MSC/M/021/2011
ADOPTED IN MSC-22

Final Minutes

Minutes of the 21st Meeting of the Member State Committee (MSC-21)
7-9 December 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 21st 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 including the changes proposed by the MSC Secretariat. The final Agenda is attached to these minutes.

Due to the number of documents sent by some stakeholder observers (StOs) very close to the meeting date, the Chair reminded MSC that according to the code of conduct for StOs all documents that are meant to be distributed for the meeting need to be sent to the Secretariat (SECR) 12 days before the meeting. Then SECR will decide if to distribute the documents or not. This time the documents did not arrive within this deadline, however, they were still distributed by SECR. The Chair encouraged StOs to provide the documents for the meeting on time.

As a follow-up from MSC-20 a member expressed the need to further discuss the legal presentation delivered on Extended One Generation Repoductive Toxicity Study (EOGRTS) and the transgenic mouse assay. Chair explained that due to the very tight schedule at this meeting these general subjects will not be discussed in this meeting. However, in the context of the specific dossier evaluation cases the topics will most likely be touched. The more general discussion will be organised in one of the coming MSC meetings when time allows.

Another member requested further detail on which basis it was agreed to have a closed session for CCH-038 in MSC-21. Chair explained that the registrant claimed the name of the substance confidential. Since the confidentiality check by ECHA may not yet be complete, and the registrant when asked, did not want the StOs present during the discussion of his case, then SECR decided to discuss CCH-038 in a closed session.

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 announced/discussed.

Item 5 – Adoption of the minutes of MSC-20

SECR presented to MSC the draft MSC-20 minutes. No written comments were received. Representatives of Registrants who had participated in the meeting have been also consulted for their respective parts of the draft minutes. One registrant sent in written comments. The public and confidential minutes were adopted as amended during the meeting. The MSC Secretariat would upload the minutes on MSC CIRCABC and on the ECHA website (public minutes).

Chair asked whether MSC accepts to provide the draft minutes of the current meeting (MSC-21) to MSC slightly later than 4 weeks, the deadline given in Rules of Procedure (RoPs) and MSC agreed.

Item 6 – Dossier evaluation

a) General topics: Status report on ongoing evaluation work

SECR gave an update on the status of evaluation work from 1 June 2008 to 30 November 2011. During MSC-20 ECHA mentioned that a batch of draft decisions targeting only substance identification would be sent outside the MSC meeting schedule to Member State Competent Authorities (MSCAs) assuming that no meeting discussion on these cases would be necessary. SECR informed MSC that these draft decisions would be sent for MSCA consultation on 19 December 2011.

Chair pointed out that the workload has increased. There are indications that the April 2012 meeting would be a tough one if the rate of proposals for amendment (PfAs) remains the same i.e. PfAs are received on around 50% of the draft decisions (DD) sent to MSCAs. This would mean that around 70 DDs would come to the April 2012 MSC meeting.

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

SECR gave a report on the written procedures of four substances – CCH-037 (Condensation products of m-phenylenebis(methylamine) with condensation products of 4-methyl-m-phenylene diisocyanate with alcohols, C10-14 (even numbered), TPE-023 ((1-Methylethylidene)di-4,1-phenylenetetraphenyl diphosphate), TPE-026 (Cyclohexane-1,4-diyldimethanol), TPE-027 (Aryl bisphosphate: E-AF098-T). Written procedure was launched on 7 November 2011. Unanimous agreement was reached for CCH-037, TPE-026, TPE-027 by the closing date 18 November 2011. Responses were received from all 27 members with voting rights and the Norwegian member. The written procedure for TPE-023 was terminated on 18 November 2011 on request of one member to discuss this during the MSC-21 meeting.

During the written procedure a member sent in some editorial suggestions to the text of the draft decision. The Chair explained that such so called editorial changes cannot simply be accepted by SECR as such. SECR analysed the changes, discussed them with the dossier manager and the legal advisers and only when it was concluded that the comments did not change the content of the draft decision, they were accepted. It is not easy to know where to draw the line of what is editorial and what is not.

It was however, advised that in such situations, members should rather ask SECR to terminate the written procedure so that the change of wording of the draft decision would then be agreed in MSC meeting and the process would be fully transparent.

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

Chair reminded StOs that they do not have any documents for this agenda item, since this was what was agreed by the Management Board when it was decided that they may follow the discussions on dossier evaluation.

TPE-024/2011 (Reaction products of Benzeneamine, N-phenyl- with nonene (branched))

Session 1 (open)

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

SECR explained that two studies were proposed; a 90-day repeated dose toxicity study and a one-generation reproduction toxicity study. Both studies were proposed to be conducted on a read across substance instead of the registered substance. ECHA has rejected the one-generation study because according to ECHA it does not fulfil the information requirements of Annex X, point 8.7.3, and requested instead two-generation reproductive toxicity study. ECHA also rejected the proposed read-across and requested in the draft decision the two tests to be carried out on the registered substance.

PfAs were received from four MSCAs all advocating for EOGRTS (OECD TG 443) instead of the two-generation study. ECHA amended the draft decision for MSC-21 based in part on the PfAs proposing to give the registrant a choice between two generation reproduction toxicity study in rat by oral route or EOGRTS in rat oral route including the extension of Cohort 1 B to mate the F1 animals to produce the F2 generation which shall be kept until weaning, but without the DNT and DIT cohorts.

The registrant reacted to the PfAs in the written comments on PfAs and indicated the preference to carry out EOGRTS: *"The submitter favours the performance of the extended one-generation study. This study was developed to reduce the number of animals and to adequately test for reproductive toxicity."*. Furthermore, in the comments on PfAs the registrant further elaborated the justification for the proposed read-across approach.

Regarding the read across, the Registrant did not present data to convincingly explain why the structural similarity would yield toxicological similarity between the read across substance and the target registered substance. There were no data available on any endpoints of the registered substance. Also there was no data to support the assumption of lack of influence of the side chains or metabolites on the toxicity of the read across substance.

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

Concerning the read across approach, the representative of the Registrant apologised for the wrong impression given in the read across proposal that there is no influence of the branched chains on the toxicology and explained that they have considered this element. Then the Registrant proposed a testing sequence by starting with Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD 422) on the registered substance followed by a better re-assessment of read across once these results are available. There was however, a general support from the MSC members to ECHA's line not to accept the read across as presented in the dossier which is the basis for the current draft decision. Rejection of the proposed read-

across was further explained by SECR in a separate note provided for MSC as well as in the given presentation.

It was agreed that the Registrant did not give enough information for the basis of the read across. However, it was acknowledged that there may be a potential for read across for these substances. It was emphasised that Registrants are expected to follow the guidance with references to the relevant literature for making their case when read-across approach is proposed to be used. SECR explained that there is no single way to make read across acceptable. It is the responsibility of the Registrant to provide all the necessary information and justification for their cases. The substance was identified as a suitable example to be discussed at the proposed workshop on read across.

The representative of the Registrant restated that they would prefer EOGRTS of the read across substance over the two generation study without the extension to the F2 generation. They claimed that the additional module on developmental neurotoxicity study (DNT) was not giving sensitive results, thus as a stand alone it would not contribute much to the study. Furthermore the validation for immunotoxicity (DIT) module had not yet been finalised. Thus the Registrant preferred not to include DNT/DIT modules in the test.

There was a difference of view amongst some of the members of MSC whether to request for the EOGRTS (OECD TG 443) with the developmental neurotoxicity (DNT) and developmental immunotoxicity (DIT) cohorts or without requesting the cohorts to be included. One view was that there was no such legal requirement for DNT and DIT cohorts under the present Annex IX, 8.7.3 of REACH. The other view was that requesting EOGRTS with the DNT and DIT cohorts is part of the test guideline 443 and these cohorts could only be waived for specified reasons. No specification of the cohorts in the decision would lead to ambiguity. The same member also emphasised that EOGRTS without the extension of Cohort 1B to mate the F1 animals allowed generation of data equivalent to the test method EU B.35 for a two-generation reproductive toxicity study according to retrospective analysis on a very large number of chemicals.

SECR explained that so far with regards to Annex X, 8.7.3 of REACH, DNT and DIT have not been mentioned suggesting that there is no such legal requirement under REACH. There are many ways on how to interpret the several options presented in EOGRTS. Clarity on the legal interpretation on how to include EOGRTS under REACH is needed and that is expected to be done by the Commission. Commission representatives in MSC however stated that the legal analysis is still ongoing within the Commission.

SECR further explained that at this point of time SECR's view was that if the Registrant proposed EOGRTS this can be accepted by ECHA if it includes the F2 generation. The F2 generation could be waived based on the acceptable arguments made by the registrant in accordance with Annex XI and the dossier itself.

Session 2 (closed)

Due to the different views on how to request EOGRTS and taking into account the legal uncertainties as explained above, it was agreed to split the draft decision into two; one decision on the 90-day sub-chronic toxicity study explaining more in detail the rejection of the read across and one decision offering the Registrant a choice between the two-generation reproductive toxicity study in rat by oral route and EOGRTS in rats, oral route including the extension of Cohort 1B to produce F2 generation, and explaining more in detail the rejection of the read across.

Since such a divergence of views is still expected in similar future cases, a member presented a Room Document supported by other three members, proposing a way forward on how to streamline the process in these cases. The Chair suggested that the proposals included in the Room Document should be explored and further discussed in upcoming meetings.

The Chair took a vote based on the draft decision (split from the original draft decision communicated to the MSC) addressing the testing proposal for fulfilling the information requirement set out in Annex X, 8.7.3., two-generation reproductive toxicity study. In this draft decision ECHA offers the Registrant a choice between the two-generation reproductive toxicity study and EOGRTS (see above). In the vote, the majority of MSC members voted for and the minority against ECHA's draft decision as provided for the current MSC meeting by ECHA.

Since there was no unanimous agreement on this draft decision, it would be referred to the Commission to take a decision according to the REACH Committee procedure described in Article 133 of REACH.

MSC reached unanimous agreement on ECHA's draft decision (split from the original draft decision communicated to the MSC) addressing the testing proposal for fulfilling the information requirement set out in Annex IX, 8.6.2, sub-chronic toxicity study (90 days) as provided for and modified in the meeting, including the statement of reasons explaining further the reasons for rejection of the read-across. MSC also adopted the formal agreement as modified to reflect the agreement on the 90-day oral toxicity in rodents test.

TPE-025/2011 (Aziridine (EC 205-793-9))

Session 1 (open)

One representative of the Registrant participated in the initial discussion (Session 1). In absence of specific confidentiality concerns in the draft decision, an open session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

ECHA explained that four proposals for amendment to ECHA's draft decision were submitted by four MSCAs. Concerning long-term toxicity test on fish, one CA proposed ECHA to delete the requirement for the long-term toxicity test on fish due to lack of any clear need indicated in Chemical Safety Assessment (CSA) by the Registrant and the uncertainty as to which taxa are more sensitive. In the view of this CA, if the Registrant wishes to perform a test for aquatic toxicity, a long-term *Daphnia magna* study should be conducted.

Three MSCAs had suggested ECHA to replace in the draft decision the request for an OECD 212 test proposed by the Registrant with OECD 210, mainly because in their view OECD 210 was a more sensitive study.

The Registrant in his written comments on the proposed amendments had clearly stated that after considering all arguments he was convinced that the fish long-term study is not needed, as the CSA did not indicate any need to further investigation of the effects on aquatic organisms.

Based on the proposed amendments, SECR in advance of the meeting had not modified the draft decision as notified to MSCAs on 2 September 2011. MSC discussed the case based on ECHA's draft decision as provided for the meeting, the proposed amendments of MSCAs and the Registrant's comments to the proposed amendments.

In the discussion, the representative of the Registrant repeated the arguments of their written comments and confirmed that it is not their intention to perform the long-term fish test. He expressed also willingness to update the registration dossier if this is considered necessary for them not to perform the test. He also clarified that originally they had included the testing proposal in the registration dossier due to misinterpretation of the requirements of point 9.1 of Annex IX.

Concerning the acceptance or rejection of the long-term fish test, some MSC members were of the view that the test could not be rejected until the registration dossier (i.e. CSA) is updated with proper justification showing no need for further testing concerning aquatic toxicity. The importance of the scientific arguments on the basis of which testing proposal to fulfil the information requirements of point 9.1 of Annex IX could be omitted was also pointed out. ECHA added that at the moment, the PNEC (Predicted No-Effect Concentration) in CSA is based on non-standard acute data which should not be the case and that the results of the proposed test could bring clarity on this issue. However, the CSA could be examined in a separate compliance check only and not in the context of the current testing proposal examination.

Session 2 (closed)

In the continued discussion ECHA further explained that if the Registrant has new data on the basis of which PNEC in CSA and consequent conclusions leading to omitting of the test can be made more solid, they should be included in an update to the registration dossier. MSC supported this view and based on the above discussions concluded that the long-term fish test should be requested in the draft decision. As also concluded by MSC , the test method OECD 212 proposed by the Registrant should be changed to OECD 210 based on the arguments of the PfAs of three MSCAs. Furthermore, the Registrant should be reminded in the cover letter as well as with a brief indication in the statement of reasons of the draft decision that he could omit the test in case an updated technical dossier (i.e. CSA) does not indicate the need to investigate further the effects on aquatic organisms.

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

TPE-023/2011 ((1-Methylethylidene)di-4,1-phenylenetetraphenyl diphosphate (EC 425-220-8))

CLOSED SESSION

The Registrant has not indicated interest to participate in the initial discussion (Session 1).

ECHA's draft decision proposed to reject the testing proposal for a two-generation study and indicated the need for the current Registrant to share the test data with another Registrant of the same substance. This other Registrant had notified the substance under the national legislation in accordance with Directive 67/548/EEC and has been requested to perform the two-generation study by a decision of the national authority. This decision is now regarded as ECHA decision according to Articles 135 and 51 of REACH.

One PfA on ECHA's draft decision was submitted. It proposes to carry out an Extended One Generation study for the substance in case if the two-generation study will not be performed by a former NONS Notifier. Registrant did not comment on the PfA. Unanimous agreement was sought via written procedure

starting on 7 November. On 18 November one member asked MSC-S to terminate the written procedure and requested discussion on the draft decision at MSC-21 instead. He then proposed some editorial changes to the draft decision.

This member explained that even though the MSCA requested a former NONS Notifier for a two- generation study the company updated the registration dossier with a 90-day study with extra parameters on reproduction toxicity claiming that the information provided fulfils the requirements. The updated dossier has to be evaluated by the CA in accordance with Article 52 applying the substance evaluation process. According to the view of the member the submitted study in a first assessment appears not to be sufficient to fulfil the requirements under Dir 67/548/EEC but a final decision can be done only after the complete evaluation by the member. He suggested that MSC should discuss how to deal with similar issues in the future. The Chair explained that this generic issue will be discussed at later meetings since this needs more preparation.

This one member reflected his editorials to the MSC. ECHA considered the proposed editorials and could take them on board.

Session 2 (closed)

MSC reached unanimous agreement on ECHA's draft decision with editorial changes as discussed in Session 1. MSC also adopted the formal agreement.

CCH-038/2011 (Organic nitrogen-phosphorous compound)
CLOSED SESSION

One representative of the Registrant participated in the initial discussion (Session 1). Due to confidentiality concerns in the draft decision, the Registrant did not accept the presence of the stakeholder observers in the discussions in Session 1, therefore, a closed session was held. The Chair informed the representative of the Registrant on the relevant practicalities during and after Session 1.

ECHA explained that one proposal for amendment to ECHA's draft decision was submitted by a MSCA proposing ECHA to request the Registrant to perform a reproductive screening study (OECD 421), in addition to the requested prenatal developmental toxicity study (OECD 414). The same CA had proposed a sequential reproductive toxicity testing strategy (i.e. to conduct preferably first the reproductive screening study (OECD 421)).

The Registrant in his written comments on the proposed amendment had indicated that the registration dossier had been updated with a revised chemical safety report (CSR) to demonstrate low exposure for the whole life cycle of the substance and with justification for exposure triggered waiving arguments.

SECR had modified the draft decision based on the proposed amendment in advance of the meeting. MSC discussed the case based on ECHA's modified draft decision as provided for the meeting, the proposed amendment of the MSCA and the Registrant's comments to the proposed amendment.

The representative of the Registrant expressed his willingness to perform the screening reproductive toxicity test in addition to the pre-natal developmental toxicity study if requested by ECHA's decision.

The MSC member from the MS proposing the screening study emphasised that from scientific point of view, the prenatal developmental toxicity study does not fully replace the screening study. Furthermore, the pre-natal developmental

toxicity study is not available in the registration dossier while according to column 2 of 8.7.1 Annex VIII, the screening study can be waived if the pre-natal developmental study is available. Therefore, the draft decision should request the Registrant to perform both the screening test and the pre-natal developmental toxicity study. Some MSC members supported this view. Some others were of the opinion that if the Registrant first performs the pre-natal developmental study, the above waiving condition would be fulfilled for the screening study because the results of the pre-natal developmental study would then be available. Therefore, the screening study should not be requested. However, it was concluded that a test proposal case where a test for TG414 is proposed and TG421 is waived by the registrant, is a different situation than this compliance check.

ECHA added that as there is clear formal incompliance for 8.7.1 of Annex VIII and the draft decision concerns a compliance check, the requirement for the screening study should be in the draft decision and not in the cover letter (in contrast to similar cases of testing proposals where the requirement for the screening study was in the cover letter of the decision).

MSC supported the proposed amendment and a reminder to the Registrant to consider the possibilities for adaptations of the standard information requirements and to determine the appropriate order of the requested studies should be included in the draft decision.

Session 2 (closed)

MSC concluded based on the above discussions that the Registrant in the draft decision is requested to perform a reproductive screening study (OECD 421) in addition to the requested pre-natal developmental toxicity study (OECD 414), and is reminded to determine the appropriate order of the requested studies and that the reproductive toxicity screening study should be performed before the prenatal development toxicity study". MSC also concluded that the time period for the Registrant to provide the required information in the updated registration dossier should be extended from 12 to 30 months. The statement of reasons was modified accordingly. MSC found unanimous agreement on ECHA's draft decision as modified in the current meeting based on the above conclusions, and adopted the formal agreement.

Item 7 – SVHC identification

a. Written procedure report on seeking agreement on identification of SVHC

SECR explained that unanimous agreement was sought for nine substances in written procedure. The written procedure started on 14 November 2011. By closing date of 24 November, 26 responses were received in favour of identifying the substances as substances of very high concern (SVHC) including Norway. Thus, MSC unanimously agreed to identify the nine substances as SVHCs in written procedure on 24 November 2011. These nine substances would go on the candidate list on top of the eight other substances that will automatically be included in the candidate list since there were no relevant comments challenging the identification. The candidate list would be updated and published before Christmas 2011.

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

- **Aluminosilicate Refractory Ceramic Fibres (RCF)**
- **Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)**

Chair introduced the two RCFs by explaining that there are already two similar entries in the candidate list but these new proposals were submitted so as to cover a wider range of fibres. The reason triggering MSC consultation was the comments in the public consultation questioning the identity of the substances to be covered by the proposed entries. The representative of the German CA as dossier submitter introduced the Annex XV proposal for the substance further clarifying what is intended to be covered by the proposed entries.

SECR presented the concerns on the proposed substance definitions. The main concern was that since there are already two RCF entries in the candidate list, when adding another two new RCF entries which do not cover all the RCFs on the market as described in Annex VI of CLP Regulation, this could lead to uncertainties concerning the substances/materials actually covered. It was emphasised that it should be avoided to add further new entries to the candidate list to cover the potential gap in the coverage of the fibres on the market.

Concerns raised by the members were that the two Annex XV dossiers do not appear to cover the fibres that have been registered. The discrepancy between the registered substance(s) and the candidate list entries could cause problems for the enforcement.

StOs explained that the substance description should clearly distinguish between the fibres that have SVHC properties and those that do not have this. Another StO supported to refer to Annex VI entry of the CLP Regulation as basis for the substance definition and the entry in the candidate list. In this regard, the German CA explained that they consider the Annex VI entry being a group entry and their intention was to only identify a sub-set of the substances covered by this entry as SVHCs. Thus the particular substances covered by the group entry needed to be identified.

The Chair concluded that the substance definitions for the aluminosilicate RCF and the zirconia aluminosilicate RCF to be included in the candidate list need to be drafted in such a way that a clear relationship to the RCF entry in Annex VI of the CLP can be recognised, but keeping it restricted to the sub-set proposed by the German CA. The substance definitions were amended accordingly and presented to the MSC. Unanimous agreement was reached on the amended substance descriptions and the identification of these substance as SVHCs based on the hazard information included in the Annex XV dossiers.

However, one member retained his concern about the unclear naming of the fibres on the candidate list which potentially may lead to uncertainties regarding the coverage of the entries.

It was agreed that MSC in a future meeting would discuss whether the two older RCF entries on the candidate list could be withdrawn.

- **4-(1,1,3,3-Tetramethylbutyl)phenol, (4-tert-octylphenol) (EC 205-426-2)**

The representative of German CA (dossier submitter) introduced the Annex XV proposal for the substance. The dossier proposes for the first time identification of a SVHC based on Article 57 (f) because of its endocrine disrupting properties and adverse effects to the environment. Documentation provided in the dossier demonstrates that there is evidence on the endocrine disrupting mode of action

causing adverse effects in the environment. The dossier submitter furthermore considered that the scientific evidence of probable serious effects to the environment is sufficient to consider that the substance gives rise to equivalent level of concern to those other substances referred to in Article 57.

The MSC members agreed that 4-tert-octylphenol can affect the endocrine system of organisms in the environment, and such cases are well-documented in the Annex XV dossier. It was concluded that 4-tert-octylphenol may exert endocrine disrupting estrogenic activity in fish, and thus is an endocrine disruptor in the environment. There was however a concern raised as to whether this could be a proper basis for the Committee's decision as at Community level there is still no definition of endocrine disruptors available to be used in EU chemicals legislation and no clear criteria for interpretation of endocrine disrupting properties established even though the discussion in Commission WGs is already going on for some time. On the other hand, MSC was aware that such discussions will not come to an end in the near future.

Concerning whether to include as well concerns regarding human health related hazards exerted by the substance, SECR explained that there needs to be clarity on the endocrine mode-of-action mediated toxicity to be assessed in potential future authorisation applications under Article 62 (4)(d) of the REACH Regulation. Thus, if MSC agreed that the endocrine disrupting properties of the substance are also of concern with regard to human health, there seemed to be a need to revise the human health section of the Annex XV report as the current version of the report does not appear to support such a conclusion. Such amendment of the conclusion would require a new consultation since this would impose new legal obligations. This was also supported by the Commission representative.

During discussion of this issue there was general support for the view that a firm conclusion on potential human health relevant adverse effects is not drawn on the basis of the information presented.

Concerning whether 4-tert-octylphenol gives rise to an equivalent level of concern, it was argued that since the substance is identified as having endocrine disrupting properties it is of an equivalent level of concern. However SECR explained that just because Article 57 (f) lists endocrine disrupting properties as an example for substance properties that may give rise to an equivalent level of concern, it does not mean that all substances with endocrine disrupting properties could actually be considered as being of equivalent concern. Article 57 (f) also requires identification on a case by case basis. Therefore, it is important that MSC explicitly agrees that the substance is of equivalent level of concern. This latter conclusion was supported by the Commission representative.

Following this discussion the support document and the respective agreement for 4-tert-octylphenol were updated to further clarify the reasons why the substance is considered to have endocrine disrupting properties in the environment and also to be a substance of an equivalent level of concern.

In conclusion, MSC unanimously agreed to identify 4-tert-octylphenol as SVHC in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because it is a substance with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH. MSC unanimously agreed on its support document and agreement as amended during the meeting.

Item 8 – (Updated) Draft recommendation for inclusion of priority substances in Annex XIV

a. Responses of ECHA to the comments received in the public consultation on ECHA's draft recommendation

SECR introduced the comments received during the public consultation and explained the approach used for responding to them: due to the large number of comments received (approximately 1400), the comments and the responses were grouped into three groups – trichloroethylene, cobalt compounds and chromium compounds. It was explained that for the cobalt and chromium group of compounds the responses were provided after grouping of similar comments. The RCOM for trichloroethylene on the other hand provides a response to each individual comment as for this substance not as many comments were received as for the other two groups. SECR also explained that some few comments from the Cobalt REACH Consortium and other industry organisations had not been fully captured due to technical failure. Thus the complete text of those comments had been separately distributed to the MSC members and the StOs. SECR also clarified that the not fully captured parts of the comments were in principle summaries of attachments provided with the comments or repetition of information available also in other comments. Therefore, all relevant information was from the beginning of the assessment available to ECHA, the MSC WG and the MSC members.

Since some comments received during the public consultation referred to risk assessment, SECR highlighted that during the prioritisation phase of the authorisation process, i.e. at the preparation of the recommendation, no risk assessment is carried out. Risk assessment in the authorisation process is part of the obligations of industry in the authorisation application phase. A StO stated that industry learns also during the process and accepts that risk assessment comes later at the authorisation application stage. When industry refers to risk assessment in their comments they mean exposure assessment done by industry in their registration dossiers.

A StO made reference to the room documents that were part of this agenda item. These room documents were summary comments on cobalt salts and wide dispersive use and on their interchangeability. StO expressed his regret that the summary comments were circulated so late and hoped that the members had enough time to go through the comments. The Chair reassured the StO that the comments were distributed on time to the members and they had enough time to go through them.

In conclusion, the MSC noted that recommending substances for inclusion in Annex XIV does not comprise a risk assessment process but a prioritisation process where the available information is taken into account for applying the agreed approach and criteria.

Prioritisation of Cobalt compounds:

The information basis for prioritising the cobalt compounds by ECHA and including them in the recommendation was the Annex XV dossiers, the registration dossiers, comments received during public consultation and information received after the public consultation. Comments opposing the recommendation of the cobalt compounds considered that volumes were estimated too high, risks of particular uses controlled and that uses of the cobalt compounds are not wide dispersive. A number of members were against the prioritisation specifically of cobalt diacetate for the same reasons as stated in the comments. Other members

did not agree with the prioritisation of the entire cobalt group. It was also mentioned that the definition of wide dispersive use needs to be revised and that for future prioritisation rounds, more emphasis should be placed on the information in the registration dossiers on volumes and emissions to be taken into account.

When discussing if there was any new information available to possibly some members from industry that the SECR did not have access to, a StO clarified that industry had tried to be completely transparent in providing information, hence the reason why some documents were still sent close to the meeting. It was however mentioned that the StOs themselves never encouraged industry to contact the MSC members. Concerns of downstream users on whether their interests were looked after could have led to this.

A StO expressed concerns by industry on the way scores were applied for the wide dispersiveness in cobalt compounds. This is because relatively high scores were given to wide dispersive use even when the use of cobalt in industry is very well controlled because it is a sensitiser, and the exposures very well documented. Also it was emphasized with reference to the room document, that it is not possible to use cobalt diacetate interchangeably with the other cobalt salts that are prioritised.

SECR explained that the purpose of the scoring system is to facilitate the discussion as multiple issues which are not easily comparable need to be assessed and summarised in a figure. Scores are easily considered to provide precise reflections of reality, which in fact they don't do. It is very important to focus on the information behind the scores and how this information has been assessed. SECR explained in the RCOMs how the new information was taken into account and why it did not prompt ECHA to change its general view on the priority of the cobalt compounds. SECR also explained that the prioritisation is based on available information on all uses at the recommendation stage. The fact that a particular use may in fact not bear a high potential for exposure (e.g. as a catalyst) is not a sufficient reason to de-prioritise the substance if it is concomitantly allocated to further uses which appear to have high potential for (worker) exposure and seem to be wide-dispersive. As already mentioned earlier, risks – or the absence of risks - exerted by particular uses will be assessed in the authorisation application and granting phase.

Regarding the interchangeability of the cobalt compounds and in particular cobalt diacetate, ECHA agrees that it may be difficult to replace the substances in some of their uses but still the concern remains that replacement is possible in the other uses. From the technical and chemistry perspective it appears improbable that it should not be possible to replace any of the cobalt salts by another cobalt salt in any of its uses.

Regarding the request raised by a Member to adjourn the decision on the inclusion of the cobalt compounds in the recommendation and to further gather and assess information on the volumes, uses and potential risks of the compounds before such a decision is taken the SECR stated that the kind of uncertainties that are currently remaining would not disappear if more time is taken, unless full risk assessments would be carried out.

Prioritisation of Chromium compounds:

There was a general agreement with the prioritisation of these compounds and agreement with the responses to the comments developed by ECHA. The concern raised was whether ECHA can handle the high number of authorisation applications that are expected for this group. Another concern was that because

chromic acid is placed on the market but not registered, problems with this substance may occur in the authorisation process later on. However, this issue is first of all a registration related problem as there is no direct link between registration and authorisation in REACH. For example, REACH specifies a tonnage threshold of 1 t/y above which substances need to be registered, but as no such threshold is specified for authorisation, substances used below this tonnage can be subject to authorisation without being registered.

A StO stated that the sodium dichromate industry had commented that volumes used in the prioritisation were too large and that several exposure data were provided to demonstrate that exposure of workers is close to background levels. It was not clear whether these comments had been taken into account. SECR explained that all information provided during consultation on volumes, uses and potential for exposure was taken into account.

Prioritisation of Trichloroethylene

No comments were made on trichloroethylene during the discussion. Thus it was concluded that there is agreement with the prioritisation of this substance.

Transitional arrangements

The discussion focused mostly on the transitional arrangements for the chromium compounds especially the use of chromium in the tin plating industry. There was a majority view towards extending the latest application dates to a maximum period of 48 months. There also seemed to be some sympathy for considering different application dates for different substances but not for different uses of the same substance. The factors that in the members' view could affect the length of the latest application dates are the complexity of the supply chain and the time needed to prepare the application. Availability of a plan for transferring to alternative substances or techniques could also be considered as justification for a later application date, for example as in case of the world wide plan for chromium (VI) in the tin plating industry by 2018.

Industry remarked that chromium and cobalt compounds are often used together, e.g. in surface treatment, and it therefore could be justified to set the same application dates for cobalt and chromium compounds.

Exemptions

One StO requested to consider exemption of cobalt salts in case they are used as essential trace elements in fermentation and biogas production. SECR explained that since there is no community legislation in place that could provide a basis for exempting those uses in accordance with Article 58(2) it is not possible to recommend such exemptions.

b. Introduction of any changes to the draft recommendation following the consultation outcome

SECR introduced the changes made in the updated draft recommendation as result of the comments received during public consultation. These were changes of the application dates for trichloroethylene (from 21 to 18 months), chromium substances (from 18 to 21 months) and a minor revision of the footnotes. The Chair reminded the MSC that the MSC committee cannot change the draft recommendation table. The SECR could choose to change it based on the opinion of the MSC. The table as presented by SECR was the basis for the MSC opinion.

Item 9 – Opinion on the draft recommendation of priority substances to be included in Annex XIV

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

The Rapporteur introduced the WG members and explained the WG's approach. He explained that for establishing the draft opinion the WG had considered all comments received, including those submitted up to the week before the present MSC meeting. The opinion has been kept as short as possible and is based on the review of the draft recommendation by ECHA, the comments from the public consultation and ECHA's responses to these comments.

A member asked to consider a review period of at least five years for chromates, which was supported also by one StO. SECR explained that in the previous recommendations there were no review periods included since in their view the information needed to be put forward to be able to have review periods in the recommendation and potentially in Annex XIV needs to be very detailed so as to have a detailed assessment in order to enable consistency. It was also pointed out that REACH refers to review periods in Article 58 (1d) and Article 60 (8), however it is not yet clear how the two review periods affect each other.

The majority of the MSC members expressed support for ECHA's draft recommendation but some members did not support the prioritisation of Cobalt diacetate (see page 7 of opinion on ECHA website http://echa.europa.eu/documents/10162/17087/opinion_draft_recommendation_annex_xiv_third_en.pdf) whereas some further members did not find enough justification for prioritisation of the entire group of Cobalt-compounds (see page 6 of opinion on ECHA website link given above).

The MSC members had also different views with regard to the latest application dates (LADs) for the chromium compounds. While the MSC agrees to the general line of reasoning offered by ECHA in the updated draft recommendation a majority of the members does not believe that the slightly delayed latest application dates suggested for the chromium compounds are sufficient to address the documented extension requests submitted by several commenters during the public consultation. According to some MSC members a longer period of time than suggested by ECHA before the application deadline would be warranted – e.g. an application date 48 months after entry into force of an updated Annex XIV might be more appropriate.

b. Adoption of the MSC opinion

Rapporteur introduced the changes made in the MSC opinion following the discussion at the MSC. Majority of MSC members supported ECHA's draft recommendation for Annex XIV. Minority of the members (five members) did not support prioritisation of Cobalt diacetate and another minority (three members, included also in the minority for Cobalt diacetate) did not support prioritisation of the entire group of Cobalt compounds. Different views were also expressed regarding LADs for Chromium-compounds. It was agreed that the opinion should reflect the view that LADs should be set between 21 to 48 months from entry into force of the updated Annex XIV. The opinion should reflect the majority and

minority views as regards the LADs and the prioritisation of cobalt compounds on the draft third recommendation on priority substances to be included in Annex XIV, which covers the following substances:

1. ***Chromium trioxide*** *(EC number: 215-607-8)*
2. ***Acids generated from chromium trioxide and their oligomers*** *(Chromic acid (EC number: 231-801-5), Dichromic acid (EC number: 236-881-5), oligomers of chromic acid and dichromic acid (EC number: n.a.)*
3. ***Sodium dichromate*** *(EC number: 234-190-3)*
4. ***Potassium dichromate*** *(EC number: 231-906-6)*
5. ***Ammonium dichromate*** *(EC number: 215-693-7)*
6. ***Potassium chromate*** *(EC number: 232-140-5)*
7. ***Sodium chromate*** *(EC number: 231-889-5)*
8. ***Trichloroethylene*** *(EC number: 201-167-4)*
9. ***Cobalt (II) sulphate*** *(EC number: 233-334-2)*
10. ***Cobalt dichloride*** *(EC number: 231-589-4)*
11. ***Cobalt (II) dinitrate*** *(EC number: 233-402-1)*
12. ***Cobalt (II) carbonate*** *(EC number: 208-169-4)*
13. ***Cobalt (II) diacetate*** *(EC number: 200-755-8)*

MSC requested for an opportunity to provide further editorial comments on the revised draft opinion in parallel with the adoption of the MSC opinion by written procedure.

Item 10 – Substance evaluation

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

- **Report by the (Co)-Rapporteur and discussion on the first draft opinion of MSC**

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

Whilst going through the justification documents the WG came up with a list of questions which were then discussed at the meeting. Following the discussion, members agreed that normally, unless major flaws are identified, an update of justification documents should not be envisaged. This would enable the MSCAs to focus their resources on substance evaluation. However, following the evaluation stage if a clear need for clarification e.g. for communication reasons, appears, actions for improvement of justification documents should be taken by the MSCA. It was indicated that it is important to include as much detail as possible in the Annex to the opinion on the draft CoRAP so that the stakeholders will have a better understanding of what was the initial concern for placing the substance on the CoRAP. This detail is even more important when considering that the justification documents are not foreseen to be published for this first round. SECR however, explained that for the CoRAP update ECHA might decide to produce justification documents for the public.

Regarding concerns that might arise about the substance identity, SECR explained that a substance ID check would be carried out for the substances

listed for evaluation in the second and third years. Also what is incompliance in terms of substance ID might not necessarily prevent MSCA from evaluating the substance, this is because a substance ID check for substance evaluation purposes is not envisaged to be the same as for dossier evaluation.

Concerning what is considered as minimum justification for placing a substance on CoRAP it was suggested that a justification should refer to the legal text i.e. either Article 44 (1) or Article 45(5); explain why the substance is being evaluated again, if this was already evaluated under a different legislation; list concerns raised by other MS if any and any other information depending on the case.

SECR explained that ECHA is considering very carefully what to publish since it is not the intention for CoRAP to be seen as a black list and to raise alarms to stakeholders on the risks since at this stage of the process the concerns are not yet confirmed as being real risks. SEC also explained that information provided in the justification, which contains errors may lead to access to documents requests.

Following the discussion the (Co)-Rapporteur encouraged MSC to submit written comments by 20 December 2011.

Meeting Document 36 – Actions to take for improving justification documents

Since the WG raised concerns on whether there is the need to update the justification documents, SECR prepared a document on how and when to update the justification documents if needed. It was explained that ECHA prepared a new template version for the justification documents so as to enable their publication for the next round. The working group is also expected to provide feedback on the current version of the justification document template which would assist ECHA in improving the new template. The new template could then be discussed in the workshop in 2012. SECR however emphasised that this document was not an invitation for a justification document update by MSCAs since the core information is there.

It was then concluded that the draft opinion will be finalised on the basis of the comments that will be received in writing. The final adoption will take place in February MSC-22 meeting during which it would also be concluded on which items of the opinion would be published.

Item 11 – MSC Rules of procedure – Update of Annex 2

MSC took note of the updated Declaration of interest form presented in document ECHA/MSC-21/2011/033. Further, MSC endorsed the MSC Rules of procedure with the updated Annex 2 where the old Annex 2 declaration template is replaced with the updated one.

MSC-S would inform the ECHA Management Board (MB) on the MSC endorsement for further MB agreement on the revised Committees' Rules of procedure.

Item 12 – Manual of Decisions (MoD)

a. Discussion on next new specific entry for the MoD

SECR presented the new entry on not to take into account updates of the corresponding registration dossier that were made after ECHA notified MSCAs of,

and invited proposals for amendment on, its draft decision. This principle is however without prejudice to updates made by a Registrant who after receipt of the draft decision indicates pursuant to Article 50(3) of the REACH Regulation that he has ceased the manufacture of a substance. MSC agreed to the text proposed without modifications.

b. Draft terms of reference for MSC Working Group on MoD

This item was postponed to MSC-22 meeting.

Item 13 – Work plan for 2012

- **Indicative meeting plan of MSC for 2012**

MSC took note on the presented Indicative meeting plan of MSC for 2012.

Item 14 – Any other business

- **Oral report from an informal PBT group meeting (Utrecht 2011)**

MSC appreciated the oral report given by a member of the MSC who was part of the organising team of this meeting. SECR explained that it is foreseen that ECHA who will be coordinating these meetings will host them in Helsinki.

Item 15 - Adoption of conclusions and action points

The conclusions and action points of MSC-21 were adopted by written procedure (see Annex IV).

Signed

Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
ANDRIJEWSKI, Michal (PL)
BIWER, Arno (LU)
COSGRAVE, Majella (IE)
DEIM Szilvia (HU)
DOUGHERTY Gary (UK)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
HUMAR-JURIC, Tatjana (SI)
KORENROMP, Rene (NL)
KULHANKOVA, Pavlina (CZ)
KYPRIANIDOU-LEONTIDOU Tasoula (CY)
LUDBORZS, Arnis (LV)
LULEVA, Parvoleta Angelova (BG)
MARTIN, Esther (ES)
MIHALCEA-UDREA, Mariana (RO)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI) (alternate member)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
Representatives of the Commission
BINTEIN Sylvain (DG ENV)
ROZWADOWSKI Jacek (DG ENTR)
Observers
ANNYS, Erwin (CEFIC)
DMYTRASZ, Bohdan (CONCAWE)
LIGHTART, Jerker (HEAL) adviser to VAN VLIET L.
LYONS Gwynne (WWF) adviser to REINEKE N.
MUSU Tony (ETUC)
NAMEROFF Tamara (ECETOC)
REINEKE Ninja (WWF)
TAYLOR, Katy (ECEAE)
VAN VLIET Lisette (HEAL)
WAETERSCHOOT, Hugo (EUROMETAUX)

ECHA staff
AJAO, Charmaine
BALOGH, Attila
BROERE, William
CARLON, Claudio
DE COEN, Wim
DE BRUIJN, Jack
DE RAAT, Karel
FEDTKE, Norbert
HUUSKONEN, Hannele
KNIGHT, Derek
KARHU, Elina
KORJUS, Pia
KOULOUMPOS Vasileios
LE CURIEUX, Frank
LEPPER, Peter
PELLIZATO, Francesca
MALM, Jukka
NAUR, Liina
RÖCKE, Timo
RODRIGUEZ IGLESIAS, Pilar
RÖNTY, Kaisu
RUOSS, Juergen
SIMONS, Rupert
SOBANSKA, Marta
SUNDQUIST, Anna-Liisa
TISSIER Chrystele
VAHTERISTO, Liisa
VASILEVA, Katya

Proxies

- HUMAR-JURIC, Tatjana (SI) also acting as proxy of CAMILLERI, Tristan (MT)
- KYPRIANIDOU-LEONTIDOU, Tasoula (CY) also acting as proxy of KOUTSODIMOU, Aglaia (EL)
- MARTIN, Esther (ES) also acting as proxy of PISTOLESE, Pietro (IT)
- VASKIMAE, Enda (EE) also acting as proxy of LUDBORZS, Arnis (LV) (Friday from 10 a.m. onwards)

Experts and advisers to MSC members
BALCIUNIENE, Jurgita (LT) (expert to DUNAUSKIENE, Lina)
GOORMACHTIGH Nando (NL) (adviser to KORENROMP, Rene)
HAAS, Claus (DE) (dossier submitter)
HEINRICH-HIRSCH, Barbara (DE) (dossier submitter)
INDANS Ian (UK) (expert to DOUGHERTY, Gary)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
LØFSTEDT, Magnus (DK) (expert to TYLE Henrik)
LUNDBERGH Ivar (expert to FLODSTRÖM, Sten)
MOELLER, Ruth (LU) (expert to BIWER, Arno)
NYITRAI Viktor (HU) (expert to DEIM, Szilvia)
SCHWÄGLER, Mark (DE) (expert to FINDENEGG, Helene)
STOCK Frauke (DE) (dossier submitter)
SULG, Helen (EE) (expert to VESKIMÄE, Enda)
TRAAS Theo (NL) (expert to KORENROMP, Rene)

By WEBEX-phone connection:
HAKKERT, Betty (NL) (expert to KORENROMP, Rene) for discussion on agenda items 6, 7
JUFFERNHOLTZ, Tanja (DE) (expert to FINDENEGG, Helene) for discussion on agenda items 6, 7, 9 and 10
KOBE, Andrej (DG ENV) for the whole meeting
BERTATO, Valentina (DG ENTR) for discussion on agenda items 8 and 9
BORRAS-HERRERO Anna (DG ENTR) for discussion on agenda items 8 and 9

Case owners:
A representative of the Registrant was attending under agenda item 6c for:
- TPE-024:
- TPE-025:
- **CCH-038**:

Apologies:
CAMILLERI, Tristan (MT)
CARMO PALMA, Maria do (PT)
HEISKANEN, Jaan (FI)
KOUTSODIMOU, Aglaia (EL)
PISTOLESE, Pietro (IT)

III Final Agenda

Final Agenda

21st meeting of the Member State Committee

7-9 December 2011
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

7 December**: starts at 9:00**
9 December**: ends at 17:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/021/2011
For adoption

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

Item 4 – Administrative issues

Item 5 – Adoption of the draft minutes of the MSC-20

MSC/M/20/2011
For adoption

Item 6 – Dossier evaluation
Closed session for 6d
Indicative time plan for 6c is Day 1 (pm), for 6d Day 2&3

a. General topics: Status report on ongoing evaluation work
For information

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

ECHA/MSC-21/2011/024
For information

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

ECHA/MSC-21/2011/019

For discussion followed by agreement seeking under 6d:

<u>Open session</u>

- TPE-024/2011 Reaction products of Benzeneamine, N-phenyl- with nonene (branched)

ECHA/MSC-21/2011/010-011 & 037

- TPE-025/2011 Aziridine (EC 205-793-9)

ECHA/MSC-21/2011/013-014

-TPE-023/2011 (1-Methylethylidene)di-4,1-phenylenetetraphenyl diphosphate (EC 425-220-8)

ECHA/MSC-21/2011/020-021

<u>Closed session</u>

- CCH-038/2011 Organic nitrogen-phosphorous compound

ECHA/MSC-21/2011/016-017
For information and discussion

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

- TPE-024/2011 Reaction products of Benzeneamine, N-phenyl- with nonene (branched)

ECHA/MSC-21/2011/010-012

- TPE-025/2011 Aziridine (EC 205-793-9)

ECHA/MSC-21/2011/013-015

-TPE-023/2011 (1-Methylethylidene)di-4,1-phenylenetetraphenyl diphosphate (EC 425-220-8)

ECHA/MSC-21/2011/020-022

- CCH-038/2011 Organic nitrogen-phosphorous compound

ECHA/MSC-21/2011/016-018

For agreement

Item 7 – SVHC identification

c. Written procedure report on seeking agreement on identification of SVHC

ECHA/MSC-21/2011/023

For information

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

- Aluminosilicate Refractory Ceramic Fibres (RCF)

ECHA/MSC-21/2011/004-006

- Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)

ECHA/MSC-21/2011/007-009

- 4-(1,1,3,3-Tetramethylbutyl)phenol, (4-tert-octylphenol) (EC 205-426-2)

ECHA/MSC-21/2011/001-003

For discussion & agreement

Item 8 – (Updated) Draft recommendation for inclusion of priority substances to be included in Annex XIV

c. Responses of ECHA to the comments received in the public consultation on ECHA's draft recommendation

ECHA/MSC-21/2011/028-030 & 038

d. Introduction of any changes to the draft recommendation following the consultation outcome

ECHA/MSC-21/2011/031

For discussion

Item 9 – Opinion on the draft recommendation of priority substances to be included in Annex XIV

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

d. Adoption of the MSC opinion

ECHA/MSC-21/2011/032
For discussion and adoption

Item 10 – Substance evaluation

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

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

ECHA/MSC-21/2011/035&036

For discussion

Item 11 – MSC Rules of procedure – Update of Annex 2

ECHA/MSC-21/2011/033
For decision

ECHA/MSC-21/2011/034
For information

Item 12 – Manual of Decisions (MoD)

a. Discussion on next new specific entry for the MoD

ECHA/MSC-21/2011/025
For discussion & decision

b. Draft terms of reference for MSC Working Group on MoD

ECHA/MSC-21/2011/026
For discussion & decision

Item 13 – Work plan for 2012

- Indicative meeting plan of MSC for 2012

ECHA/MSC-21/2011/027

For information

Item 14 – Any other business

- Oral report from an informal PBT group meeting (Utrecht 2011)
- Any other suggestions from members

For information

Item 15 – Adoption of conclusions and action points

- Table with action points and decisions from MSC-21

For adoption

IV Main Conclusions and Action Points

Main conclusions and action points

MSC-21, 7-9 December 2011
(adopted by written procedure on 21 December 2011)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
5. Adoption of the minutes of MSC-20	
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 minutes on MSC CIRCABC and to publish the non-confidential version of the minutes on the ECHA website.
6. Dossier evaluation **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 on MSC CIRCABC the final ECHA decisions and agreements on cases CCH037/2011, TPE026/2011 and TPE 027/2011 that were agreed in written procedure..
6c) Introduction to and preliminary discussion on draft decisions on compliance checks after MSCAs' reactions *(Session 1, open)* **6d) Seeking agreement on draft decisions on compliance checks when amendments were proposed by MSCAs *(Session 2, closed)***	
<u>TPE-024/2011 Reaction products of Benzeneamine, N-phenyl- with nonene (branched)</u> **Discussion (6c, Session 1)** MSC discussed the case based on the amended ECHA draft decision, the proposed amendments of MSCAs and the Registrant's comments on the proposed amendments. ECHA has rejected the testing proposal for one generation study and requested instead two-generation study which is the standard information requirement on this tonnage level. The registrant highlighted their testing plans to start with the read-across substance for repeated dose 90-day oral toxicity study (OECD 408) and to continue with reproductive toxicity testing indicating preference for the extended one-generation reproductive toxicity study (EOGRTS) (OECD 443) as proposed by some CAs but without the cohorts for immunotoxicity and neurotoxicity (DNT/DIT). As suggested by ECHA MSC did not support the read across proposed by the Registrant for the tests due to insufficient existing data in support of applying this approach in this case. MSC considered also the proposal of the registrant of conducting EOGRTS instead of two-generation reproductive toxicity study; it was further discussed whether testing with or without further cohorts of DNT/DIT and the second generation are needed and should be requested. In the draft decision modified for the	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
meeting ECHA is proposing to the registrant to either perform the two-generation study or the EOGRTS with the second generation. As different views on requesting EOGRTS were expressed MSC concluded to issue two separate decisions for these testing proposals (with rejection of the read-across), i.e. that one decision would cover the repeated dose 90-day oral toxicity study and the other decision would cover the two-generation study with an option for the registrant to carry out EOGRTS with the second generation. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on the (split) draft decisions on repeated dose 90-day oral toxicity testing amended in the meeting with further explanation on rejection of read-across in the statement of reasons part. Also the deadline for the Registrant to submit the information required is shortened respectively to 18 months from 24 and the statement of reasons changed accordingly. MSC adopted the formal agreement on the split draft decision on repeated dose 90-day oral toxicity testing. Furthermore, it was concluded that MSC unanimous agreement on the (split) draft decision on the generation study (two options for the registrant: two-generation study or EOGRTS with the second generation) could not be reached. The outcome indicated positive votes of 21 members (also the Norwegian member supported ECHA DD) and negative votes of four members who were in favour of asking EOGRTS only. One other member was not present. **<u>TPE-025/2011 Aziridine (EC 205-793-9)</u>** **Discussion (6c, Session 1)** MSC discussed the case based on ECHA's draft decision as referred to MSC, the proposed amendments of MSCAs and the registrant's comments on the proposed amendments. MSC concluded that the chronic long term toxicity test with fish is a standard information requirement in Annex IX, column 1 unless waived by the registrant based on adequate data in the CSA/CSR. MSC considered whether this testing proposal is acceptable for this endpoint on the basis of the scientific considerations. The Registrant stated as indicated in the written comments on the proposals for amendment that his intention to propose long term toxicity fish study (originally considered a most sensitive species) has changed in the meantime while further considering the CSR for the substance; therefore, he does not consider the test necessary any longer taking into account also animal welfare reasons. MSC concluded to consider accepting this testing	Members with minority views to submit their positions with the grounds and the justification for their votes regarding generation testing after the meeting. Justification for positions of the members at the vote will be attached to the minutes. SECR to provide to COM further decision making a package of the documents (DD on generation testing, MSC DA, RCOM, minutes, outcome of the vote, and justification for the position at the vote).

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
proposal with clear indication to the Registrant to consider providing an update of the dossier showing the outcome of the CSA did not trigger the need for further testing. ECHA was requested to make the relevant changes in the draft decision for agreement seeking in Session 2. **Agreement seeking (6d, Session 2)** MSC agreed that the testing proposal would be accepted and the Registrant would be reminded that there are no arguments provided in the current chemical safety assessment according to Annex I for omission of the long term toxicity fish testing; however, fish test could be waived if an update of the technical dossier with proper arguments is provided. Otherwise, the Registrant is requested to conduct the testing with fish using the test method OECD 210. MSC reached unanimous agreement on the draft decision as referred to MSC and modified in the current meeting on the basis of the above conclusions. MSC adopted the formal agreement. **TPE-023/2011 (1-Methylethylidene)di-4,1-phenylenetetraphenyl diphosphate (EC 425-220-8)** **Discussion (6c, Session 1)** MSC discussed the case based on the amended ECHA draft decision, the proposed amendments of MSCAs and the registrant's comments on the proposed amendments. A MSC member, who had requested for termination of the written procedure for agreement seeking on this case and asked discussion at the meeting, requested some editorial modifications to draft decision. No further changes to the draft decision were suggested by MSC members for discussion in Session 2 (agreement seeking). **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on the amended ECHA's draft decision modified in the meeting based on the editorial suggestions proposed. MSC adopted the formal agreement. **CCH-038/2011 Organic nitrogen-phosphorous compound** **Discussion (6c, Session 1)** MSC discussed the case based on the amended ECHA draft decision, the proposed amendment of a MSCA and the registrant's comments on the proposed amendment. The Registrant expressed his agreement with the CA proposal to conduct the screening reproductive toxicity test in addition to the pre-natal developmental toxicity study if requested by the decision. Members discussed whether the Annex VIII information requirements would be met with the test already proposed at Annex IX, 8.7.2. (pre-natal developmental toxicity) and whether the	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
screening test would be needed at all. Whereas there is an adaptation possibility for omitting the screening study when information based on Annex IX, 8.7.2 is available, MSC considered that when the data are not yet available on the pre-natal developmental study the dossier is incompliant with the REACH requirements. MSC concluded that the screening test should be requested for filling in this data gap. Besides extending the deadline a paragraph on the need to consider sequential testing was added. **Agreement seeking (6d, Session 2)** MSC reached unanimous agreement on amended draft decision as provided to MSC and modified in the current meeting on the basis of the above conclusions. Also, the deadline for the Registrant to submit the information required was extended to 30 from 12 months and the statement of reasons changed accordingly. MSC adopted the formal agreement.	MSC-S to upload in MSC CIRCABC the final ECHA decisions and agreements on cases CCH 038/2011, TPE 023/2011, TPE 024/2011 (on 90-day study) and TPE 025/2011.
Item 7 – SVHC identification **a. Written procedure report on seeking agreement on identification of SVHC**	
MSC unanimously agreed to identify the following nine substances as SVHCs in written procedure (and unanimously agreed on their SDs and agreements as presented in the respective documents) : - ***dichromium tris(chromate)*** (EC 246-356-2) (carcinogenic substance, fulfilling the criteria of Art. 57(a) of REACH Regulation), - ***potassium hydroxyoctaoxodizincatedichromate*** (EC 234-329-8) (carcinogenic substance, fulfilling the criteria of Art. 57(a) of REACH Regulation), - ***pentazinc chromate octahydroxide*** (EC 256-418-0) (carcinogenic substance, fulfilling the criteria of Art. 57(a) of REACH Regulation), - ***1,2-dichloroethane*** (EC 203-458-1) (carcinogenic substance, fulfilling the criteria of Art. 57(a) of REACH Regulation), - ***arsenic acid*** (EC 231-901-9) (carcinogenic substance, fulfilling the criteria of Art. 57(a) of REACH Regulation), - ***calcium arsenate*** (EC 231-904-5) (carcinogenic substance, fulfilling the criteria of Art. 57(a) of REACH Regulation), - ***trilead diarsenate*** (EC 222-979-5) (carcinogenic and toxic for reproduction substance, fulfilling the criteria of Art. 57(a)&(c) of REACH Regulation), - ***N,N-dimethylacetamide (DMAC)*** (EC 204-826-4) (toxic for reproduction substance, fulfilling the criteria of Art. 57(c) of REACH Regulation), - ***2,2'-dichloro-4,4'-methylenedianiline (MOCA)*** (EC 202-918-9) (carcinogenic substance,	SECR to add the newly identified SVHCs to the Candidate List (update foreseen by 20 December 2011). SECR to upload the agreements and support documents on MSC CIRCABC and on the MSC webpage of ECHA website after final editing. SECR to publish the non-confidential RCOMs on the MSC webpage of the ECHA website.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
fulfilling the criteria of Art. 57(a) of REACH Regulation).	
7b. Seeking agreement on Annex XV proposals for identification of SVHC	
MSC unanimously identified the following substances as a SVHC (and unanimously agreed on its SD and agreement as presented and amended during the meeting): • ***4-(1,1,3,3-Tetramethylbutyl)phenol, (4-tert-octylphenol) (EC 205-426-2)*** (substance of equivalent concern, fulfilling the criteria of Art. 57(f) of REACH Regulation, • ***Aluminosilicate Refractory Ceramic Fibres (RCF)*** (carcinogenic substance, fulfilling the criteria of Art. 57(a) of REACH Regulation) • ***Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)*** (carcinogenic substance, fulfilling the criteria of Art. 57(a) of REACH Regulation). The exact entry taking into account the intentions in the Annex XV dossier were formulated for RCF and Zr-RCF.	SECR to add to the updated Candidate List (before Christmas) the following substance: • ***4-(1,1,3,3-Tetramethylbutyl)phenol, (4-tert-octylphenol) (EC 205-426-2)*** • ***Aluminosilicate Refractory Ceramic Fibres (RCF)*** • ***Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)*** SECR to upload the agreements and support documents on MSC CIRCABC and on the MSC webpage of the ECHA website after final editing. SECR to publish the non-confidential RCOMs on the MSC webpage of the ECHA website. SECR to consider and come back at MSC-22 with a proposal what to do with the current two RCF entries on the Candidate List.
8. Draft recommendation for inclusion of priority substances in Annex XIV **8a. Responses of ECHA to the comments received in the public consultation on ECHA's draft recommendation** **8b. Introduction of any changes to the draft recommendation following the consultation outcome**	
MSC took note of the SECR report on how all comments provided during the public consultation have been considered. MSC noted that this is not a risk assessment process but a prioritisation process where the available information is taken into account applying the criteria. Risk assessment will be the obligation of the registrant when applying for the authorisation. As many uncertainties remain with regard to the uses and releases a precautionary approach is taken for prioritisation of substances. Dissenting views on ECHA's conclusion were expressed regarding prioritisation of cobalt diacetate and cobalt compounds. It was suggested based on the comments provided in the public consultation to further consider extending the time for preparation of authorisation applications for some chromium compounds.	-
Item 9 – Opinion on the draft recommendation of priority substances to be included in Annex XIV **9a. Discussion on the draft opinion based on the (updated) draft recommendation**	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
of priority substances to be included in Annex XIV	
MSC took note of the draft opinion presented by the rapporteur who also reported on the opinion development process. As indicated in the draft opinion majority of MSC members expressed support for ECHA's draft recommendation for Annex XIV but some members did not support prioritisation of Cobalt diacetate and some members did not find enough justification for prioritisation of Cobalt-compounds. Different views were also expressed regarding the latest application dates (LADs) for the chromium compounds. It was agreed to reflect these issues in the draft opinion by the Rapporteur and the Working Group.	-
Item 9 – Opinion on the draft recommendation of priority substances to be included in Annex XIV **9b. Adoption of the MSC opinion**	
Majority of MSC members supported ECHA's draft recommendation for Annex XIV. Minority of the members (five members) did not support prioritisation of Cobalt diacetate and another minority (three members) did not support prioritisation of Cobalt compounds. Different views were also expressed regarding LADs for Chromium-compounds. It was agreed that the opinion should reflect the view that LADs should be set at 21 to 48 months from entry into force of the updated Annex XIV. The opinion will reflect the majority and minority views as regards the LADs and the prioritisation of cobalt compounds on the draft third recommendation on priority substances to be included in Annex XIV, which covers the following substances : 14. ***Chromium trioxide*** *(EC number: 215-607-8)* 15. ***Acids generated from chromium trioxide and their oligomers*** *(Chromic acid (EC number: 231-801-5), Dichromic acid (EC number: 236-881-5), oligomers of chromic acid and dichromic acid (EC number: n.a.)* 16. ***Sodium dichromate*** *(EC number: 234-190-3)* 17. ***Potassium dichromate*** *(EC number: 231-906-6)* 18. ***Ammonium dichromate*** *(EC number: 215-693-7)* 19. ***Potassium chromate*** *(EC number: 232-140-5)* 20. ***Sodium chromate*** *(EC number: 231-889-5)* 21. ***Trichloroethylene*** *(EC number: 201-167-4)* 22. ***Cobalt (II) sulphate*** *(EC number: 233-334-2)* 23. ***Cobalt dichloride*** *(EC number: 231-589-4)*	MSC-S to launch an urgent 5-day written procedure for adoption of the draft opinion starting on 12 December 2011. Members may provide further editorial comments in writing in parallel with the written procedure. ECHA to take into account MSC opinion for finalisation of the recommendation for inclusion of substances in Annex XIV. MSC-S to publish the final MSC opinion on ECHA website and in MSC CIRCABC.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
24. ***Cobalt (II) dinitrate*** *(EC number: 233-402-1)* 25. ***Cobalt (II) carbonate*** *(EC number: 208-169-4)* 26. ***Cobalt (II) diacetate*** *(EC number: 200-755-8)* MSC requested for an opportunity to provide further editorial comments on the revised draft opinion in parallel with the adoption of the MSC opinion by written procedure.	
10. Substance evaluation **Preparations for the MSC opinion on the draft Community Rolling Action Plan (CoRAP)** • **Report by the Rapporteur and discussion on the first draft opinion of MSC**	
MSC took note of the report of the rapporteurs. Members gave feedback to rapporteurs for the finalisation of the draft opinion on the draft CoRAP. Following the discussion, members agreed that normally, unless major flaws are identified, an update of justification documents should not be envisaged. However, following the evaluation stage if a clear need for clarification e.g. for communication reasons, appears actions for improvement of justification documents should be taken.	Members to send to the rapporteurs written comments on the draft opinion by 20 December 2011. Rapporteurs and WG members to consider the comments received and to reflect them in the revised draft opinion.
11. MSC Rules of procedure – Update of Annex 2	
MSC took note of the updated Declaration of interest form presented in document ECHA/MSC-21/2011/033. Further, MSC endorsed the MSC Rules of procedure with the updated Annex 2 where the old Annex 2 declaration template is replaced with the updated one.	MSC-S to inform the ECHA MB of the MSC endorsement for further MB agreement on the revised Committees' Rules of procedure.
Item 12 – Manual of Decisions (MoD) **c. Discussion on next new specific entry for MoD**	
MSC adopted the text of the proposed new entry without modifications.	SECR to update the MoD and upload the new version on MSC CIRCABC.
13. Work plan for 2012 • **Indicative meeting plan of MSC for 2012**	
MSC took note on the presented Indicative meeting plan of MSC for 2012.	-
15. Adoption of conclusions and action points	
Due to the lack of quorum, the draft conclusions and action points from this meeting will be proposed for adoption by written procedure or at the next MSC meeting.	MSC-S to upload the MSC-21 conclusions and action points when adopted