as it does not cover long term reproductive effects, it is necessary to perform the test using the ISO 22030 test in order to meet the registrant's stated aim. If the registrant would use a higher assessment factor, the OECD test would also be acceptable.

Two MSC members pointed out that REACH does require a long term toxicity test on plants and not a chronic test. However, from scientific point of view a chronic test is required in this case, taking into account the registrant's intention to use the chronic AF. It was noted also that the ISO test allows for adaptation when testing substances with nutrient effects.

It was acknowledged by SECR that the species sensitivity with the OECD test would be higher (eight species), but also the ISO test can be performed on more than the two species recommended in the guideline. Furthermore, even when the ISO test is performed with fewer species, there is coverage of additional endpoints not addressed by the OECD test.

One MSC member reminded that partial lifecycle tests are usually accepted for fish long term toxicity while it does not seem to be the case here with the plants. SECR replied that aquatic toxicity and terrestrial toxicity would not be directly comparable in this regard.

One MSC member pointed out that based on solid scientific argumentation it is possible to deviate from the default AFs laid down in the guidance.

Session 2 (closed)

After considering all of the above reflections MSC concluded that the ISO 22030 test should be required in the draft decision. MSC found unanimous agreement on

ECHA's draft decision as provided for MSC for the current meeting without further amending it, and adopted the formal agreement.

CCH16/2011 (HFO-1234ze)

Session 1 (closed)

The representative of the registrant participated in the initial discussion (Session 1). He informed the MSC Secretariat that stakeholder observers can not be present at the same discussions. Therefore a closed session was held. The Chair informed the representative of the registrant on the relevant practicalities during and after the Session 1.

ECHA explained that six proposals for amendment to ECHA's draft decision were submitted by four MSCAs.

One MSCA proposed to add in the draft decision a full consumer risk characterisation and to require a prenatal developmental toxicity study with rabbit instead of rats if the test can not be waived. The same MSCA proposed adaptations to the two-generation reproductive toxicity study. Another MSCA did not agree with the draft decision requesting a further inhalation developmental study in rats due to the lack of signs of maternal toxicity in the original study. This MSCA considered the original study as sufficiently well conducted and the need for a further study as not justified. Two other MSCAs had proposed to replace the request for the two-generation study with one for EOGRTS (extended one-generation reproductive toxicity study).

SECR was of the view that the draft decision needed to be amended based on one of the proposed amendments (the heart was to be considered as the target organ to be examined). In ECHA's view, the other proposals for amendment were not sufficiently justified to amend the draft decision.

The registrant provided comments on the proposed amendments which were repeated and slightly extended by the representative of the registrant in the meeting. The registrant agreed with the third proposal of the first MSCA (adaptations to the two-generation reproductive toxicity study) and the proposal of the second MSCA (no further inhalation developmental study is needed) and disagreed with the other proposals.

The representative of the registrant emphasised in the meeting that it is not their intention to perform the pre-natal developmental toxicity study with a dose higher than 15000 ppm although they have not seen any signs of maternal toxicity in the developmental toxicity studies they have provided. The representative of the registrant said that the doses used were based on the cardiac toxicity observed in repeated dose toxicity studies as accordance with the guideline. The representative of the registrant emphasised that they do not support the proposed amendment for EOGRTS due to technical difficulties related to EOGRTS performed via the inhalation route. The test would be much more expensive and it is difficult to find a test laboratory to carry out the test as there is no former experience on such tests.

MSC discussed the case based on ECHA's draft decision, the proposed amendments of MSCAs and the registrant's comments on the proposed amendments.

Session 2 (closed)

The continued discussion was focused on EOGRTS vs two-generation test (proposed amendments of two MSCAs). SECR made clear that Annex X 8.7.3 requires a two-generation reproductive toxicity test. Furthermore, ECHA is constrained by Article 13(3) of REACH saying that tests shall be conducted in accordance with international test methods recognised by the COM or the Agency. EOGRTS is not a two-generation

test and not recognised by COM or the Agency. SECR pointed out that CARACAL is the appropriate forum for more detailed discussion on this topic. COM confirmed that on 9 June 2011 the EOGRTS versus two-generation reproductive toxicity study will be discussed in the CARACAL meeting for the second time.

The MSC members proposing the two MSs' amendments for EOGRTS expressed their concerns that if the decision making in COM on EOGRTS takes too long, EOGRTS could not be used for high volume substances registered by 2010 anymore. Use of EOGRTS instead of the two-generation tests could save high number of test animals. Furthermore, according to the current status of science, this test is also the most appropriate to test substances with potential endocrine disruption properties. One MSC member also supported these views considering EOGRTS as a very valuable study and required ECHA to be as proactive as possible in the use of EOGRTS. As a legal possibility to use EOGRTS already now, application of 1.1.2 of Annex XI was mentioned. Many members preferred to get legal clarity to the issue of using EOGRTS before starting to use it in REACH context.

SECR replied that the current REACH information requirements allow limited possibilities to apply EOGRTS although the additional information provided by EOGRTS is acknowledged. It was clarified by SECR that 1.1.2 of Annex XI in ECHA's view can not be used to request EOGRTS as this section refers to already existing study results and this is here not the case. COM acknowledged the urgency of the issue. MSC acknowledged that a statement could be submitted to the COM emphasising the urgent need for action concerning EOGRTS and their applicability as soon as possible.

Extensive discussion took place on determining the dose for the prenatal developmental study.

Based on the above discussions, MSC reached unanimous agreement on ECHA's draft decision after deleting the requirement for the pre-natal developmental toxicity study and adding a statement that at this stage ECHA cannot determine whether the prenatal developmental toxicity endpoint is compliant with REACH. The need for the pre-natal developmental toxicity test will depend on the outcome of the two-generation reproductive study. The respective parts of the statement of reasons were also modified accordingly.

Upon the request of some MSC members, a statement on importance of introducing EOGRTS in REACH was attached to these minutes (see part V of the minutes). This statement will be passed to the Commission and to the forthcoming CARACAL meeting in June 2011.

MSC adopted the formal agreement.

CCH014/2011 (BHT)

Session 1 (closed)

The representative of the registrant did not participate in the initial discussion (Session 1). The registrant did not agree to the presence of stakeholder observers during the initial discussion, and therefore a closed session was held.

SECR explained that five proposals for amendment on ECHA's draft decision were submitted by three MSCAs.

One MSCA first proposed to use alternative, non-validated test methods to replace *in vivo* eye irritation studies. Secondly, they proposed that it should be verified whether the fifth strain *in vitro* mutation study was available or not. If the study in the fifth strain were to be available, there would be no need to request that test again. The proposal of a second MSCA for an amendment was related to the same issue but focused on the further consequences of the results of that study. Thirdly, the first MSCA suggested reconsidering the dose-response assessment factors that were incorrectly cited in the draft decision as well as to reconsider uncertainties in the applied route-to-route extrapolation procedures and the route specific absorption values that were used. A third MSCA proposed to reconsider ECHA requests to refine the worker exposure assessment in certain uses of the substance.

SECR clarified that, in respect of the question of the MSC member representing the MSCA that proposed to use alternative non-validated test methods for eye irritation, at the level of Annex VII *in vitro* studies are required, while at the level of Annex VIII and above it is *in vivo* studies that are required. For Annex VIII level and above, ECHA may, after careful evaluation, also accept results of pre-validated *in vitro* studies if the study is suitable to fill the data gap. If the test results are negative, the *in vivo* study has to be performed.

ECHA cannot require the registrant to fulfill the information requirements with pre-validated test methods. The introductory paragraph of Annex XI allows the registrant the possibility of adapting of the standard tests but it does not state that ECHA could require the registrant to do so. However, ECHA reminds the registrants of this possibility of adaptation. When an *in vivo* study is required in REACH, ECHA is bound to the test specified in the relevant Annex. Still, the registrant can decide if they want to adapt the test required. A risk of asking for pre-validated tests would be that the conditions of the tests still can be changed in the validation phase.

The registrant provided comments on the proposals for amendment. The registrant agreed with the proposal for amendment of the third MSCA and informed about a planned update to the registration dossier and CSR. The registrant confirmed that the results of the fifth strain *in vitro* mutation study are available and thus supported the relevant proposals for amendment. The registrant also concluded that because of negative result in this study, an *in vitro* gene mutation study in mammalian cells in accordance with Annex VIII 8.4.3 is required. The registrant confirmed that no data sharing activities between registrants of the same substance have taken place.

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 amended draft decision included all proposals for amendments except for the proposal to refine the worker exposure in certain uses of the substance. It was concluded that the results of the fifth strain *in vitro* mutation study was available and the request for that was obsolete whereas the *in vitro* gene mutation study in mammalian cells based on the results of the fifth strain was needed and kept in the draft decision. According to the registrant the information on eye irritation test is already available and in practice no new test would be required. However, this information requirement is kept in the draft decision. The requirements for improvement of the CSR regarding assessment factors and derivation of DNEL would be required based on proposals for amendments.

MSC generally supported the draft decision as provided for the current meeting.

Session 2 (closed)

After the part of the statement of reasons dealing with AFs and DNEL derivation for workers was slightly modified and this modified version was provided to MSC as a room document, MSC found unanimous agreement on ECHA's draft decision as provided for MSC for the current meeting, and adopted the formal agreement.

CCH015/2011 (TIB KAT 223)

Session 1 (closed)

The representative of the registrant did not participate in the initial discussion (Session 1). As no response has been received from the registrant concerning the question on the possible presence of stakeholder observers at the same discussions, a closed session was held.

SECR explained that four proposals for amendment to ECHA's draft decision were submitted by four MSCAs. All proposals for amendment were made on the ecotoxicological testing due to the new information on the physical chemical properties of the substance obtained from the updated registration dossier.

SECR considered that the draft decision needs to be amended based on the proposals for amendment. However, SECR was of the view that on this tonnage level there is no legal basis to request information on the partition coefficient n-octanol/water and ready biodegradability of hydrolysis products. Furthermore, due to the tonnage band of this registration, the decision would not request additional information on hydrolysis, adsorption/desorption, short-term toxicity to fish and PBT assessment of the substance.

In the comments of the registrant submitted to the proposed amendments the registrant generally agreed with the proposed amendments, and identified the hydrolysis products and provided QSAR estimates for them concerning Kow, Koc, short term toxicity and water solubility.

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 main point for discussion was whether the short-term toxicity test on invertebrates and the growth inhibition study on aquatic plants should be required. The concern in this respect was that tests for these two endpoints were available in the registration dossier but unclear exposure data were provided (composition of the test solutions in these tests was not determined) that did not allow for clear conclusions applicable for classification and labelling. Following the proposed amendments the registrant in his comments provided data which partly clarified the situation. However, these data were not yet available in the registration dossier so the draft decision could not yet take them into account.

To solve the problem, some MSC members proposed that the registrant should be requested to update the registration dossier with all available and relevant data for the registration dossier before repetition of the two tests would be required.

MSC concluded that the requirements for the repeated performance of Daphnia and algae tests should be deleted from the draft decision. MSC was of the opinion that instead of repeating these tests, the registrant should be required to update the registration dossier with the similar data provided in the registrant's comments , i.e. to provide information on the qualitative composition of the test solutions (including identity of hydrolysis products of the registered substance), the toxic effect concentrations

of the hydrolysis products of the substance as predicted by valid QSAR models and any other relevant available information on the intrinsic properties of the hydrolysis products. The data to be provided should be sufficient for classification and labelling of the substance.

Session 2 (closed)

MSC reached unanimous agreement on ECHA's draft decision as modified on the basis of the conclusions drawn by MSC in the discussion in Session 1. The relevant parts of the statement of reasons were also modified accordingly. The deadline to provide requested information in the form of an updated IUCLID dossier to ECHA was changed from 12 to 6 months from the date of decision.
MSC also adopted the formal agreement.

TPE004/2011 (1,5-bis[1,2-bis (ethoxycarbonyl)ethylamino]-2-methylpentane)

Session 1 (closed)

The representative of the registrant did not participate in the initial discussion (Session 1). As no response was received from the registrant concerning the question on the possible presence of stakeholder observers at the same discussions, a closed session was held.

ECHA explained that three proposals for amendment on ECHA's draft decision were submitted by two MSCAs. One MSCA questioned the legal basis for accepting a testing proposal for the pre-natal developmental toxicity as substitute for the screening study, when the dossier is registered for the tonnage level of Annex VIII. This MSCA also proposed to delete the reference to the ECHA fact sheet ECHA-09-FS-05-EN considering dossiers of 100–1000tpa substances being technically complete even if they do not contain the results of a screening study but do contain a testing proposal for a pre-natal developmental toxicity study.

Another MSCA proposed to include in the draft decision a recommendation to the registrant to provide reproductive/developmental toxicity information in accordance with Annex VIII. Furthermore, this MSCA disagreed with ECHA's draft decision to reject conduction of a 90-day sub-chronic toxicity study that the registrant has proposed to be performed.

SECR considered that the draft decision as presented to the MSCAs does not need to be amended.

SECR was also of the view that the first proposal of the second MSCA to include a recommendation in a decision is not acceptable, and pointed out that such a recommendation has already been included in the cover letter to the draft decision. However, SECR welcomed the discussion on whether or not to reject the testing proposal for 90-day study.

The registrant submitted comments on the proposals for amendment supporting ECHA's draft decision and explaining that tests in accordance with Annex IX have been proposed for the reason that the tonnage level of Annex IX will be reached very soon, and that this approach would best take into account the animal welfare considerations. The registrant did not see a scientific need to carry out the 90-day sub-chronic toxicity study but recognised that adaptation of the standard information requirements indicated in column 2 of Annex IX was not formally justified and made therefore the testing proposal for the 90-day study for formal reasons.

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 main issue for discussion was whether to accept or reject the two testing proposals (pre-natal developmental study and 90-day sub-chronic toxicity study) proposed by the registrant on a higher tonnage level than the registration is made, and whether both testing proposals should be treated similarly.

COM noted that the rejections of proposed tests should only be done very carefully and only exceptionally on a well-grounded basis.

Several MSC members argued that ECHA should not take over the registrant's responsibility and generally would not be in a position to reject tests proposed by registrants. Even if the registrant does not express it clearly, there may always be good reasons why certain test was proposed. A number of MSC members argued that a poor justification for a testing proposal by the registrant is not sufficient grounds for ECHA to reject the testing proposal. Although the rejection of the 90-day study seems to be in accordance with the guidance, the rejection of the study was not considered to be the right decision.

Some MSC members were concerned that ECHA would like to treat the pre-natal study and the 90-day study in the draft decision differently, although the situation is very similar for the two tests: both tests are standard information requirement for Annex IX. Therefore, both tests should be either accepted or rejected for consistency reasons. SECR replied that there are two significant differences between these two endpoints. First, there is a data gap in the dossier for the endpoint addressed by the testing proposal for the pre-natal development toxicity study, whereas there was no such data gap for the repeated dose toxicity study, as the registrant had fulfilled the information requirements for Annex VIII by including the results of a 28-day study.

Other MSC members reminded that the waivers of Column 2 of 8.7.1 of Annex VIII not to provide the screening information on reproductive/developmental toxicity should be applicable only if the data are already available from the pre-natal study; testing proposal would not be sufficient for the adaptation to the screening test which is the standard requirement under this endpoint in Annex VIII. Thus, he proposed to accept the pre-natal test and to require in addition the screening study even though he realised that it could be required only by opening a compliance check.

Considering all options to reject both testing proposals, to accept both testing proposals, to accept only one of the testing proposals, to open a compliance check on Annex VIII information requirements were brought up in the discussion. MSC, in this occasion, concluded in favour of asking both tests to be carried out as proposed by the registrant. SECR stressed that this was a special case and should not be considered as a precedent for future cases, and that normally proper justification would be needed for testing proposals in those cases where tests would not be required under REACH.

Session 2 (closed)

MSC modified the requirements in the draft decision so that the registrant is required to perform both the pre-natal developmental toxicity study and the 90-day sub-chronic toxicity study.

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

Item 7 – Substance evaluation (SEV)

a) Oral report from the ECHA workshop on Substance Evaluation (23-24 May 2011) and update by ECHA on the work on CoRAP development

SECR in its presentation informed the meeting about the outcome of the workshop and the state-of-play concerning CoRAP development. The full presentation was made available to MSC members and stakeholders on MSC CIRCA. In addition, a separate document on the state of play of preparation of CoRAP was provided for stakeholder observers.

MSC took note of the report.

In the detailed discussion, stakeholder observers expressed their willingness to take part in the development of CoRAPs in the future. SECR replied to a question that only the final SEV reports will be published and questions around targeting and re-opening a SEV will be clarified soon. It was also stressed that transparency will be one of the key elements in SEV work and the prioritisation for CoRAP will follow not only hazard but also risk concerns.

b) Planning of substance evaluation work in MSC - Draft MSC working procedure on providing the opinion on CoRAP

SECR introduced the draft working procedure revised on the basis of the written comments received from MSC members. MSC took note of and generally supported the revised working procedure on providing the MSC opinion on CoRAP. It was agreed that the rapporteurs in the process of providing MSC opinion on the draft CoRAP will be appointed for one whole year and that MSC will give its opinion on proposals made by MSCAs under Article 45(5) of REACH during the running year and will not wait until the next CoRAP update. Some more editorial comments were proposed by the MSC members too.

Based on the comments made in the current meeting, SECR will revise again the document and invite MSC members for written comments on the revised version. Based on those written comments, SECR will finalise the working procedure and launch a written procedure for adoption.

Item 8 – SVHC identification

a) Reporting back on identification of SVHCs in written procedure

SECR gave a brief report on the written procedure on identification of five substances as SVHC that was launched on 10 May 2011. By the closing date 20 May 2011, 23 responses from MSC members with voting right were received, all of which were in favour and none were against the proposed agreements. Also the Norwegian member responded positively. It could be concluded that the agreements and respective support documents on the identification of the five substances (*2-ethoxyethyl acetate, strontium chromate, 1-methyl-2-pyrrolidone, 1,2,3-trichloropropane, 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich)* as SVHC has been reached by MSC on 20 May 2011. MSC agreed unanimously to identify the above five as SVHC meeting the criteria referred to in Article 57 of REACH.

The final documents will be made available on MSC CIRCA and on the ECHA website. These five substances will be included in the Candidate List of SVHCs.

b) Seeking agreement on Annex XV proposals for identification of SVHC

Discussion and seeking agreement on the identification of SVHCs based on the proposals and the comments received

1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)(EC number 271-084-6)

The representative of the Danish CA as dossier submitter introduced the Annex XV proposal for the substance. The presentation was made available on MSC CIRCA. The reason triggering MSC consultation was the comment in the public consultation questioning the identity of the substance and thus also the identification of the substance as SVHC. The dossier submitter replied to the comment that the substance identity in the Annex XV proposal was identical to that in Annex VI of the CLP Regulation and would not need to be further defined. Thus the entry on the Candidate List would cover only the substance as identified by the entry in the CLP-Regulation. In the discussion no other issues were raised.

MSC unanimously agreed that 1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP) as a substance toxic for reproduction 1 B meets the criteria of Article 57 (c) of REACH. Therefore, the substance is identified as SVHC. Agreement and support document for the substance were unanimously agreed without any modifications.

Hydrazine (EC number 206-114-9)

ECHA SECR as dossier submitter introduced the Annex XV proposal for the substance. The presentation was made available on MSC CIRCA. The reason triggering MSC consultation was the comment in the public consultation questioning the identity of the substance and thus also the identification of the substance as SVHC. The dossier submitter replied to the comment that the substance identity description in the Annex XV proposal was identical to that in Annex VI of the CLP Regulation i.e. covering both the hydrated and anhydrous forms of the substance. This perception of the substance identity is supported by the fact that the substance registered is hydrazine but that the uses in the registration dossiers are mostly referring to the hydrated forms. The classification of hydrazine was also questioned in some comments but as the classification is harmonised in the legislation such comments are not taken into account in the identification of a substance as SVHC.

In the discussion, SECR agreed that also hydrazine hydroxide will be mentioned in the table of the support document as an additional synonym for the substance name. SECR clarified that salts of the substance will not be covered by the Candidate List entry of the substance.

SECR explained that due to time constrains coming from COM ECHA has not prepared any RMO analysis for the proposal. Several members requested COM to explain the reasons for this Annex XV SVHC dossier. SECR made clear that an RMO analysis can be prepared later in the process as it can be used to support decision making on the need to instigate any further regulatory risk management measures.

It was also clarified in the discussion that the Candidate List may not be only a step in the authorisation process but can also be used to trigger obligation to provide information on substances of very high concern down the supply chain. For substances that are on the Candidate List (but not yet in Annex XIV), the restriction procedure can be started. After a substance is placed on Annex XIV, new restrictions may not be imposed to address risks which arise from the intrinsic properties specified in Annex XIV. However, after the inclusion of the substance in Annex XIV it is still possible to

impose new restriction due to risks from the presence of the substance in articles. A member requested a clarification of the role of the Candidate List stating that in its view the Candidate List should be considered only as part of the authorisation process. Reference was made to the conclusions of the workshop on authorisation and restrictions in 2009 that reflected the different possible roles of the Candidate List.

As no comments challenging the identification of the substance as SVHC were raised, MSC unanimously agreed that hydrazine as a carcinogen 1B substance meets the criteria of Article 57 (a) of REACH. Therefore, the substance is identified as SVHC. Agreement and support document for the substance were unanimously agreed with addition of the synonym for the name of hydrazine to the support document (see above).

SECR informed that the Candidate List update with the substances agreed upon as SVHC in written procedure and in the meeting is foreseen by 17 June 2011.

c) Update on other topics related to SVHC identification

Cobalt dichloride - update of its identification as SVHC on the basis of Article 57 (c) of REACH

SECR informed that in the SVHC identification process none of the 15 comments received in the pubic consultation challenged the additional hazard property "toxic for reproduction 1B" for identification of the substance as SVHC. Therefore, the substance is identified as SVHC as it is classified as toxic for reproduction 1B and meets the criteria of Article 57 (c) of REACH. The new identification basis will be added to the entry of the substance on the Candidate List without MSC involvement.

SECR also clarified that a conclusion on a potential threshold mechanism for the carcinogenic properties of the substance may be drawn by the Risk Assessment Committee of ECHA. For the time being, ECHA, in its prioritisation of the cobalt(II) salts on the Candidate List for inclusion in Annex XIV, considered the non-threshold mechanism as a worst case assumption. This assumption does not pre-empt or have an effect on any conclusions for RAC.

MSC took note of the report.

Update on REACH Annexes

SECR gave a brief report on the main changes in Annex XIII of REACH after its amendment on 15 March 2011. The presentation was available in MSC CIRCA. The revised criteria will apply to the next Annex XV SVHC proposals when made because of their PBT/vPvB properties.

MSC took note of the report.

Update by HEAL on some endocrine disruptors

An expert on behalf of HEAL gave a brief report on the updated SIN 2.0 list by explaining the assessment process resulting in addition of 22 additional substances of endocrine disrupting properties to the list. The methodology used was explained in details. The presentation was made available on MSC CIRCA.

MSC took note of the report.

Item 9 –Discussion on ECHA's 3rd draft recommendation for inclusion of priority substances in Annex XIV

Discussion on ECHA's 3rd draft recommendation – prioritisation of the substances on the Candidate List and draft Annex XIV entries of the substances suggested for inclusion in the recommendation

SECR gave a presentation on the draft results of the prioritisation as revised on the basis of the comments received from the MSC during and after the MSC-17 meeting. The presentation was made available on MSC CIRCA. The comments were briefly introduced. SECR clarified that some relevant information on uses and volumes has been provided on cobalt(II) compounds and 2-methoxyethanol but these have not changed the overall priority of these substances for Annex XIV. Concerning borates, further assessment of the information available led to some modifications of use descriptions but this did not change the conclusions on priority on the basis of the generic criteria either. Based on the generic criteria, the three borate compounds would have a high priority for inclusion in Annex XIV. However, as the regulatory effectiveness of subjecting these substances at present to authorisation appears for several reasons (e.g. some further borate compounds with the same classification as "repr. 1B" are currently not on the Candidate List and hence could be used to evade the authorisation requirement, placing on the market and use of borate compounds will soon be restricted for consumer uses as substances and substances in mixtures above the specific concentration limits by a COM Regulation) questionable, ECHA does not propose the three borate compounds (sodium tetraborate, boric acid, tetraboron disodium heptaoxide hydrate) for inclusion in Annex XIV now, but recommends to first wait for the impacts of the new restriction on consumer uses and of the registrations in accordance with the classification of the substances as "Repr. 1B" on use patterns and resulting worker exposure. COM confirmed that the restriction on the borate compounds is expected to be in force by around the end of 2011.

The following substances from the Candidate List will be included in the draft recommendation that will be published for public consultation by ECHA (foreseen by 15 June 2011): trichloroethylene, the seven chromium(VI) compounds and the five cobalt(II) compounds.

In the discussion, some MSC members expressed their support for industry's request for extension of application and sunset dates for chromium(VI) compounds. The Chair reminded that prioritization in MSC is discussed on the basis of the agreed criteria. Some other MSC members informed that according to their information industry will have alternatives available for these compounds by the sunset date. An observer expressed his concerns of the sunset date of chromium(VI) compounds regarding particularly packaging applications for sodium dichromate and chromium-trioxide and could not confirm the information of MSCA regarding available alternatives for chromium(VI) compounds. He reminded that in his view the biological essentiality of cobalt(II) compounds has not been reflected in the prioritization and noted that sunset date will likely be a challenge for industry for these compounds due to the wide applications and extensive use of these compounds.

SECR replied to these comments that concerns and information on sunset dates, application dates and alternatives should be provided to ECHA in writing in the public consultation. Regarding transparency, SECR noted that the table with the detailed results of prioritization containing also the substances not proposed by ECHA to be prioritized will also be published in the public consultation for information. Also the at-

tachment table with the list of non-prioritised substances in the same document will be published. SECR stated that public versions of background documents for substances recommended for prioritization will be made available for the public consultation.

SECR gave a brief presentation on the table of draft Annex XIV entries (available on MSC CIRCA). Generally, the table was prepared following the principles used for the 2nd recommendation. Review periods, exempted uses and PPORD exemptions were not included in the draft recommendation. Based on the latest application dates, substances were split into three groups. Assuming that Annex XIV will be updated with the substances of the current 3rd Recommendation in January 2013, the latest application date for one group of substances was set for July 2014 (18 months after entry into force of the update of Annex XIV). Two other latest application dates were set three and six months later, reflecting ECHA's limited capacity to deal with the potentially high number of authorization applications.

In the discussion, one MSC member asked ECHA to keep the latest application dates as early as possible for all substances proposed for the 3rd recommendation for Annex XIV, at least in the version of the draft recommendation prepared for the public consultation. Two industry observers expressed their concerns again on the very short period between publication of the updated Annex XIV and the latest application date. One MSC member asked ECHA for practical reasons to set the latest application date as a period of time from the entry into force instead of a date.

As other comments were not raised, the Chair concluded that MSC widely supported ECHA's results for the prioritisation of substances to be included in the 3rd recommendation and the draft Annex XIV entries. She invited the meeting participants to submit written comments on the above documents, on ECHA's prioritisation approach and on the background documents for the substances proposed for the 3rd recommendation by 3 June 2011. Based on the current meeting discussion and on the written comments submitted by this deadline, ECHA will finalise the documents for the public consultation (foreseen from 15 June 2011 to 14 September 2011).

Item 10 – Opinion on the draft recommendation of priority substances to be included in Annex XIV: Tasks and appointment of Rapporteur and possible working group

a) Tasks of the Rapporteur in drafting the opinion of the MSC

b) Appointment of Rapporteur

c) Establishment of a working group to support the Rapporteur

SECR briefly presented the tasks of the rapporteur. MSC agreed on the mandate, and the tasks and the person of the rapporteur. MSC established the working group with eight members supporting the rapporteur.

Item 11 – Manual of Decisions (MoD)

- **Discussion on next new entries for the MoD**

SECR briefly introduced the text proposals for two items to be included in MoD.

COM expressed its concerns on one of these items. In the view of COM, the statement "MSC in its opinion on ECHA's draft recommendations on substances to be included in Annex XIV would normally not be in favour of including the route of au-

thorisation in the recommendation" would prejudice ECHA's future actions when preparing ECHA's recommendations for inclusion of substances in Annex XIV. The Chair explained that the MoD of MSC is not binding for ECHA's future actions. Should it happen that ECHA SECR suggested in its draft recommendation that a threshold for an effect exists for some of the substances, MSC would be obliged to consider this in its opinion.

After short discussion and some minor modifications proposed by MSC members, the two entries were adopted and will be included in the MoD of MSC.

Item 12 – Proposals to tackle MSC's workload - Discussion on how to increase efficiency of MSC work

SECR introduced the document by reviewing the tasks and the estimated rapidly increasing workload of MSC in the coming years.

SECR pointed out that the dossier evaluation task has the highest impact on the MSC workload. The most important area where this workload could be reduced is the decreased number of amendments proposed by MSCAs to ECHA's draft decisions.

In the general discussion, several MSC members expressed their support for the proposals. Some MSC members, however, did not agree that policy matters should not be discussed in MSC at all. In their view, MSC in some cases has to interpret REACH as well not only to implement. MSC members made also some proposals to make MSC work more efficient such as MSC Secretariat should send a document with MSC identification codes, names of the relevant CIRCA folders and of the substances, and with registration numbers to MSC members at the beginning of each MSC process for dossier evaluation. One member suggested that RCOMs should be provided to MSC only once in the process (i.e. the final version would suffice). SMILES codes should also be prepared and sent to MSC by SECR whenever it is possible. Cover letters and quality observation letters (QOBLs) should be provided as well. Some MSC members proposed to establish small working groups which could work in parallel with the plenary on dossier evaluation draft decisions. One MSC member asked the MSC Secretariat to avoid embedding documents into other ones. One MSC member welcomed the idea of developing templates for proposals for amendment but emphasised that these templates should not be too restrictive. SECR was asked to send ECHA's responses (RCOM) to the proposed amendments also to the proposing MSCA not only to MSC members. Some MSC members pointed out the need for enhanced cooperation between MSC members.

One stakeholder observer asked how stakeholders could learn about SVHCs agreed on in written procedures. She also reminded that establishing more working groups should not lead to less involvement of stakeholders in the work of MSC. The rationale for having the recommendation for Annex XIV in each year instead of every second year was supported by her.

The Chair concluded that a continued discussion on the topic needs to be held in the next MSC meting in September. MSC members were invited to send their written comments to MSC Secretariat by 15 June. SECR will revise the document and the revised version will be presented for MSC-19 in September 2011.

Item 13 – Any other business

- **Letter (24 March 2011) from the German CA to ECHA concerning draft decisions on compliance checks and testing proposal examinations, and ECHA's response to it (closed session)**

The German MSC member briefly introduced the four issues included in the German CA's letter. SECR then explained briefly ECHA's responses to the three most relevant questions in the letter.

- **Report from the Informal Expert Meeting on identification of substances as SVHC because of their endocrine disrupting properties - 12 April 2011 (closed session)**

The German MSC member gave a brief report of the meeting organised by the German CA and hosted by ECHA.

MSC took note of the report.

- **Outline for a workshop on the status of raw materials' use for manufacturing of glass and frits, and ceramics and enamels**

The MSC observer of CEFIC introduced a room document on the joint initiative of CEFIC and Eurometaux supported by some MSCAs to organise a workshop with the aim to clarify the (non)-intermediate status of several organic and inorganic raw materials in the manufacturing of glass and frits, and ceramics and enamels. He invited MSC to submit proposals for the agenda of the planned workshop that is foreseen for the autumn of 2011, possibly back to back with one of the CARACAL or MSC meetings.

SECR clarified that due to the high workload of MSC the planned workshop can not be organised back to back with an MSC meeting in the autumn of 2011.

- **Document flow**

One MSC member asked MSC Secretariat to number meeting documents according to the order of agenda items and to send to MSC members only the final version of RCOM in the dossier evaluation process. He also expressed his concerns that some meeting documents were placed on MSC CIRCA only a few days before the current meeting.

The Chair said that these pleas will be considered. She pointed out that some documents were provided late for the current meeting because the MSCA consultation on two dossier evaluation draft decisions had to be restarted due to some administrative mistakes. In accordance with the Rules of Procedures of MSC, MSC members were asked in an e-mail whether they accept the late submitted documents for decision making. As no negative replies were received, the documents were handled as regular meeting documents. Otherwise all documents that were provided for MSC decision were sent to the members in accordance with RoPs at least ten days before the meeting.

Item 14 - 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
ANASTASI, Audrey Anne (MT) (alternate member)
ANDRIJEWSKI, Michal (PL)
BIWER, Arno (LU)
COSGRAVE, Majella (IE)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
HEISKANEN, Jaana (FI)
HUMAR-JURIC, Tatjana (SI)
KORENROMP, Rene (NL)[1]
KULHANKOVA, Pavlina (CZ)
PALEOMILITOU, Maria (CY) (alternate member)
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)
STESSEL, Helmut (AT)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)

Representatives of the Commission
GARCIA JOHN, Enrique (DG ENTR)
KOBE, Andrej (DG ENV)

Observers
ANNYS, Erwyn – CEFIC
BOHDAN, Dmytrasz – CONCAVE
DOOME, Roger – IMA-Europa, EBA, only for item 9
LIGHTHART, Jerker (CHEMSEC)
STAIRS, Kevin (Greenpeace)
TAYLOR, Katy (ECEAE)
VAN VLIET, Lisette (HEAL)
WAETERSCHOOT, Hugo - EUROMETAUX

ECHA staff
BALOGH, Attila
BELL, David
BONNOMET, Vincent
BROERE, William
CARLON, Claudio
CESNAITIS, Romanas
DE COEN, Wim
FEDTKE, Norbert
HAUTAMAKI, Anne
KARHU, Elina
KOJO, Anneli
KOULOUMPOS, Vasileos
LE CURIEUX, Frank
LEPPER, Peter
MALM, Jukka
NAUR, Liina
ROCKE, Timo
RODRIGUEZ IGLESIAS, Pilar
SOBANSKA, Marta
STILGENBAUER, Eric
SUMREIN, Abdelqader
SUNDQUIST, Anna-Liisa
TISSIER, Chrystele
VAHTERISTO, Liisa
YLÄ-MONONEN, Leena

[1] Not present during agreement seeking on CCH008/2011 (Item 6d)

Proxy's

COSGRAVE, Majella (IE), also acting as proxy of DEIM, Szilvia (HU)
PALEOMILITOU, Maria (CY) also acting as proxy of KOUTSODIMOU, Aglaia (EL) and as proxy of ANASTASI, Audrey Anne (MT) on 27 May 2011
VANDERSTEEN, Kelly (BE), also acting as proxy of BIWER, Arno (LU) on 27 May 2011
VESKIMÄE, Enda (EE) also acting as proxy of LUDBORZS, Arnis (LV) on 27 May 2011

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)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
HAKKERT, Betty C (NL) (expert to KORENROMP, Rene
INDANS, Ian (UK) (expert to DOUGHERTY, Gary)
KJELDBY, Marit (NO) (adviser to REIERSON, Linda)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
MESSIER, Cedric (FR) (adviser to DRUGEON, Sylvie)
MICHEL, Cécile (FR) (expert to FANGUET, Céline)
PARRAGA, Helena (ES) (adviser to MARTIN, Esther)
RAMOS, Cesaltina (PT) (expert to MARTINS, Ana Lilia)
SCIMONELLI, Luigia (IT) (adviser to PISTOLESE, Pietro)
SULG, Helen (EE) (expert to VESKIMÄE, Enda)
TALASNIEMI, Petteri (FI) (adviser to HEISKANEN, Jaana)
VAN ELSACKER, Paul (BE) (expert to VANDERSTEEN, Kelly)
VAN IERSEL, Peter (NL) (adviser to KORENROMP, Rene)
WALENDZIK, Gudrun (DE) (expert to FINDENEGG, Helene)

Case owners:
A representative of the registrant was attending under agenda item 6c for:
- TPE 006/2011, 11-aminoundecanoic acid)
- CCH 008/2011, UB 2740
- TPE 003/2011, DPF
- CCH 016/2011 HFO-1234ze.

Apologies:
DEIM, Szilvia (HU)
KOUTSODIMOU, Aglaia (EL)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
PALMA, Maria do Carmo (PT)
BIWER, Arno (LU) for 27 May
PISTOLESE, Pietro (IT) for 27 May

III. Final agenda

Final Agenda
18th meeting of the Member State Committee

25-27 May 2011
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

25 May**: starts at 9:00**
27 May**: ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/018/2011
For adoption

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

Item 4 –Administrative issues

Item 5 –Draft minutes of the MSC-17

- Adoption of the draft minutes of MSC-17

MSC/M/17/2011
For adoption

Item 6 –Dossier evaluation
Closed session for 6c (partially)& 6d
Indicative time plan for 6c is Day 1 (11:30->), for 6d Day 2&3

a. General topics:

- **Continued discussion about possibilities for waiving repeat dose studies for low-toxicity substances**

ECHA/MSC-18/2011/001
For discussion

- **Status report on ongoing evaluation work**

For information

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

For members only: ECHA/MSC-18/2011/002

For information

c. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals after MS-CA reactions *(Session 1, closed except for case CCH 007/2011 and TPE 006/2011)*

ECHA/MSC-18/2011/021
For closed session: ECHA/MSC-18/2011/032

For discussion followed by agreement seeking under 6d:

Open session:

- CCH 007/2011 4-hydroxy-3,5-dimethoxybenzonitrile (EC 700-251-2)
ECHA/MSC-18/2011/037 - 038

- TPE 006/2011 11-aminoundecanoic acid (EC 219-417-6)

ECHA/MSC-18/2011/003 - 004

Closed session:

- CCH 008/2011 UB 2740 / 50 (EC 480-680-7)

ECHA/MSC-18/2011/040 - 041

- TPE 005/2011 BDP (1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate (EC 425-220-8)

ECHA/MSC-18/2011/043 - 044

- TPE 003/2011 DPF (EC 442-709-3)

ECHA/MSC-18/2011/006 - 007

- CCH 016/2011 HFO-1234ze (EC 471-480-0)

ECHA/MSC-18/2011/009 - 010

- CCH 014/2011 BHT (EC 485-290-0)

ECHA/MSC-18/2011/012 - 013

- CCH 015/2011 TIB KAT 223 (EC 483-270-6)

ECHA/MSC-18/2011/015 - 016

- TPE 004/2011 1,5-bis[1,2-bis(ethoxycarbonyl)ethylamino]-2-methylpentane (EC 433-260-2)

ECHA/MSC-18/2011/018 - 019

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)*

- CCH 007/2011 4-hydroxy-3,5-dimethoxybenzonitrile (EC 700-251-2)

ECHA/MSC-18/2011/037 - 039

- TPE 006/2011 11-aminoundecanoic acid (EC 219-417-6)

ECHA/MSC-18/2011/003 - 005

- CCH 008/2011 UB 2740 / 50 (EC 480-680-7)

ECHA/MSC-18/2011/040 - 042

- TPE 005/2011 BDP (1-methylethylidene)di-4,1-phenylenetetraphenyl diphosphate (EC 425-220-8)

ECHA/MSC-18/2011/043 - 045

- TPE 003/2011 DPF (EC 442-709-3)

ECHA/MSC-18/2011/006 - 008

- CCH 016/2011 HFO-1234ze (EC 471-480-0)

ECHA/MSC-18/2011/009 - 011

- CCH 014/2011 BHT (EC 485-290-0)

ECHA/MSC-18/2011/012 - 014

- CCH 015/2011 TIB KAT 223 (EC 483-270-6)

ECHA/MSC-18/2011/015 - 017

- TPE 004/2011 1,5-bis[1,2-bis(ethoxycarbonyl)ethylamino]-2-methylpentane (EC 433-260-2)

ECHA/MSC-18/2011/018 - 020
For agreement

Item 7 – Substance evaluation

a. Oral report from the ECHA workshop on Substance Evaluation (23-24 May 2011) and update by ECHA on the work on CoRAP development

ECHA/MSC-18/2011/022
For information

b. Planning of substance evaluation work in MSC

Draft MSC working procedure on providing the opinion on CoRAP

ECHA/MSC-18/2011/023
For discussion and adoption

Item 8 – SVHC identification

a. Reporting back on written procedure on identification of SVHC's in written procedure

ROOM DOCUMENT
For information

b. Seeking agreement on Annex XV proposals for identification of SVHC

Discussion and seeking agreement on the identification of SVHCs based on the proposals and the comments received on:

Substance	*EC number*	*Documents*
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	271-084-6	ECHA/MSC-18/2011/026-028
Hydrazine	206-114-9	ECHA/MSC-18/2011/029-031

For discussion& decision

c. Update on other topics related to SVHC identification

- Update on REACH Annexes
- Update by HEAL on some endocrine disruptors

For information

Item 9 –Discussion on ECHA's 3rd draft recommendation for inclusion of priority substances in Annex XIV

Discussion on ECHA's 3rd draft recommendation – prioritisation of the substances on the Candidate List and draft Annex XIV entries of the substances suggested for inclusion in the recommendation.

ECHA/MSC-18/2011/046-048
Background documents: ECHA/MSC-18/2011/049 -061

For discussion

Item 10 – Opinion on the draft recommendation of priority substances to be included in Annex XIV: Tasks and appointment of Rapporteur and possible working group

a. Tasks of the Rapporteur in drafting the opinion of the MSC

ECHA/MSC-18/2011/033
For discussion & decision

b. Appointment of Rapporteur

For discussion & decision

c. Establishment of a working group to support the Rapporteur

ECHA/MSC-18/2011/034
For discussion & decision

Item 11 – Manual of Decisions (MoD)

- Discussion on next new specific entries and new topics for the MoD

ECHA/MSC-18/2011/035
For discussion & decision

Item 12 – Proposals to tackle MSC's workload

- Discussion on how to increase efficiency of MSC work

ECHA/MSC-18/2011/036
For discussion

Item 13 – Any other business

- Suggestions from members

For information

Item 14 – Adoption of conclusions and action points

- Table with action points and decisions from MSC-18

For adoption

IV. Main conclusions and action points

MSC-18, 25-27 May 2011
(adopted in written procedure after the MSC-18 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
5. Adoption of the minutes of MSC-17	
Written comments received from meeting participants had been taken into account. The confidential and non-confidential versions of the minutes were adopted with some further changes proposed in the meeting.	MSC-S to upload the adopted versions on MSC CIRCA and to publish the non-confidential version of the minutes on the ECHA website.
6. Dossier evaluation **6a) General topics**	
(1) Continued discussion about possibilities for waiving repeat dose studies for low-toxicity substances	
MSC supported the initiative to continue exploring scientific basis for proposal for waiving repeat dose studies for low-toxicity substances. The Weight of Evidence approach in accordance with Annex XI. 1.2 is already now applicable for the registrants but this would always require case-by-case analysis.	
(2) Status report on ongoing evaluation work	
MSC took note of the report of ECHA.	
6b) Written procedure report on seeking agreement on draft decisions on dossier evaluation	
MSC took note of the report of ECHA.	MSC-S to upload in MSC CIRCA the final ECHA decisions and agreements on cases CCH009/2011, CCH010/2011, CCH 013/2011 and TPE 002/2011.
6c) Introduction to and preliminary discussion on draft decisions on compliance checks after MSCAs' reactions ***(Session 1, closed session except for CCH 007/2011 and TPE 006/2011)*** **6d) Seeking agreement on draft decisions on compliance checks when amendments were proposed by MSCAs** ***(Session 2, closed)***	
CCH 007/2011 (Syringonitrile) **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's draft decision and the concern raised in the previous written procedure by one MSC member. It was agreed that the algae test should be repeated with measurement of the test substance concentration according to EU C3 (OECD 201) guidelines. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on ECHA's draft decision without further amendments in the meeting (as	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
provided for the current meeting). MSC adopted the formal agreement. **<u>TPE 006/2011 (11-aminounecanoic acid)</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 concluded that further studies for reproductive toxicity should not be required from the registrant. No changes on the draft decision as provided for the current meeting were suggested by MSC members for further discussion in Session 2 (agreement seeking). **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on ECHA's draft decision (as provided for the current meeting). MSC adopted the formal agreement. **<u>CCH 008/2011</u> (UB 2740 / 50 [06-04-2061])** **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's draft decision and the concern of the MSC member namely that the perinatal effects are not mentioned in the notification letter. ECHA agreed to include the word "perinatal effects" in the notification letter. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on ECHA's draft decision without amendments in the meeting (as provided for the current meeting). MSC adopted the formal agreement. **<u>TPE 005/2011</u> (BDP)** **Discussion (6c, Session 1)** The case was raised for meeting discussion from written procedure based on one concern by one MSC member. The MSC member proposing the meeting discussion withdrew his discussion proposal. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on ECHA's draft decision without amendments in the meeting (as provided for the current meeting). MSC adopted the formal agreement. **<u>TPE 003/2011(DPF)</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.	

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The main discussion point was whether the long-term toxicity test on plants should be performed according to the ISO 22030 or the OECD 208 test method. The justification to use the ISO test was that only this test of the two covers reproductive effects on plants. No other issues were suggested by MSC members for further discussion in Session 2 (agreement seeking). **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on ECHA's draft decision keeping the requirement for the registrant to perform the long term toxicity test on plants according to the ISO 22030 test method. MSC did not introduce any amendments to the draft decision as provided for the current meeting. MSC adopted the formal agreement. **<u>CCH 016/2011(HFO-1234ze)</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 main discussion points were: - The need for a further prenatal developmental toxicity study - The use of a limit dose in the pre-natal developmental toxicity study, and the aim to induce maternal toxicity effects (possible need for range-finding study) - Choice of species (rat vs rabbit) in the prenatal developmental toxicity study - Possible requirement for an extended one-generation reproductive toxicity study (EOGRTS) **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on ECHA's draft decision after deleting the requirement for the pre-natal developmental toxicity study and adding a statement that at this stage ECHA cannot determine whether the prenatal developmental toxicity endpoint is compliant with REACH. The need for the pre-natal developmental toxicity test will depend on the outcome of the two-generation reproductive study. The respective parts of the Statement or Reasons were also modified accordingly. Some members wanted to attach to the minutes of MSC-18 a statement on importance to introduce in REACH the EOGRTS. This statement is intended to be passed to the Commission and to the forthcoming CA-	

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RACAL meeting. MSC did not introduce any other amendments to the draft decision. MSC adopted the formal agreement. **<u>CCH 014/2011 (BHT)</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 generally supported the draft decision as provided to the current meeting as a room document. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on ECHA's draft decision without amendments. MSC adopted the formal agreement. **<u>CCH 015/2011 (TIB KAT 223)</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 main point for discussion was whether the short-term toxicity test on invertebrates and the growth inhibition study on aquatic plants are required. The concern in this respect was that tests for these two endpoints were available in the registration dossier but unclear exposure data provided (composition of the test solutions in these tests was not determined) did not allow for clear conclusions. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on ECHA's draft decision after deleting the requirements for the repeated performance of above two tests and including the requirements to the registrant to provide information on - the qualitative composition of the test solutions (including identity of hydrolysis products of the registered substance) of the tests provided in the registration dossier - toxic effect concentrations of the hydrolysis products of the substance relevant for the tests provided in the registration dossier, as predicted by valid QSAR models - any other relevant available information on the intrinsic properties of the hydrolysis products. The respective parts of the Statement or Reasons were also modified accordingly. The deadline to provide requested information in the form of an updated IUCLID	SECR to pass a message to CARACAL/COM regarding the concern of MSC on applicability of EOGRTS for the purposes of REACH Regulation in the near future.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
dossier to ECHA was changed to 6 months from the date of decision. MSC did not introduce any other amendments on the draft decision as provided for the current meeting. MSC adopted the formal agreement. **<u>TPE004/2011</u>(1,5-bis[1,2-bis(ethoxy-carbonyl) ethylamino]-2-methylpentane)** **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 main issue for discussion was whether there were grounds to accept or reject the two testing proposals (pre-natal developmental study and 90-day sub-chronic toxicity study) proposed by the registrant in accordance with the standard information requirements of the next higher tonnage level than the registration is made, and if both testing proposals should be treated similarly. MSC concluded in favour of accepting that both tests are carried out as proposed by the registrant. No other issues were suggested by MSC members for further discussion in Session 2 (agreement seeking). **Agreement seeking (6d, Session 2)** MSC modified the requirements in the draft decision so to accept that the registrant performs both the prenatal developmental toxicity study and the 90 day sub-chronic toxicity study. MSC reached unanimous agreement on ECHA's draft decision after the above modifications. MSC did not introduce any other amendments to the draft decision. MSC adopted the formal agreement.	MSC-S to upload in MSC CIRCA the final ECHA decisions and agreements on cases CCH 007/2011, CCH008/2011, CCH014/2011, CCH015/2011, CCH016/2011, TPE003/2011, TPE004/2011, TPE005/2011 and TPE006/2011.
7**. Substance evaluation** **7a) Oral report from the ECHA workshop on Substance Evaluation (23-24 May 2011) and update by ECHA on the work on CoRAP development**	
MSC took note of the report of ECHA.	ECHA to upload the presentations of the Workshop on Substance Evaluation on 23-24 May 2011 by 27 May 2011.

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7b) Planning of substance evaluation work in MSC – Draft MSC working procedure on providing the opinion on CoRAP	
MSC took note and generally supported the working procedure on providing the MSC opinion on CoRAP.	Based on the current meeting discussion, SECR to revise the document and invite MSC members for written comments on the revised version. Based on the written comments, SECR to finalise the working procedure and launch written procedure for adoption.
8. SVHC identification **8a) Reporting back on written procedure on identification of SVHC's in written procedure**	
MSC unanimously identified the following five substances as SVHC in written procedure (and unanimously agreed on their SDs and agreements as presented in the respective documents) : - *2-ethoxyethyl acetate* (EC 203-839-2) (reprotoxic substance, fulfilling the criteria of Art.57(c) of REACH Regulation), - *strontium chromate* (EC 232-142-6) (carcinogenic substance, fulfilling the criteria of Art. 57(a) of REACH Regulation), - *1-methyl-2-pyrrolidone* (EC 212-828-1) (reprotoxic Substance, fulfilling the criteria of Art. 57(c) of REACH Regulation), - *1,2,3-trichloropropane* (EC 202-486-1) (carcinogenic and reprotoxic substance, fulfilling the criteria of Art. 57(a) and (c) of REACH Regulation), - *1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich* (EC 276-158-1) (reprotoxic substance, fulfilling the criteria of Art.57(c) of REACH Regulation). MSC took note of the report.	SECR to add to the Candidate List the following substances (foreseen by 17 June 2011): - *2-ethoxyethyl acetate* (EC 203-839-2) - *strontium chromate* (EC 232-142-6) - *1-methyl-2-pyrrolidone* (EC 212-828-1) - *1,2,3-trichloropropane* (EC 202-486-1) - *1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich* (EC 276-158-1). SECR to upload the agreements and support documents (SDs) on MSC CIRCA and the MSC section of the ECHA website after final editing. SECR to publish RCOMs on the MSC section of the ECHA website without any confidential information.
8b) Seeking agreement on Annex XV proposals for identification of SVHC	
MSC unanimously identified the following two substances as SVHC (and unanimously agreed on their SDs and agreements as presented in the respective meeting documents): - *1,2-Benzenedi-carboxylic acid, di-C7-11-branched and linear alkyl esters* (EC 271-084-6) (reprotoxic substance, fulfilling the criteria of Art. 57(c) of REACH Regulation, - *Hydrazine* (EC 206-114-9) (carcinogenic substance, fulfilling the criteria of Art. 57(a) of REACH Regulation.	SECR to add to the Candidate List the following substances (foreseen by 17 June 2011): - *1,2-Benzenedi-carboxylic acid, di-C7-11-branched and linear alkyl esters* (EC 271-084-6) - *Hydrazine* (EC 206-114-9) SECR to upload the agreements and support documents on MSC CIRCA and the MSC section of the ECHA website after final editing. SECR to publish RCOMs on the MSC section of the ECHA website without any con-

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	fidential information.
8c) Update on other topics related to SVHC identification **1. Update on REACH Annexes** **2. Update by HEAL on some endocrine disruptors**	
MSC took note of the reports.	
9. Discussion on ECHA's 3rd draft recommendation for inclusion of priority substances in Annex XIV - Discussion on ECHA's 3rd draft recommendation – prioritisation of the substances on the Candidate List and draft Annex XIV entries of the substances suggested for inclusion in the recommendation	
MSC generally supported ECHA's 3rd draft recommendation for inclusion of priority substances in Annex XIV including - ECHA's prioritisation approach - the substances recommended and not recommended for inclusion in the authorisation list - the background documents for the recommended substances and - the draft Annex XIV entries of the substances proposed for inclusion in the 3rd recommendation.	MSC members and MSC stakeholders to submit their written comments on the presented documents by 3 June 2011. Based on the current meeting discussion and on the comments submitted, ECHA to finalise the presented documents for the public consultation and to start the public consultation (foreseen for 15 June to 15 September 2011).
10. Opinion on the draft recommendation of priority substances to be included in Annex XIV: Tasks and appointment of Rapporteur and possible working group **10a) Tasks of the Rapporteur in drafting the opinion of the MSC** **10b) Appointment of Rapporteur** **10c) Establishment of a working group to support the Rapporteur**	
MSC adopted the mandate and tasks of the rapporteur and appointed the rapporteur and the members of the working group supporting the rapporteur.	
11. Manual of Decisions (MoD) - Discussion on next new entries for the MoD	
MSC adopted the proposed two new entries with minor modifications.	SECR to update the MoD and upload the new version on MSC CIRCA.
12. Proposals to tackle MSC's workload - Discussion on how to increase efficiency of MSC work	
MSC took note of and generally supported the proposals of SECR how to increase efficiency of MSC work.	MSC members to submit their written comments to SECR by 15 June 2011.
13. AOB **13a) Eurometaux workshop**	
MSC took note of the proposal of an industry observer concerning the planned workshop on metals in the context of authorisation.	
13b) Discussion on document flow	
MSC took note of the proposals of one MSC member on how to improve the workflow between SECR and MSC.	SECR to consider and implement the proposed changes to the workflow as appropriate.
14. Adoption of conclusions and action points	
The conclusions and action points were adopted in	MSC-S to upload the conclusions and

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written procedure.	action points on MSC CIRCA together with the presentations delivered at the meeting, by 30 May 2011.

V. Statement from the NL and DK MSC participants

Use of EOGRTS under REACH

We urge the Commission to initiate appropriate actions that quickly can ensure that ECHA can request registrants under REACH to obtain higher tier information on reproductive toxicity according to the newest scientific standards and in accordance with EU policies on endocrine disrupting chemicals and for minimizing the use of laboratory animals without compromising the basis for chemicals safety assessment.,

A new OECD Test Guideline on the Extended One-Generation Reproductive Toxicity Study (EOGRTS, Test Guideline 443) was adopted by the OECD Joint Meeting in November 2010 and is now awaiting final formal adoption by the EPOC and the OECD Council.

The EOGRTS is a modernisation of the existing Two-Generation Reproductive Toxicity Test Guideline (OECD 416, EU B.35) and includes compared to that test a number of new parameters relating to endocrine disruption (ED). In addition, the EOGRTS also may include, cohorts for determining the impact on the developing nervous system (DNT cohort) and on the developing immune system (DIT cohort), as well as the possibility to extend the duration of the test to also include the F2 generation.

At this moment, the REACH information requirements on point 8.7 Reproductive Toxicity still specify that for substances > 1000 tpa in Annex X, a Two-Generation Reproductive Toxicity study should be available. For substances in the 100-1000 tpa range, Annex IX specifies that a Two-Generation Reproductive Toxicity study should be available if a 28-day and/or 90-day repeated dose toxicity study indicates adverse effects on reproductive organs and tissues.

We note that a high number of registration dossiers do not include information from the Two-Generation Reproductive Toxicity test; instead the dossiers include test proposals for such tests. Moreover, it has also been concluded from compliance checks conducted so far that higher tier information on reproductive toxicity is often missing in registration dossiers. Thus, the MSC often needs to agree on decisions on how registrants shall fill identified data gaps on reproductive toxicity at the higher tonnage levels.

As mentioned the new Test Guideline on EOGRTS is in its final adoption stage at the OECD Council. At the same time the REACH information requirements refer to the existing Two-Generation Reproductive Toxicity study. We feel uncomfortable that the legally specified information requirements of REACH in Annex IX & X do not reflect the latest scientific developments. The EOGRTs has a higher sensitivity for identification of chemicals with endocrine disrupting properties than the existing Two-Generation Reproductive Toxicity test. We also note that the Commission and the EU member States have initiated various initiatives concerning EDs and established special provisions on chemicals with ED properties (c.f. the ongoing Commission Strategy on EDs and REACH art. 57 (f), respectively). It is furthermore recognized that the EOGRTS normally uses only around half the number of laboratory animals than the current Two-Generation Reproductive Toxicity. Thus use of this test guideline will promote one of the major article 1 objectives of REACH, which is minimization of the use of laboratory animals without compromising the basis for chemicals safety assessment.