MSC/M/024/2012
ADOPTED AT MSC-25

Minutes
of the 24th Meeting of the Member State Committee (MSC-24)
6-8 June 2012

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 24th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes). Several members indicated a need to give a proxy to another member from about 11 am on Friday (8 June). As the number of proxy requests was high the Chair concluded that all decision issues should be dealt with before that time, so that no additional proxy arrangements would be needed for Friday, after 11 am.

Item 2 - Adoption of the Agenda

The Agenda was adopted including the changes proposed by the MSC Secretariat (MSC-S) and one stakeholder observer. 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 at this meeting.

Item 5 – Adoption of the minutes of the MSC-23 meeting

The Committee was recalled on its decision taken at MSC-23 on having only non-confidential set of minutes from their plenary meetings. Further, the Secretariat (SECR) informed the members that no written comments on the draft MSC-23 minutes were received by MSC within the commenting period. Representatives of Registrants for six dossier evaluation cases who had participated in that meeting have been also consulted for their respective parts of the draft minutes and tree of them provided comments taken into account in the presented version. In conclusion, the minutes were adopted with some further changes suggested by three MSC members and one STO observer and done at the meeting. The SECR would upload the minutes on MSC CIRCABC and on the ECHA website.

Item 6 – Dossier evaluation

a. General topics:

1. Applicability of testing proposals using a read across approach (CLOSED SESSION)

ECHA introduced its current approach for the handling of testing proposals that are submitted together with a read-across/category justification and where the proposed test(s) are intended to cover information needs for multiple substances. Various scenarios of such read across/category approaches used by Registrants may occur and were presented. ECHA considers the suggested adaptations for read-across/categories as testing proposals. As a first step any examination of such testing proposal(s) requires a preliminary assessment of the plausibility of the read-across/category justification that has to meet the Annex XI, 1.5 REACH criteria. ECHA explained that where the read-across/category justification is not at least plausible, the suggested adaptation will be rejected and experimental studies will be required for all substances involved individually. According to ECHA's current view, this should not be left for a possible later compliance check (CCH) as there may remain uncertainty towards the appropriateness of the substance to be tested and Registrants have a legitimate expectation to receive feedback on the suggested testing strategy. Where the read-across/category adaptation is found to be plausible, no final decision on the acceptance is taken as this is subject to the generation and use of new experimental data in the read-across/category justification. In this regard a statement will be included in the testing proposal decision indicating that the final acceptability of read-across will be considered only in the context of follow-up evaluation when the requested data have been made available. When either

rejecting or accepting 'plausibility' of read-across the Registrant would get ECHA's response to the strategy/plan how to proceed with the testing. ECHA emphasised that in unclear situations the Registrants are always offered a chance informally to clarify their cases and improve justification for read-across approach.

Replying to questions ECHA highlighted that the risk of duplicate testing of the same substance for the same endpoint will be avoided based on Article 53 of REACH.

MSC took note of ECHA's presentation. Some MSC members had general and specific comments and questions to ECHA's proposed draft approach MSC appreciated the rationale for the approach presented and emphasised the need for closer cooperation and communication between ECHA and MSCA on Read Across approaches and issues in the future including the ongoing informal interactions with Registrants.

Concerning the preliminary assessments of read across/category approaches, MSC was of the view that a very clear disclaimer should be added to DDs clarifying for the Registrant that the statement on "plausibility" is only a preliminary judgement and ECHA might change its preliminary opinion on the read across/category approach and require more data to fulfil the relevant information requirements after all relevant available information required from the Registrant for justification of the read across/category approach are provided.

The Chair invited MSC to further consider the discussed topic and to provide written comments to SECR after the meeting if appropriate.

2. Inclusion of bronchoalveolar lavage (BAL) analysis in an OECD TG 413

SECR gave a presentation on BAL analysis which is an optional element of OECD TG 412 (28 day repeated dose toxicity by inhalation) and OECD TG 413 (90 day repeated dose toxicity by inhalation). BAL analysis is not part of the corresponding EU test method B.8 or B.29 which are based on the old version of the OECD test guidelines. SECR explained the scientific and legal criteria for inclusion BAL analysis in inhalation toxicity studies. MSC took note of the presentation. One MSC member pointed out that for poorly water-soluble but inhalable substances BAL analysis could help to better understand the mechanism and extent of inhalation and deposition in lungs and could lead to better risk characterisation and more reliable NOEL values. The Chair concluded that if BAL analysis is considered to be justified for scientific reasons, it can be requested and the reference in a DD should be made to the OECD test guideline (412 or 413) and not to the EU test method which is outdated.

3. Status report on ongoing evaluation work

SECR gave a detailed statistics and update on the status of evaluation work until end of May 2012. High workload of MSC resulting from dossier evaluation was also projected for the second half of 2012.

MSC members were invited to send their expression of interest for participation in the Experts Workshop on Read-Across Assessment on 2-3 October 2012 by 15 June 2012. They were also reminded that a Webinar open also for MSC members on the Read-Across Assessment Framework will take place on 11 June 2012.

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

SECR gave a report on the outcome of the written procedure (WP) for agreement seeking on 30 dossier evaluation cases (see Section V for more detailed identification of the cases). The WP was launched on 10 May and closed on 21 May 2012. For five cases, DDs were split thus resulting in two DDs for these cases and overall 35 draft decisions for the 30 cases. By the closing dates, responses to WP were received from 24 members with voting rights and from the Norwegian member. Unanimous agreement was reached on 23 DDs. For four DDs the WP was terminated by the MSC Chair on the basis of MSC member's request and they were referred to the MSC-24 meeting for agreement seeking. For eight DDs involving the standard information requirement for Annex X, 8.7.3, four votes were indicating disagreement with a requirement for EOGRTS only, 18 votes were in favour of them and three MSC members did not vote. Thus, these eight

cases are to be referred to COM for further decision-making under Article 133 (3) of REACH.

The Chair drew the attention of MSC members to the fact that in this current round very high number of PfAs was received (for 36 of the 50 cases) and to the potential consequences of this for the resource management of ECHA and the MSs.

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

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

CCH-020/2012 m-phenylenebis (methylamine) (EC No. 216-032-5)

Session 1 (open)

Representatives of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in the draft decision (DD), an open session was held.

Based on a CA proposal for amendment (PfA) for covering a two-generation requirements with EOGRTS, SECR explained that due to the pending commitology procedure to determine the appropriate test method, the data gap for reproductive toxicity for Annex X, 8.7.3 (two-generation reproductive toxicity) was not addressed in the current DD. Regarding sub-chronic toxicity (90-day), another PfA proposes to conduct the study via inhalation route and not via oral route because inhalation route is a likely route of exposure for workers and a long term DNEL for local effects needs to be derived due to the likely respiratory tract irritation. Further PfA suggests reformulating expression of the requirement for the second species in PNDT study for which a standard text has been developed earlier by MSC and which would be used also in this case. Regarding operational conditions and risk management measures, a PfA also proposes further requirements for protective gloves.

ECHA modified partially some sections of DD prior to the meeting based on few PfAs.

Registrant's comments on PfAs of the MSCAs and discussion

The Registrant in the written comments on the PfAs considers that based on the actual concentrations of the substance in the mixture, the exposure to the substance by inhalation at uses (PROC 10 (roller application or brushing) and PROC 11 (non-industrial spraying)) is lower than indicated in the calculations of the MSCA who questioned the proposed oral route of administration for the 90-day study. Regarding the classification for acute toxicity the Registrant indicates that new information has become available and that the substance should not anymore be classified as 'toxic if inhaled' but only as 'harmful if inhaled'. At the meeting, the representatives of the Registrant confirmed the readiness to carry out the 90-d sub-chronic toxicity study by the most appropriate route of administration and pointed out on the need to address the main concerns on the systemic effects as the corrosive effects (local effects) of the substance are already known. As regards the MSCA's PfA proposing further requirements for the protective gloves, the Registrant agreed with the recommendation and informed MSC of their intention to include the duration for the gloves' use in the safety data sheet of the substance.

MSC considered the Registrant's comments on the PfAs.

The MS CA, proposing the route of administration for the 90-d toxicity study to be changed from oral to inhalation, presented their arguments (presentation uploaded to CIRCABC) on requesting such a change due to the likelihood of local effects in respiratory tract and to the low toxicity of the substance and therefore to low likelihood of the systemic effects in 90-day study as well as due to uses and exposure by inhalation described by the Registrant (in particular roller application or brushing and non-industrial spraying) which would require risk assessment to be done and proper RMM to be taken by other means than with personal protective equipment (PPE). It was explained also that derivation of DNEL for local effects is considered necessary to be able design the necessary measures for controlling the risk. Therefore the inhalation study would be necessary to be able to derive which concentration in the air would not cause

adverse effects. Furthermore, some animal welfare considerations were reflected due to the requested testing with a corrosive/irritating substance for avoiding severe damages in respiratory tract of animals. Test would therefore need to be conducted with concentrations of the substance sufficiently low to avoid corrosivity.

Session 2 (closed)

SECR pointed out that both routes of administration are considered as appropriate for meeting the standard information requirement (IR) for sub-chronic toxicity (90-day) but the most appropriate route of administration was to be specified. It was concluded that although more information on both oral and inhalation toxicity would be needed, it would not be proportionate to request both oral and inhalation tests. It was pointed out that long term local effects in the respiratory tract most probably would be more critical to be identified for worker protection reasons.

MSC concluded that 90-day sub-chronic toxicity study should be requested as this is a standard IR and the inhalation route is the most appropriate route of administration for deriving information on long term local effects in the respiratory tract and setting DNELs for this substance.

MSC found unanimous agreement on ECHA's DD as provided for the current meeting and further amended based on the above conclusions.

TPE-081/2012 Diethyl ether (EC No. 200-467-2)

Session 1 (open)

No representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in the DD, an open session was held.

SECR explained that PfAs to ECHA's DD were submitted by four MSCAs. Three PfAs are suggesting to request an extended one generation reproductive toxicity study (EOGRTS) for Annex X, point 8.7.3 instead of ECHA's proposal to give two options for the Registrant to perform either the two-generation reproductive toxicity test (EU B.35) or EOGRTS (OECD 443) with the second generation. The fourth PfA suggests rejecting the testing proposal made in the dossier of this registered substance for testing of a related substance and is of the view that such testing proposal should be considered only in the context of the dossier for the related substance.
SECR did not modify DD for MSC-24 based on the PfAs.

Registrant's comments on the PfAs of the CAs and discussion

The Registrant in the written comments on the PfA to reject the testing proposal on the related substance informed that the registration dossier has been updated with read-across arguments and deletion of the testing proposal. This update has taken place after launching the CA consultation. The Registrant did not comment on the PfAs regarding EOGRTS.

MSC considered the Registrant's comments on the PfAs.

The three MSC members representing the MSCAs that submitted PfAs with the request for EOGRTS maintained the position of their MSCAs expressed in the PfAs. Concerning the fourth PfA ECHA pointed out that the dossier was updated with read-across arguments and deletion of the testing proposal after the start of the MSCA consultation and as such, this update can not be considered for the current DD. The MSC member representing the MSCAs that submitted the PfA concerning read-across and deletion of request for a generation test accepted ECHA's arguments for keeping the requirement for the generation study in the DD but joined to the view of the other three MSC members that EOGRTS should be requested and ECHA's DD providing two options for the generation study to the Registrant should be modified.

It was concluded that unanimous agreement on DD is not likely due to the diverging views of MSC members on the "generation" study.

Session 2 (closed)

The Chair initiated a formal voting on the DD updated with procedural steps since presented to MSCAs. At the formal vote, as MSC did not reach a unanimous agreement

on the DD, the Chair invited the disagreeing MSC members to provide written justifications for their disagreement if the justification were different from the previous cases. Otherwise SECR would use the justification provided by the four members before in similar cases. ECHA will refer the case to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

TPE-090/2012 Acetalization products between glucose and C20-22(even numbered)-alcohol (List No. 923-835-0)

Session 1 (open)

No representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in the DD, an open session was held.

SECR explained that two PfAs were submitted by one MSCA. Regarding sub-chronic toxicity (90-day) and earthworm reproduction test the MSCA considers that there is no testing proposal for these end points because the proposed studies were flagged as "data waiving" in the dossier of the substance subject to the DD and the data requirements are proposed to be fulfilled by data generated on a related substance. According to the MSCA a category approach has been proposed by the Registrant based on three substances, including the substance subject to the present DD. Thus, they note that they do not agree with reasoning of SECR for rejecting the read-across proposal.

SECR did not modify the DD for MSC-24 based on the PfAs.

Registrant's comments on the PfAs of the MSCAs and discussion

The Registrant in the written comments on the PfAs explains the proposed category approach and re-states that the substance has been registered as a member of a category. The Registrant notes that the testing proposal was initially made for four members of the category to meet the information requirements for Annex IX, 9.4.1 (Effects on terrestrial organisms, short term toxicity to invertebrates). According to the comments of the Registrant the category will consist of six substances, instead of the three originally indicated in the dossier. In the original testing proposal they proposed to carry out earthworm acute toxicity test in accordance with OECD 207 on one of the members of the category and to use the results for the other members of the category for this end point. The substance proposed to be tested was not the substance subject to the present DD (i.e. it was an analogue). The Registrant is now agreeing in the comments to conduct the earthworm long-term toxicity test in accordance with OECD 222 on the substance subject to the DD and use the results for read-across for all members of the category. They plan to amend the testing proposals for the other substances accordingly.

MSC considered the Registrant's comments on the PfAs.

With regards to sub-chronic toxicity study (90-day), SECR accepted the read across proposed by the Registrant i.e. accepted the testing proposal of the Registrant on the analogue substance for the reason that sufficient justification was provided in the dossier for the basis of the read-across for this end-point.

Since the registered substance has a longer hydrocarbon chain than the analogue substance proposed to be tested and based on screening tests on biodegradation in water, the registered substance is predicted to be less biodegradable than the analogue substance, it was considered to be justified to request the registered substance to be tested on earth worms.

Thus regarding the earthworm long-term toxicity test the MSC members supported the DD since the Registrant also accepted in the written comments to conduct the OECD 222 on the registered substance and not OECD 207 on the analogue substance as originally proposed to fulfil the information requirement under Annex IX, 9.4.

The member representing the MS responsible for making the PfAs and some other members were still doubtful whether there are actually testing proposals to consider. It was pointed out that ECHA could consider the read-across as plausible but still under development since the results of the test proposed by Registrant are not available.

Session 2 (closed)
MSC modified Section III (Statement of Reasons) to reflect the above conclusions by specifying that even though the read-across is considered plausible, still the responsibility to amend and substantiate the read-across and category justification according to Annex XI, 1.5 is with the Registrant. Regarding toxicity testing on invertebrates, reference to the Registrant's comments to the PfA was included.

MSC found unanimous agreement on ECHA's DD as provided for the meeting and amended during the meeting discussion as described above.

TPE-080/2012 Activated Carbon - High Density Skeleton (List No. 931-328-0)

Session 1 (open)

No representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in the DD, an open session was held.

SECR explained that one PfA was submitted on sub-chronic toxicity (90 day) study by inhalation suggesting that the optional bronchoalveolar lavage (BAL) analysis with the parameters as indicated in OECD TG 413 should be made mandatory for the substance. SECR did not modify the DD before MSC-24 based on the PfA.

Registrant's comments on the PfAs of the MSCAs and discussion
The Registrant did not provide written comments on the PfA.

The MSC member representing the MSCA that submitted the PfA stated that the BAL analysis would be a tool to identify a pattern of the effect on the lungs due to the particle size of the substance. SECR explained that according to Annex IX, 8.6.2, column 2, further studies may be required by the Agency in case of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation. In such cases it may be more appropriate to perform specific toxicological studies that are designed to investigate these effects. In this case the substance is a dust highly insoluble in water with a particle size distribution indicating that the lower respiratory tract might be the primary site of deposition and retention of the substance. MSC considered that when criteria for use of BAL analysis in this case are met, BAL analysis can be requested to be an obligatory part of the 90-day inhalation study. MSC therefore concluded that the DD should be modified to request the Registrant to perform BAL on the registered substance.

Session 2 (closed)
Reference to BAL analysis according to OECD 413 was added in Section II (Testing required) (specifying that test item needs to have a low content of crystalline silica) and in Section III (Statement of Reason). Furthermore, the legal basis was changed from Article 40 (3)(a) to Article 40 (3)(b).

MSC found unanimous agreement on ECHA's DD as provided for the meeting and amended during the meeting discussion as described above.

TPE-092/2012 Di-tert-butyl peroxide (EC No. 203-733-6)

Session 1 (open)
No representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in the DD, an open session was held.
ECHA explained that four PfAs to ECHA's DD were submitted by two MSCAs. One PfA proposes adding to the DD that there is a data gap for reproductive toxicity according to Annex X, 8.7.3 (two-generation reproductive toxicity). According to SECR this does not need to be raised because it is not part of the testing proposal examination. Another PfA is proposing to delete the request for long-term toxicity test to fish because there is no evidence that the Registrant has considered other options before making the testing proposal and whether the data are necessary for CSA. The third PfA is proposing to delete the request for simulation testing on ultimate degradation in surface water. This PfA considers that the Registrant should first clarify log K_{ow} to conclude whether the substance screens as B/vB and only then consider evaluation for P. According to this PfA it is not clear which part of the CSR would be refined by the proposed test. The fourth

PfA similarly does not see the required test necessary as it does not agree that the substance is a potential PBT/vPvB.

SECR did not modify the DD before MSC-24 based on the PfAs.

Registrant's comments on the PfAs of the MSCAs and discussion

The Registrant in the written comments on the PfA proposing to delete the request for the long-term fish test from the DD explains that integrated testing strategy will be followed and fish test conducted only if necessary. The Registrant thinks that testing is needed as there is a potential to remove classification and labelling for the environment depending on the results on Daphnia and fish (if necessary) studies. The Registrant agrees with the PfAs not to request simulation testing in surface water (OECD 309).

MSC considered the Registrant's comments on the PfAs.

Concerning the long-term fish test, support was expressed to ECHA's view that the test is necessary to be performed to fulfil the standard IR of Annex IX, 9.1.6 and as such should be requested. However, some MSC members stressed that the concept of integrated testing strategy (ITS) should be better elaborated for the Registrant in the DD (i.e. first chronic Daphnia study should be performed; chronic fish study should be carried out only if the results of the chronic Daphnia study indicate a need to do so).

Concerning the simulation test on ultimate degradation in surface water, some MSC members argued that based on QSAR estimations and high water solubility, the substance is likely to have a rather low Log Kow value (closer to 3 than to 5) and as such is unlikely to have high bioaccumulation potential (B/vB). However, as the Registrant provided two valid Log Kow values (3.2 and 5.2) the higher one of which does not seem realistic, they suggested that first the Registrant should be reminded to clarify the log Kow value and based on this examine the B/vB properties of the substance. These MSC members also suggested not requesting the Registrant to perform the simulation test on ultimate degradation in surface water to clarify persistency (P/vP) as data potentially allowing waiving of this test may be available in the dossier.

Session 2 (closed)

MSC agreed that the simulation test on ultimate degradation in surface water shall not be required from the Registrant. However, the Registrant should be reminded in the DD that the OECD 303A test cannot be used to cover the simulation biodegradation endpoint. Furthermore, the available Enhanced Ready Biodegradation Test (OECD 301D) results indicate that the substance is not readily biodegradable and the Registrant considers on this basis the substance to be persistent (P). It was pointed out that based on available test results the substance is only potentially meeting the P or the vP criterion. The Registrant should be reminded that that the above uncertainty in the PBT assessment should be taken into account when updating the CSR of the dossier. MSC also agreed on editorial changes in section II and III of the DD concerning PNDT test and refined the text of Section III for long-term toxicity test on fish and aquatic invertebrates. No other changes of the DD were agreed upon by MSC.

MSC found unanimous agreement on ECHA's DD as provided for the current meeting and amended based on the above conclusions.

TPE-093/2012 Tris(2-methoxyethoxy)vinylsilane (EC No. 213-934-0)

Session 1 (open)

No representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in the DD, an open session was held.

ECHA explained that two PfAs to ECHA's DD were submitted by two MSCAs. One PfA proposes addition to the DD to indicate that there is a data gap for reproductive toxicity according to Annex X, 8.7.3 (two-generation reproductive toxicity). According to SECR this does not need to be raised because it is not part of the testing proposal examination. Regarding pre-natal developmental toxicity study in rats, the other PfA considers that based on results of OECD 422 study the results sufficiently support classification as category 1B reproductive toxicant. The substance rapidly hydrolyses to

a well known category 1B (toxic to reproduction) substance. Therefore it was suggested that the Registrant should classify the substance accordingly and the proposal for the PNDT study should be rejected.

SECR partly modified the DD before MSC-24 on the basis of the PfA concerning PNDT and classification.

Registrant's comments on the PfAs of the MSCAs and discussion

The Registrant in the written comments on the PfAs agrees with the PfA concerning PNDT and classification. The Registrant stated his intention to apply the category 1B classification for reproductive toxicity for the registered substance and to withdraw the proposal for the PNDT study. The Registrant did not comment the PfA concerning the data gap for Annex X, 8.7.3.

MSC considered the Registrant's comments on the PfAs.

In the discussion, MSC came to the conclusion that the PNDT study (in Annex IX, 8.7.2) should be required but the Registrant should be reminded that if the conditions for adaptation of the requirement in column 2 of Annex IX, 8.7.2 are met, the PNDT study would not be needed. MSC was of the opinion that although self-classification of the substance as proposed by the Registrant in the comments on PfAs would be acceptable as part of these conditions, the Registrant should be advised to consider launching the procedure for a community-wide harmonised classification.

Session 2 (closed)

MSC agreed that section III of the DD should be modified based on the conclusions of the discussions in Session 1. MSC also agreed that the advice to launch the procedure for a community-wide harmonised classification should be communicated to the Registrant in the notification letter of the DD.

MSC found unanimous agreement on ECHA's DD as provided for the current meeting and amended based on the above conclusions.

TPE-061/2012 Hexyl 2-(1-(diethylaminohydroxyphenyl)methanoyl)benzoate (EC No. 443-860-6)

Session 2 (closed)

SECR explained that agreement seeking on this DD was sought in WP. However, WP was terminated by the Chair of MSC on request of a MSC member suggesting to discuss at the meeting the request to perform the long-term toxicity test on fish.

MSC concluded not to amend the DD and to request the Registrant to perform the long-term toxicity test on fish.

MSC found unanimous agreement on ECHA's DD as provided for the current meeting. One member was not present for the vote.

TPE-070/2012 1,3-Diphenylguanidine (EC No. 203-002-1)

Session 2 (closed)

SECR explained that agreement seeking on this DD was sought by WP. However, WP for this case was terminated by the MSC Chair based on members' request, asking further discussion on the proposed modifications to the DD as regards the sediment simulation testing and long-term toxicity to sediment organisms as well as on the proposed FELS test.

In the following discussion, the member from the CA proposing the rejection of FELS test suggested that the further justification for the need of the test provided by the Registrant in the comments on the PfAs should be added to the text of DD. According to the Registrant this test would be needed due to the likely rapid increase of the substance tonnage on the market. MSC agreed to keep the information requirement regarding the FELS test but agreed to add to the Statement of Reasons part of the DD further explanation provided by the Registrant why the test is necessary. MSC also agreed with the proposed modifications to the DD by another CA on the sequential

environmental testing strategy by removing any reference to the choice of log Kow as a discriminatory criterion.

MSC found unanimous agreement on the ECHA's DD as provided for the WP and further amended based on the suggestions proposed at the meeting.

TPE-072/2012 3-Hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropionate (EC No. 214-222-2)

Session 2 (closed)

SECR explained that agreement seeking on this DD was sought by WP. However, WP for this case was terminated by the MSC Chair based on a member's request, due to suggested MSC discussion on the most appropriate route of administration for the 90-day sub-chronic toxicity study, based on a MSCA PfA for conducting the study via inhalation route and not via oral route.

SECR presented the outcome of the analyses on the IUCLID dossier and on the chemical safety report (CSR) for this substance, in particular as regards uses PROC 10, 11 and 19 which indicate aerosol formation and exposure by inhalation. According to SECR the most relevant exposure scenario would be the one where the substance is used as an aerosol in its solid form. In two other uses the substance is used as dissolved in a solvent in a liquid form. The particle size distribution of the solid indicates that the particles would not get to lower parts of the lungs, and therefore oral route of administration in the test would be justified. It was also clarified that the substance is an eye irritant. The main concern is lack of information on systemic toxicity, and not on irritant effects in the respiratory tract. To investigate systemic toxicity the oral route would be recommended. It was also mentioned that there is no information on sub-chronic toxicity of the registered substance. The only information on 28 day study is available on a read-across substance which shows signs of systemic toxicity. If more information on inhalation exposure were needed, it could be requested under the substance evaluation process.

The member and experts representing the MSCA raising the issue further clarified their concerns regarding the particle size distribution arising from the lack of information on substance distribution in spraying applications as well as potential irritant property of the substance. The particle size may not be the same in spraying applications as described for the manufactured substance in the dossier. However, the MSCA considered the occupational exposure limit (OEL) of an analogous substance which was a magnitude higher than the exposure assessed for the relevant exposure scenarios under discussion.

MSC concluded that in this case, the oral route of administration should be the most appropriate route of administration in this case, as the inhalation toxicity, i.e. irritation effects, is not of particular concern but systemic toxicity is indicated by the relevant 28-day read across study. MSC agreed that considerations regarding the chosen route of administration to be further clarified in the Statement of reasons section of DD.

MSC found unanimous agreement on the ECHA's DD as provided for the WP and further amended based on the suggestions proposed at the meeting.

TPE-077/2012 Boron trifluoride (EC No. 231-569-5)

Session 2 (closed)

SECR explained that agreement seeking on this DD was sought in WP. However, WP was terminated by the Chair of MSC based on member's request, asking further discussion on the test method to be used for *in vivo* mutagenicity testing, i.e. Comet assay instead of *in vivo* micronucleus study to fulfil the information requirement of Annex IX, 8.4.

Support for ECHA's view was expressed that as there is no internationally adopted test guideline for the Comet assay, it cannot be imposed on the Registrant. If the Registrant had proposed Comet assay to be used for mutagenicity testing that could be considered for the basis of the decision because the Registrant's own proposal would indicate that the protocol is known to the Registrant and reference to a specific protocol would give a possibility to ECHA to evaluate its applicability to the case. On the other hand some

members considered that the available protocols for Comet assay (although not yet internationally adopted) would produce better results in this case. It was also stated that the proposed test may not be appropriate for testing of the substance in question. Therefore, MSC concluded to keep the request for the *in vivo* micronucleus study in the DD to be performed with the dehydrated form of the registered substance but the test should be conducted according to the conditions specified in amended section III. Section III of the DD was amended with a reminder that if the Registrant can not show that the test method is applicable to the test substance in accordance specifically with paragraph 7 of the OECD 474 guideline, the proposed test is not considered appropriate to meet the information requirement of Annex IX, 8.4 and a new TP for an *in vivo* mutagenicity test such as the Comet assay with specified test conditions paying special attention to the site-of-contact has to be submitted to ECHA.

MSC found unanimous agreement on ECHA's DD as provided for the current meeting and amended on the basis of the above conclusions.

e. Items for discussion following commenting by MSCAs *(Tentatively closed session)*

- **Items from current cases if not addressed during 6c**

ECHA explained that comments of MSCAs flagged by them for discussion in the current MSC meeting have already been replied to either in the current MSC discussions (TPE-090/2012) or in RCOMs of the case (TPE-077).

Concerning one MSCA comment on a case agreed already by MSC in WP on 21 May 2012, MSC highlighted that a scientific discussion paper on the terrestrial plant testing (comparative assessment of TG OECD 208 and ISO22030) is being currently finalised by ECHA. MSCAs will be invited to comment on the paper in mid June 2012 and the further refined document will be addressed with MSCAs/MSC members in September 2012 in a Webex meeting and/or in the MSC-25 meeting.

Item 7 – SVHC identification

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

SECR gave a brief report on the outcome of the written procedure for agreement seeking on the identification of *diboron trioxide (EC No. 215-125-8)* as a SVHC. It was explained that MSC agreed unanimously on this substance identification as an SVHC in the written procedure launched on 14 May and closed on 24 May 2012 to which 21 members with voting rights responded in favour of and none was against the proposed agreement. Also the Norwegian member responded positively. SECR explained that the final documents will be made available on MSC CIRCABC and on the ECHA website and the substance will be included in the Candidate List of SVHCs.

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

- [4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) (EC No. 208-953-6)

- [4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) (EC No. 219-943-6)

- α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) (EC No. 229-851-8)

- 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol (EC No. 209-218-2)

SECR presented the main comments received during the public consultation on the Annex XV SVHC proposals for the above-mentioned four dyes, suggesting improving the clarity of the entry by including in the entry itself the reference to the impurities which make the substance a SVHC. It was proposed to add to the entry for each of these

substances reference to the condition that the substances are identified as SVHC only when they contained Michler's ketone or Michler's base as impurity equal to or above 0.1% ww, and not to have this clarification only as a footnote. The substance identity (name of the substance) according to the ECHA guidance is, however, without this specification. Therefore the clarification was proposed to be added to the CL entry in italics and square brackets indicating that it is not part of the substance name.

A member from the MSCA who had commented on identification of these substances as SVHCs explained their concerns which were related to the approach chosen in inclusion of the substances in the Candidate List (CL). Instead of listing individual substances as SVHCs based on concentration of impurities (Michler's ketone and Michler's base) the impurity-substances could have been listed as SVHCs with inclusion of all substances containing these impurities in concentrations equal to or above 0.1%. Listing of SVHCs this way would follow the example of entries in Annex VI of CLP Regulation. According to him this substance-in-substance (SiS) approach would make proposals for SVHCs significantly simpler as well as make tracing of SVHCs in articles clearer for the purposes of Article 7(2) and 33.

Members expressed different views on the issue, as some shared the concerns raised; SECR provided further clarification pointing out on the recent discussions on the SiS approach at the Regulatory Risk Management workshop and RiME working group meetings and the ongoing Commission's analyses on legality and practicalities of this approach in different processes. SECR reminded on the need to take a holistic view on the whole process of the authorisation and pointed out that SiS approach may not be the most appropriate one e.g. for prioritisation of SVHCs from the CL to the authorisation list as it would leave a lot of uncertainty which substances would be subject to authorisation. In practice, the substance containing an SVHC as an impurity would most likely need to be identified in any case for Annex XIV purposes which would add to the workload at that stage of the authorisation process.

Some members noted on the potential enforceability problems in the supply chain when the CL entry would not provide clear information on the relation between the substance listed and its constituent substances of concern.

SECR agreed that substance-in-articles provisions are challenging for both industry to apply and CAs to enforce, as the way how to identify the substance in supply chain depends on the case.

The Chair pointed out that in any case the SiS issue would rather be for discussion in the fora of the MSCAs in which issues in relation to the identification of SVHCs and the making of SVHC Annex XV dossiers are discussed and co-ordinated. MSC will consider the proposals made and cannot challenge the entry as proposed if it fulfils the criteria for identification as SVHC. However, clarity improvements for the entry can be considered or rejection of the proposal would be possible if the substance does not meet the criteria for SVHC.

MSC unanimously agreed on the identification of the four above-mentioned substances as SVHC when they contain Michler's base or Michler's ketone in concentrations at or above 0.1%. The identification as SVHC based on Michler's ketone or Michler's base will be made explicit within the entry.

Item 8 –Discussion on ECHA's 4th draft recommendation for inclusion of priority substances in Annex XIV

- Discussion of the 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 presented the draft results of the prioritisation and the 4th draft recommendation for a second discussion at MSC. Main changes, both general and substance specific, to the previous version were introduced. Proposal for an amendment to leave one of the substances out, namely 1-methyl-2-pyrrolidone (NMP), from the draft recommendation for public consultation was also introduced by SECR compared to the versions that had

been submitted for this meeting. For NMP a confirmed intention for a restriction proposal for certain uses of NMP had been submitted by one MS only few days in advance of the meeting, and thus the circumstances for its prioritisation had changed.

MSC generally supported the 4th draft recommendation including the draft Annex XIV entries of the substances and the justification documents for the ten substances. However, MSC further discussed calcium arsenate and NMP, the latter of which ECHA was no longer proposing to include in the draft recommendation for the public consultation.

Regarding calcium arsenate also written comments had been submitted by the Norwegian member suggesting to prioritise the substance for Annex XIV due to the possibility that it could be an alternative to other arsenic compounds already included or proposed for Annex XIV. In addition, the assumption that occupational exposure is controlled was also considered as questionable. In the discussion one member questioned why the grouping approach was not applicable for this substance. Several members and an environmental NGO supported including calcium arsenate into the public consultation to collect more information, and only then to decide if it should be recommended for inclusion in Annex XIV or not. SECR explained that uncertainties regarding the nature of the uses of calcium arsenate need still be clarified before conclusion can be made on its priority for Annex XIV. Registration data, as also pointed out by one StO, did not directly support prioritisation, and obtaining better data was considered more likely to be achieved by other means than public consultation for this substance.

In the discussion on NMP some members considered omission of NMP from the current draft recommendation premature as an intention for a restriction proposal was not a fully convincing argument to deprioritise. Some other members however supported removing NMP from the recommendation. One of the arguments was that inclusion of NMP into the Annex XIV would seem inconsistent with the IPPC legislation as currently some reference documents on Best Available Techniques (BATs) suggest using NMP in certain conditions. Second argument not to include NMP was that having two parallel processes (restriction and authorisation) would be confusing to many. In its response SECR explained that it was better to explore first the restriction route because if a substance was included in the authorisation list (Annex XIV), according to REACH no restriction of uses can anymore be initiated if the unacceptable risk is related to the hazard properties for which the substance was identified as SVHC and included in Annex XIV. However, with a restriction in place, subjecting the remaining uses to authorisation, if appropriate, would still be possible later.

Regarding the other substances few more clarifying questions e.g. about the grouping to the latest application dates and suggestions to update some data in the background documents were made.

Following the discussion and justifications by SECR it was concluded that calcium arsenate and NMP will not be included in the draft recommendation that will be made available for public consultation.

Item 9 – 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

MSC agreed on the tasks of the rapporteur and on the mandate of the newly-established working group to support the MSC rapporteur in drafting the MSC opinion on the 4th draft recommendation.

Further, MSC appointed volunteering MSC members as a rapporteur and respectively as members of the working group for this opinion development.

Item 10 – MSC Rules of Procedure (RoPs)

- **Update to MSC RoPs**

SECR presented a proposal for updating the MSC RoPs. First suggested update is based on the suggestion of the Court of Auditors that the RoPs of all ECHA Committees should include provisions that members are not allowed to participate in meetings unless they have a valid declaration of interest. Second part of the proposed update suggests, in line with the discussion at MSC-23, that the non-confidential presentations at MSC that are prepared to introduce the individual cases on dossier evaluation can be made available to case-owners and stakeholder observers. In addition, some minor editorial updates had been introduced to the draft. After few clarifying questions MSC endorsed the proposed modifications in the Rules of procedure of MSC. It was concluded that the changes will become valid only after the ECHA Management Board approval.

Item 11 – Update of participation of stakeholder organisations in MSC meetings

- **Discussion and update of the MSC decision about the invited organisations**

SECR presented a report on the STO participation in the work of MSC over the past year. The aim of the update was to take account of any changes in the list of eligible stakeholder organisations that have expressed an interest to follow MSC work and to review the situation in general. Besides the eligibility criteria established by ECHA's Management Board, one important development is that any StO selected must be registered in the Register of Interest representative maintained by the European Commission, before a Committee or the Forum of ECHA may invite any stakeholder organisations to attend its meetings.

SECR made a proposal for organisations to be invited to take part in MSC work in which the existing organisations would mostly continue to follow MSC work. However, two industry organisations, two NGOs and Eurotox were suggested to be removed due to different reasons: Business Europe (had not nominated a representative and never participated); DUCC/CEPE (no transparency registry number submitted to ECHA), BEUC and Friends of the Earth (both had not nominated a representative and never participated). Eurotox had also not submitted a transparency registry number. MSC agreed with this proposal and further supported inclusion of four new organisations: International Chemical Secretariat (ChemSec), European Environmental Bureau (EEB) and Client Earth as well as an Only Representatives Organisation (ORO). According to the suggestion the environmental NGOs will themselves rotate their participation in the meetings. In order to keep a balanced representation, a maximum of seven industry organisations and seven other NGOs will be present at the meetings.
MSC also decided that those stakeholder organisations, mainly sectoral ones, that had showed interest in the MSC work but are not to be regularly invited, can continue to be invited on a case by case basis, depending on the items on the agenda. This will be done at the discretion of the MSC Chair and/or MSC.

The Chair also informed the Committee that the new list will be posted on ECHA website after the organisations have been contacted.

Item 12 – Substance evaluation

a) Report from the ECHA workshop on Substance Evaluation (4-5 June 2012) and update by ECHA on the work on CoRAP development

SECR explained that the aim of the workshop was to discuss and enhance the collaboration with MSCAs and ECHA in the substance evaluation (SEV) process. Main conclusions of the SEV workshop were presented by SECR to MSC on CoRAP manual

screening, allocation criteria, selection criteria; on interaction with stakeholders; on tight timelines of the decision making process; on follow-up under Article 48 in drawing conclusions for regulatory risk management after the substance evaluation of a substance; and on reporting on the progress made in the Article 54 report. The presentation has been uploaded to MSC CIRCABC.

MSC members and representative of COM expressed appreciation to the well organised workshop and its active discussion.

Regarding the CoRAP update, SECR gave a brief summary report on the work of the CoRAP update on the substance pre-selection, manual screening and combining the new substances selected with the previous CoRAP and next steps. 365 substances were pre-selected for the manual screening using IT screening. ECHA and 13 volunteering MSCAs started the manual screening in March. MSs screened 144 substances and ECHA screened 221 substances. 70 substances seem to be candidates for CoRAP update. With the CoRAP update the total number of substances on the updated CoRAP could result in 109-127 substances. Substances already in the CoRAP can also be revised by the evaluating MS.

Draft CoRAP would be provided to MSC by mid October. CoRAP is planned to be published by end of March 2013.

b) Work plan of MSC for CoRAP and substance evaluation

SECR presented the future plans for MSC in relation to CoRAP update and SEV process and stressed the tight legal timelines for evaluating MSCAs for the SEV process. MSC recognised the amount of dossier evaluation work to be done before MSCAs receive a DD. MSC was interested in the plans of ECHA for the creation of the common repository for receipt of comments from Registrants in SEV by both ECHA and evaluating MSCA which was one of the recommendations from the SEV workshop to reduce potential bottlenecks in the SEV decision making process and to release some more time for MSCA activities within the process. It was, however, explained that its feasibility is still to be assessed by ECHA.

SECR also explained that in order to avoid all SEV DD to reach the same MSC meeting, MSCAs would have an excel table available on Evaluation CIRCABC where they are encouraged to show their intentions of which MSCA/ECHA consultation deadline they plan to go for.

Item 13 – Manual of Decisions (MoD)

- **Suggestion for a new topic for the MoD**

MSC concluded that the topic proposed to be included in MoD may not yet be mature enough to be decided and some more experience would probably be needed before the topic would be ready for MoD. Based on the experience so far MSC has concluded based on the proposals of the registrant to include optional elements of test methods in the tests so that these elements would be left for the registrant's discretion. This has normally been indicated in Section III of the draft decision and Section II has specified only the mandatory part of the information requirement. On the other hand there is already some experience that MSC and ECHA, based on the provisions of REACH (e.g. Annex IX, 8.6.2, column 2 and Annex X, 8.6.4, column 2), can make some optional part of a test method mandatory if there is substance specific justification for the measure.

MSC was of the view that the topic might need to be revisited later on when more experience with relevant cases is gained.

Item 14 – Report from other ECHA bodies and activities

- **Report from Risk management workshop held in ECHA on 10-11 May 2012**

SECR gave a report from the recently organised Risk management workshop and its outcome. The main issues considered were the use of REACH and CLP information for regulatory risk management, the current status and further development of the risk management options (RMO), roles of the Candidate list, Restriction and Authorisation processes, as well as the approach to be used when substance in substances cases and substances in articles obligations. The presentation has been made available in MSC CIRCABC.

In the following brief discussion, it was further clarified that based on the RiME discussions on substance-in-substance approach, the Commission in cooperation with ECHA will develop a document on the issue and the possible ways forward in such cases. This document will most probably be addressed in CARACAL.

- **Reports from 1st GAARN meeting held on 29 May 2012 and from Nanomaterials Workshop held on 30-31 May 2012**

SECR gave to MSC a report from the first meeting of the Group Assessing Already Registered Nanomaterials (GAARN) held in ECHA on 29 May 2012 and the following Nanomaterials workshop. The Committee was briefly introduced with the objectives of the GAARN working group and of the workshop, the outcomes of these events and next steps envisaged with regard to the nanomaterials' management under REACH. It was recognised that an ECHA Nanomaterials working group was decided to be set up.

The presentations have been made available in MSC CIRCABC.

Item 15 – Any other business

- **Workshop on the inorganic substances used as surface treatment of articles to be held in ECHA in October 2012**

A STO observer announced to MSC a forthcoming sectoral technical workshop on a use of inorganic substances as an article surface preliminary scheduled for October 2012 and invited MSC to consider possible participation in this industry event. SECR promised to circulate the information documents on workshop provided by the STO observer for information of MSC.

- **Recent appeal cases (CLOSED SESSION)**

MSC was introduced with the recently received appeal cases on ECHA dossier evaluation decisions, the Registrants' argumentation for the appeals and the Secretariat's considerations on the way forward for each of them.

In the following discussion, some further clarification was provided on issues relevant for the MSC decision making under the dossier evaluation process. In conclusion, it was agreed that MSC will be further informed on the Board of Appeal's rulings for these particular cases once they are concluded.

Item 16 – Adoption of conclusions and action points

MSC reviewed the draft conclusions and action points of MSC-24 at the meeting. However, due to the lack of quorum, they will be proposed for adoption in a written procedure launched after the meeting and upload to MSC CIRCABC IG when adopted.

Signed
Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
BIWER, Arno (LU)
CONWAY, Louise (IE) (alternate member)[1]
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK),
DRUGEON, Sylvie (FR)[2]
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
HUMAR-JURIC, Tatjana (SI)
KORENROMP, Rene (NL)[3]
KULHANKOVA, Pavlina(CZ)
LUDBORZS, Arnis (LV)
LULEVA, Parvoleta (BG)
MAJKA, Jerzy (PL) (alternate member)
MARTINS, Ana Lilia (PT) (alternate member)
MIHALCEA-UDREA, Mariana (RO)
PALEOMILITOU, Maria (CY) (alternate member)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)[5]
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI)
TRAAS, Theo (NL) (alternate member)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
Representatives of the Commission
GARCÍA-JOHN, Enrique (DG ENTR)
KOBE,Andrej (DG ENV)
STRECK Georg (DG ENTR)
Observers
ANNYS, Erwin (CEFIC)
BASTIJANCIC-KOKIC, Biserka (HR)
DMYTRASZ Bohdan (CONCAWE)
FRANCHIOLI, Luigi (UEAPME)
REINEKE Ninja (WWF)
TAYLOR, Katy (ECEAE)
VAN VLIET, Lisette (HEAL)
WAETERSCHOOT, Hugo (EUROMETAUX)

ECHA staff
AJAO, Charmaine
BALOGH, Attila
BICHLMAIER, Ingo
BROERE, William
CESNATIS, Romanas
CONSTANTINI Camelia
CARLON, Claudio
DE COEN, Wim
DELOFF-BIAŁEK, Anna
DE WOLF, Watze
FALCK, Ghita
FEDTKE, Norbert
FEEHAN, Margaret
KARJALAINEN Antti
KARHU, Elina
KOJO, Anneli
KORJUS, Pia
LE CURIEUX, Frank
KOULOUMPOS, Vasileios
LEPPER, Peter
LUOTAMO, Marita
MÜLLER, Birgit
NAUR, Liina
REUTER, Ulrike
REGIL, Pablo
RIALA, Riitta
RÖCKE, Timo
RÖNTY, Kaisu
RYAN, Paul
SCHÖNING, Gabriele
SOBANSKA, Marta
VAHTERISTO, Liisa
VASILEVA, Katya

Proxies

- PISTOLESE, Pietro (IT) also acting as proxy of CAMILLERI, Tristan (MT)
- DRUGEON, Sylvie (FR) also acting as proxy of MARTIN, Esther (ES)
- PALEOMILITOU, Maria (CY) also acting as proxy of KOUTSODIMOU, Aglaia (EL)
- DOUGHERTY, Gary (UK) also acting as proxy of COSGRAVE, Majella (IE) on 7 and 8 June 2012
- LULEVA, Parvoleta (BG) also acting as proxy of PALEOMILITOU, Maria (CY) on Friday
- MIHALCEA UDREA, Mariana (RO) also acting as proxy of MAJKA, Jerzy (PL) and of MARTINS, Ana Lilia (PT) on 8 June 2012

[1] Present at the meeting only on 6 June 2012.
[2] Present only in the afternoon of 6 June and on 7 June 2012.
[3] Present only on 6 June 2012 and replaced by his alternate member on 7 June 2012 starting at 4 p.m. and on 8 June 2012.

Experts and advisers to MSC members
ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BUDAŠOVA, Jana (EE) (expert to VESKIMÄE, Enda)
DUTTON, Sarah (UK) (adviser to DOUGHERTY Gary)
GRACZYK, Anna (PL) (expert to MAJKA Jerzy)
GUHE, Christine (DE) (adviser to FINDENEGG, Helene)
INDANS, Ian (UK) (adviser to DOUGHERTY Gary)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
LUNDBERGH, Ivar (expert to FLODSTRÖM, Sten)
MARCSEK Zoltán (HU) (expert to DEIM, Szilvia)
MERCKEL, Daniel (UK) (expert to DOUGHERTY Gary)
MOELLER, Ruth (LU) (expert to BIWER, Arno)
RAMOS, Cesaltina (PT) (expert to MARTINS, Ana Lilia)
VERIKAITE Vilma (LT) (expert to DUNAUSKIENE, Lina)
WALENDZIK, Gudrun (DE) (expert to FINDENEGG, Helene)

By WEBEX-phone connection:
Cécile ROUSSEAU (from ANSES, FR) during dossier evaluation on case 1,3-diphenylguanidine TPE-70 *(closed session).*
Valentina BERTATO *and* Anna BORRAS from DG ENTR for items 7, 8 and 9

Case owners:
Representatives of the Registrant were attending under agenda item 6c for:
CCH-020/2012

Apologies:
ANDRIJEWSKI, Michal (PL)
CAMILLERI, Tristan (MT)
COSGRAVE, Majella (IE)
FIGUEIRA, Maria do Carmo (PT)
KOUTSODIMOU, Aglaia (EL)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
MARTÍN, Esther (ES)

III. Final Agenda

Final Agenda

24th meeting of the Member State Committee

6-8 June 2012
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

6 June**: starts at 9:00**
8 June**: ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/024/2012
For adoption

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

Item 4 – Administrative issues

For information

Item 5 – Adoption of the draft minutes of the MSC-23

MSC/M/23/2012
For adoption

Item 6 – Dossier evaluation

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

a. General topics:

2. Applicability of testing proposals using a read across approach

For discussion

3. Inclusion of bronchoalveolar lavage (BAL) analysis in an OECD TG 413

For discussion

4. Status report on ongoing evaluation work

For information

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

ECHA/MSC-24/2012/001

For information

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

For discussion followed by agreement seeking under 6d:

Compliance checks

CCH-020/2012 m-Phenylenebis(methylamine) (EC No. 216-032-5)

ECHA/MSC-24/2012/002-003

Testing proposals

TPE-081/2012 Diethyl ether (EC No. 200-467-2)

ECHA/MSC-24/2012/08-009

TPE-090/2012 Acetalization products between glucose and C20-22(even numbered)-alcohol (List No. 923-835-0)

ECHA/MSC-24/2012/010-11

TPE-080/2012 Activated Carbon - High Density Skeleton (List No. 931-328-0)

ECHA/MSC-24/2012/06-007

TPE-092/2012 Di-tert-butyl peroxide (EC No. 203-733-6)

ECHA/MSC-24/2012/012-013

TPE-093/2012 Tris(2-methoxyethoxy)vinylsilane (EC No. 213-934-0)

ECHA/MSC-24/2012/014-015

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)*

- As listed above under **6c** and the cases returned from written procedures for agreement seeking in the meeting[4]:

TPE-061/2012 Hexyl 2-(1-(diethylaminohydroxyphenyl)methanoyl)benzoate (EC No. 443-860-6)

ECHA/MSC/D/2012/0173

TPE-070/2012 1,3-Diphenylguanidine (EC No. 203-002-1)

ECHA/MSC/D/2012/0153

TPE-072/2012 3-Hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropionate (EC No. 214-222-2)

ECHA/MSC/D/2012/0157

TPE-077/2012 Boron trifluoride (EC No. 231-569-5)

ECHA/MSC/D/2012/0195

For agreement

[4] Note to members: The documents listed for each case here may be found in the substance specific folders in CIRCABC, as were made available for the written procedures, and are not available in the MSC-24 folders.

e. Items for discussion following commenting by MSCAs *(Tentatively closed session)*

- Items from current cases if not addressed during 6c

For discussion

Item 7 – SVHC identification

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

ECHA/MSC-24/2012/004
For information

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

- [4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) (EC No. 208-953-6)

ECHA/MSC-24/2012/016-018

- [4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26) (EC No. 219-943-6)

ECHA/MSC-24/2012/019-021

- α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) (EC No. 229-851-8)

ECHA/MSC-24/2012/022-024

- 4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol (EC No. 209-218-2)

ECHA/MSC-24/2012/025-027

For agreement

Item 8 –Discussion on ECHA's 4th draft recommendation for inclusion of priority substances in Annex XIV

Discussion of the 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-24/2012/031-033
For discussion

Item 9 – 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-24/2012/028
For discussion & decision

b. Appointment of Rapporteur

For discussion & decision

c. Establishment of a working group to support the Rapporteur

ECHA/MSC-24/2012/029
For discussion & decision

Item 10 – MSC Rules of Procedure (RoPs)

Closed session

- Update to MSC RoPs

ECHA/MSC-24/2012/005
For decision

Item 11 – Update of participation of stakeholder organisations in MSC meetings

Closed session

- Discussion and update of the MSC decision about the invited organisations

ECHA/MSC-24/2012/030
For discussion and decision

Item 12 – Substance evaluation

a) Report from the ECHA workshop on Substance Evaluation (4-5 June 2012) and update by ECHA on the work on CoRAP development

b) Workplan of MSC for CoRAP and substance evaluation

For information

Item 13 – Manual of Decisions (MoD)

- Suggestion for a new topic for the MoD

ECHA/MSC-24/2012/035
For discussion and adoption

Item 14 – Report from other ECHA bodies and activities

- Report from Risk management workshop held in ECHA on 10-11 May 2012
- Report from 1st GAARN meeting held on 29 May 2012 and from Nanomaterials Workshop held in ECHA on 30-31 May 2012 and upcoming Working group

For information

Item 15 – Any other business

- Workshop on the inorganic substances used as an article surface to be held in ECHA in October 2012
- Recent appeal cases (CLOSED SESSION)

For information

Item 16 – Adoption of conclusions and action points

- Table with conclusions and action points from MSC-24

For adoption

IV. Conclusions and Action Points

Main conclusions and action points
MSC-24, 6-8 June 2012
(adopted in written procedure on 22 June 2012)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
5. Adoption of the minutes of MSC-23	
MSC adopted the minutes as modified at the meeting.	MSC-S to upload final version of the minutes on MSC CIRCABC by Tuesday 12 June 2012.
6. Dossier evaluation **6a) General Topics**	
1. Applicability of testing proposals using a read across approach **2. Inclusion of bronchoalveolar lavage (BAL) analysis in an OECD TG 413** MSC took note of ECHA presentations. **3. Status report on ongoing evaluation work** MSC took note of the report and the announcements made for the forthcoming ECHA events in regard to the evaluation process.	MSC members to consider participation to: • a Webinar on Read-Across Assessment Framework, Tier II on 11 June 2012 (deadline for registration is 8 June 2012), • an Experts Workshop on Read-Across Assessment on 2-3 October 2012 (deadline for expression of interest is 15 June 2012).
6. Dossier evaluation **6b) Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the report.	MSC-S to upload on MSC CIRCABC the final ECHA decisions on cases agreed in written procedures. MSC-S to provide COM for further decision

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	making with documents (DD on generation testing, RCOM, minutes, outcome of the vote, justification for the position at the vote) of cases on which MSC did not reach agreement.
6c) Introduction to and preliminary discussion on draft decisions (DD) on compliance checks after MSCAs' reactions *(Session 1, tentatively open session)* **6d) Seeking agreement on draft decisions (DD) on compliance checks when amendments were proposed by MSCAs *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions of: **CCH-020/2012 m-Phenylenebis(methylamine)** (EC No. 216-032-5) **TPE-061/2012 Hexyl 2-(1-(diethylaminohydroxyphenyl) methanoyl)benzoate** (EC No. 443-860-6) **TPE-070/2012 1,3-Diphenylguanidine** (EC No. 203-002-1) **TPE-072/2012 3-Hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropionate** (EC No. 214-222-2) **TPE-077/2012 Boron trifluoride** (EC No. 231-569-5) **TPE-080/2012 Activated Carbon - High Density Skeleton** (List No. 931-328-0) **TPE-090/2012 Acetalization products between glucose and C20-22(even numbered)- alcohol** (List No. 923-835-0) **TPE-092/2012 Di-tert-butyl peroxide** (EC No. 203-733-6) **TPE-093/2012 Tris(2-methoxyethoxy)vinylsilane** (EC No 213-34-0) MSC could not reach unanimous agreement on the following draft decision: **TPE-081/2012 Diethyl ether** (EC No. 200-467-2) on the information requirements for Annex X, point 8.7.3 due to different views of MSC members on the most appropriate generation test (B.35 (TG 416) or OECD TG 443) to be requested for fulfilling the standard REACH information requirements for this endpoint. MSC agreed in the light of the discussions on: • TPE-080/2012: MSC considered that when criteria for use of bronchoalveolar lavage (BAL) analysis are met, BAL analysis can be requested to be an obligatory part of 28 day or 90 day inhalation study.	SECR to provide COM for further decision making with documents (DD on generation testing, RCOM, minutes, outcome of the vote, justification for the position at the vote) of case TPE-081/2012.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
7. SVHC identification	
a) Written procedure report on seeking agreement on identification of SVHC MSC unanimously agreed to identify ***diboron trioxide*** *(EC No. 215-125-8)* as a SVHC in written procedure. **b) Seeking agreement on Annex XV proposals for identification of SVHC** MSC unanimously agreed to identify the following four CMR substances as SVHCs when they contain as impurity ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2) : • ***[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)*** *(EC No. 208-953-6)* • ***[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26)*** *(EC No. 219-943-6)* • ***α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4)*** *(EC No. 229-851-8)* • ***4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol*** *(EC No. 209-218-2)* Discussion on substance in substances issues relevant for SVHC identification in MSC will be continued in other fora.	SECR to add the newly identified SVHCs (in written procedure and at the meeting) to the Candidate List (update foreseen in a few weeks). 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 also RCOMs on the MSC webpage of the ECHA website.
8. Discussion on ECHA's 4th draft recommendation for inclusion of priority substances in Annex XIV **Discussion of the 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 took note on ECHA's 4th draft recommendation for inclusion of priority substances in Annex XIV, as amended at the meeting, including the draft Annex XIV entries of the substances. Further discussion on calcium arsenate and NMP took place in the meeting.	ECHA to finalise the draft recommendation and related documentation for public consultation.
9. 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	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
b. Appointment of Rapporteur **c. Establishment of a working group to support the Rapporteur** MSC adopted the mandate and the tasks of the rapporteur and the established working group supporting her in drafting the MSC opinion on the 4th draft recommendation. Further, the Committee appointed the volunteering members as a MSC rapporteur and members of the working group.	
10. MSC Rules of Procedure (RoPs)	
MSC took note on the proposed modifications in the Rules of procedure of MSC and endorsed them without further changes.	MSC-S to send the draft MSC RoPs, as endorsed, to the ECHA Management Board for their approval at the next MB meeting.
11. Update of participation of stakeholder organisations (STO) in MSC meetings	
MSC took note of the annual report on the STO participation in the work of MSC and agreed with the Secretariat's proposal on inclusion of new/exclusion of previous MSC STO observers.	MSC-S to inform the concerned STO on the MSC decision regarding their status of MSC observers from now on.
13. Manual of Decisions (MoD)	
	MSC members to provide proposals to be included in the MoD of MSC.
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-24 conclusions and action points when adopted.

V. Dossier evaluation cases addressed for MSC agreement seeking in WP

Cases unanimously agreed by MSC in WP:

MSC ID number	Substance name used in draft decision	EC No
CCH 018/2012	2,2'-ethylenedioxyethyl bis(2-ethylhexanoate)	202-319-2
CCH 019/2012	1,2-dichlorobenzene	202-425-9
TPE 062/2012	Coconut oil, reaction products with polyethylene glycol and trimethylolpropane	640-964-5
TPE 063/2012	p-Phenylenediamine	203-404-7
TPE 064/2012	Glycerides, C8-18 and C18-unsatd. mono- and di-, acetates	293-170-2
TPE 066/2012	Methyl undec-10-enoate	203-910-8
TPE 067/2012	2,2'-ethylenedioxyethyl bis(2-ethylhexanoate)	202-319-2
TPE 068/2012	Diethylmethylbenzenediamine	270-877-4
TPE 069-B/2012	Alcohols, C18-22, distn. residues	641-136-6
TPE 071/2012	Vinyl laurate	218-414-7
TPE 073-B/2012	Polysulfides, bis[3-(triethoxysilyl)propyl]	915-673-4
TPE 075/2012	2,2’-dimethyl-4,4’-methylenebis(cyclohexylamine)	229-962-1
TPE 076/2012	Triamine C16-18, C18-unsaturated	628-863-4
TPE 078/2012	Green liquor	268-612-2
TPE 079/2012	Dichloromethylbenzene	249-854-8
TPE 083/2012	di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide	229-782-3
TPE 084/2012	Bis(α,α-dimethylbenzyl) peroxide	201-279-3
TPE 086-B/2012	Bis (2-chloroethoxy)methane	203-920-2
TPE 088-B/2012	2-hydroxy-2-methylpropiophenone	231-272-0
TPE 094/2012	Pentane-1,2-diol	226-285-3
TPE 095/2012	Fatty acids, lanolin	270-302-7
TPE 096/2012	Ethanol, 2,2'-iminobis-, N-(C13-15-branched and linear alkyl) derivs.	308-208-6
TPE 098-B/2012	2,4,6-tris(2,4,6-tribromophenoxy)-1,3,5-triazine	426-040-2

Cases to be referred to COM:

TPE 069-A/2012	Alcohols, C18-22, distn. residues	641-136-6
TPE 073-A/2012	Polysulfides, bis[3-(triethoxysilyl)propyl]	915-673-4
TPE 082/2012	Diisopropyl ether	203-560-6
TPE 085/2012	1,2,3,4-Tetrahydronaphthalene	204-340-2
TPE 086-A/2012	Bis (2-chloroethoxy)methane	203-920-2
TPE 087/2012	Decahydronaphthalene	202-046-9
TPE 088-A/2012	2-hydroxy-2-methylpropiophenone	231-272-0
TPE 098-A/2012	2,4,6-tris(2,4,6-tribromophenoxy)-1,3,5-triazine	426-040-2

Cases for which WP was terminated (with further agreement seeking in the MSC-24 meeting):

TPE 061/2012	302776-68-7 master Benzoic acid, 2-[4-	443-860-6

	(diethylamino)-2-hydroxybenzoyl]-, hexyl ester	
TPE 070/2012	1,3-diphenylguanidine	203-002-1
TPE 072/2012	3-hydroxy-2,2-dimethylpropyl 3-hydroxy-2,2-dimethylpropionate	214-222-2
TPE 077/2012	Boron trifluoride	231-569-5