MSC/M/029/2013
ADOPTED AT MSC-30

Final Minutes
of the 29th Meeting of the Member State Committee (MSC-29)
24-25 April 2013

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 29th 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 Chair introduced to MSC the draft Agenda for the meeting. The Agenda was then adopted as provided for the meeting by the MSC Secretariat without further changes (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

- **Tentative MSC meeting dates for 2014**

SECR informed MSC of the six plenary meetings of the Committee scheduled for 2014 (with similar distribution during the year to the one for 2013) pointing out that each meeting is tentatively scheduled for a full week and its duration would be further confirmed closer to the meeting dates after considering the actual workload.

- **Other administrative issues**

SECR informed the Committee that following the MSC-28 conclusions and action points, the MSC Satisfaction survey report was prepared and uploaded to MSC CIRCABC for members' information.

Further, MSC was informed that as a follow-up of the Annual Satisfaction Survey 2011, a note on MSC closed/open sessions was prepared and published on the ECHA website for increasing the transparency on the principles followed by the SECR when setting up closed sessions.

Members were also informed that from 1 May 2013 a new travel agency would start providing travel and accommodation services for the Committee meetings and other events.

Item 5 – Minutes of the MSC-28 meeting

The MSC Chair informed the participants that minutes from MSC-28 were adopted by written procedure and published on MSC CIRCABC and on the ECHA website shortly after their adoption.

Item 6 – Dossier evaluation

a. 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 34 dossier evaluation cases (see Section V for more detailed identification of the cases). WP was launched on 27 March and closed on 8 April 2013. For ten cases, the draft decision (DD) was split thus resulting in two DDs for these cases and overall 20 DDs for the ten cases. By the closing date, responses to WP were received from 26 members with voting rights and from the Norwegian member. One member had declared potential conflict of interest with three dossier evaluation cases and did not vote on them in this WP. Unanimous agreement was reached on 26 DDs. For eight DDs involving the standard information requirement for Annex X, 8.7.3, four votes indicated disagreement, 17 votes were in favour of these eight DDs and two 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. For nine DDs, the WP was terminated by the MSC Chair

on the basis of Article 20.6 of the MSC Rules of Procedure as at least one MSC member requested meeting discussion at the MSC-29 meeting.

b. General topics

1) Update on developments concerning 'generation studies' for reproduction toxicity

COM reported that, as CARACAL had already been informed in March 2013, the COM proposal for co-financing a pilot project to conduct extended one-generation reproductive toxicity studies (EOGRTS) for the 2nd generation (F2) on certain selected substances was not supported by MSs. The pilot project was intended to evaluate the necessity and usefulness of F2 in the context of dossier evaluation. However, COM remains convinced that these projects are necessary not for the reason that authorities should finance the work that is the responsibility of the companies but to contribute to dealing with the costs that are associated to an exercise the purpose of which is clarifying the uncertainties regarding the added value of the F2 generation in EOGRTS design and, ultimately to allow the final decision by the authorities. COM indicated it had a high certainty in being able to provide funds, with the final availability of funds to be confirmed hopefully by June this year. COM is currently working on two elements of this project. The first element is the development of criteria for selection of a limited set of substances where EOGRTS with F2 should be performed. These criteria will rely on exposure based considerations with maximum interest on substances with high exposure and low toxicity. ECHA assists COM in this activity by e.g. providing its data mining tools to be used in screening of substances. The outcome of this screening as a preliminary outcome might already be presented in one of the coming CARACAL meetings. Within five years, the studies with the selected substances should be finalised and further indications on the need to test up to the F2 generation, if appropriate, would be developed. ECHA will assist COM in the refinement of criteria.

The second element of the project is to secure that at the end of the 5-year period a robust study design for EOGRTS and two-generation study agreed by MSCAs, COM and ECHA is available. COM mentioned that it would provide a way for MSCAs to be involved in the project via CARACAL or other relevant fora.

COM also highlighted that preparations for the parallel inclusion of EOGRTS (OECD TG 443) in the REACH Annexes as well as in the Test Methods Regulation (TMR) are on-going. Inclusion of EOGRTS in TMR is intended via the 5th Adaptation to Technical Progress (ATP) containing 31 test methods; if progress with the 5th ATP proves to be slow, COM considers a separate effort to include EOGRTS in TMR earlier.

Replying to questions COM explained that the 5th ATP is expected by the end of 2013. COM clarified that DDs involving generation studies and referred to COM for decision making will be decided in comitology in the meantime i.e. the clock cannot be stopped for these cases while waiting for the conclusions of the pilot project. COM also explained that the number of substances included in the pilot project depends on the eventual availability of funding and the outcome of the currently on-going screening.

One MSC expert pointed out that the outcome of the pilot should be very critically analysed. There are already scientific reviews concluding that F2 is not necessary and F2 provides useful information only for very few substances. If the pilot is performed only on a small number of substances meaningful results/conclusions cannot be expected and the pilot might not help clarifying the situation. He also stressed the importance of involving MSs in the design of the pilot and he referred to the similar procedures of OECD.

SECR was of the opinion that currently available reviews from the OECD work have also some shortcomings which have led to lack of full scientific agreement on the outcome and therefore the planned pilot would be justified. As the study is planned by COM, it is at its discretion to involve MSs as appropriate.

2) Improving Consistency in the Evaluation of Terrestrial Testing Proposals - revised proposal following MSCA comments and considerations *and* Scientific Discussion paper on Terrestrial microorganisms

SECR presented to MSC its proposal for improving consistency in the evaluation of terrestrial testing proposals supported by scientific discussion paper (on soil microorganisms and on improving coherence in terrestrial TPs). It was reminded that terrestrial toxicity studies are standard information requirements in Annex IX and X covering three taxonomic groups. Some further specific considerations were shared with regard to different Registrants' approaches used in their testing proposals on terrestrial toxicity. MSC was informed that SECR is following in the evaluation of TPs the principles described in the document. The principles were applied in several specific cases addressed for agreement seeking in the present meeting or in the written procedure before the present meeting. MSC was invited to consider and contribute to the evaluation principles (regarding terrestrial toxicity testing) outlined in the SECR's document and the members were invited to submit to SECR any remaining comments on these papers by 15 May 2013. The principles will be proposed for inclusion in the ECHA guidelines later.

3) Discussion on Areas of Concern-approach (AoC) (closed)
ECHA introduced the implementation plans for AoC based compliance checks (CCH) and gave a report on the first experience gained with AoC-CCH. One MSC expert gave a presentation on her MS's experience, views and concerns regarding ECHA's AoC-approach. The concerns are about the clear data gaps that are identifiable in the dossiers but which are not addressed in the context of an AoC driven DD based on a certain AoC scenario. COM fully supported ECHA's efforts with the AoC approach mentioning that AoC is one tool in the compliance check arsenal, providing an efficient way of conducting specific CCHs. All outcomes of the project should be as visible as possible for MSCAs. SECR highlighted that one of the many benefits of the AoC-approach is ensuring consistency in and reducing the drafting/processing time for DDs during the evaluation phase as well as in the decision making process (i.e. due to absence of proposals for amendment). SECR agreed that it takes time until the AoC-approach will be fully implemented and all benefits will be clearly visible. SECR also noted that the approach is not developed to handle very complex incompliances but these need to be addressed in targeted or full CCHs which will also be carried out in addition to AoC-driven CCHs. The Chair concluded that regular discussions with MSCAs are needed at CARACAL (or in next ad-hoc CA meeting in July in Helsinki) and any other appropriate fora to ensure transparency and to come to a common understanding in all aspects of the AoC approach.

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

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

CCH 023/2013 Dibutyltin oxide (DBTO) (EC No. 212-449-1)

Session 1 (open)
Two representatives of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

SECR explained that two proposals for amendment (PfAs) to ECHA's DD had been submitted where the first one suggests changing the reference in section II and III from the draft TG 305 to the final version of TG 305 adopted in July 2012 and the second PfA suggests accepting the Registrant's proposal for the read-across (RA) from dibutyltin dichloride (DBTC) to the registered substance DBTO and the weight of evidence (WoE) approach and deleting the requirement for a bioaccumulation study in aquatic species from DD.

SECR modified DD based on the first PfA. Motivated by the second PfA, SECR shared the view that additional explanation would be necessary in DD on why the RA and weight of evidence approach is rejected and why the requirement for the bioaccumulation test should be kept.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs agreed with the PfA on acceptability of the RA between DBTC and DBTO and with the suggestion that the OECD 305 study (bioaccumulation test in aquatic species) is not necessary.

The Registrant's representative further confirmed at the meeting that, in their view, the available information on DBTC provides enough relevant information on DBTO and sufficient grounds to allow reasonable conclusions to be drawn for DBTO. In response to a MSC member's questions, it was clarified that the Registrant believes that the exposure likelihood depends on properties of the substance and the BCF values are not, and should not be, exposure-route specific as they are applied independently of the exposure route within the risk assessment. Based on the available literature information, the Registrant concludes that DBTC hydrolyses rapidly and he has no more precise information of the rate of hydrolysis conversion from DBTC to DBTO. He also noted that due to the absence of a validated analytical method, it is not possible to differentiate analytically between the specific organotin species and the available field data have not been considered prior to the submission of the registration dossier, due to reservations regarding their usefulness on this specific issue.

Session 2 (closed)

The member representing the CA making the PfA for acceptance of RA admitted that the Registrant has not been able to provide sufficient evidence in the dossier and in the meeting discussion for RA but at the same time expressed some reservations on the interpretation of the study results once they become available. MSC concluded based on the above discussion that Section III of DD should be modified to further clarify the reasons for rejecting the proposed read across and the proposed weight of evidence justification, and therefore to ask for the bioaccumulation test in fish (OECD 305-III).

MSC found unanimous agreement on ECHA's DD as amended in the meeting based on the above conclusions. One member abstained from voting.

TPE 001/2013 Dibenzoyl peroxide (EC No. 202-327-6)

Session 1 (open)

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

SECR explained that nine PfAs to ECHA's DD had been submitted. One PfA suggested modifying the statement of reasons (SoR) in line with the conclusion at MSC-28. The CSA should be updated without reference to any default Assessment Factor (e.g. 50) but only if risk is obtained a further fish study needs to be proposed.

Another PfA suggested that based on the results (high number of runts) of an available reproduction/ development toxicity screening study (OECD 422) on rat by the oral route that PNDT test should be conducted also by the oral route with rat as the first species.

Third PfA pointed out that for a hydrolytically unstable and not highly adsorptive substance simulation testing may not be warranted and if any further degradation simulation studies should be conducted a test in accordance with OECD 309 would be more relevant. Regarding soil and sediment simulation testing, two CAs in their PfAs proposed to advice the Registrant to consult ECHA guidance on PBT assessment to determine the sequence in which the simulation tests should be conducted and to consider the necessity to conduct the second simulation test.

Furthermore one CA suggested adding in Section II a requirement for short-term toxicity to invertebrates using Earthworm acute toxicity test (OECD 207) or, if long-term testing is considered appropriate, long-term toxicity to terrestrial invertebrates using Earthworm reproduction test (OECD 222), or Enchytraeid reproduction test (OECD 220) or Collembolan reproduction test (OECD 232). Alignment of Section III was proposed accordingly. For long-term toxicity testing on plants the same CA proposed to add a requirement in Section II to conduct short-term toxicity testing on plants using OECD 208 with at least three species (as a minimum one monocotyledonous species and two dicotyledonous species), or if long-term testing is considered appropriate, long-term testing on plants using OECD 208 with at least six species tested (as a minimum

two monocotyledonous species and four dicotyledonous species), or chronic toxicity testing in higher plants using ISO 22030. Section III was proposed to be aligned accordingly.

SECR modified DD for MSC consideration based on all PfAs except PfA regarding questioning of the proposed tests (and using OECD 309 instead) and PfA regarding rat as a test species for PNDT study.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs agreed that the rat would be the appropriate first species. Consequently, the PfA suggesting that rat be specified in the DD is redundant and need not be included. The Registrant in the written comments on PfAs agreed that some tests depend on the outcome of the tests performed in a first tier and therefore, the Registrant confirmed his testing strategy to perform the chronic daphnia (OECD 211) for water compartment and based on the test results, to consider whether to carry out the OECD 309 (as proposed by one CA) and/or the long-term fish (OECD 210 as proposed by another CA). Similarly, for soil compartment, the Registrant intends to test the toxicity to terrestrial plant (OECD 208) in a first tier, as the toxicity to soil macro-organisms (OECD 207) and the toxicity to soil micro-organisms (OECD 216) are considered as optional, and could be performed based on the outcome of the OECD 208. Furthermore, the Registrant proposed the deadline for submitting the updated registration dossier to be changed from 24 to 30 months from the date of the decision due to the dependency of some tests' initiation (effects on terrestrial organisms) of the outcome of the simulation testing before they can be launched, as well as due to potential technical issues that may arise when testing the substance.

Prior to the discussion, the SECR introduced the case and explained that in his response to PfAs, the Registrant presented his tiered testing strategy regarding the sequence of testing. With regard to the degradation simulation testing, it was further explained that although the Registrant had initially proposed OECD 309 (simulation test in surface water) in the original registration dossier, with the later updates, he withdrew the OECD 309 test. However, based on the CA PfA concerning possibility to consider the OECD 309 test as the most relevant simulation test, in his written response, the Registrant expressed his intension to "remove" the testing proposals for OECD 307 and 308 and perform the OECD 309 test only.

Some members underlined that it would be necessary to consider the usefulness of the results of each of the simulation tests also taking into account that dibenzoyl peroxide is unstable, rapidly hydrolysing substance that would be difficult to test. Based on the PfA from one CA and the Registrant's agreement on it in the written comments it was proposed that OECD 309 should also be requested as a relevant environmental fate test. SECR emphasised that PfAs provide the framework for DD modifications and in this particular case, three different standard information requirements of Annex IX, 9.2.1.2, 9.2.1.3 and 9.2.1.4 with simulation testing in surface water, in soil and in sediment should be covered advising the Registrant to consult the relevant guidance for making decisions on the order of testing and regarding justifications to be used for possibilities to adapt any of the tests. Therefore, it was concluded as there is a data gap for the simulation test on ultimate degradation in surface water (OECD 309) this requirement should be added to the soil simulation test and sediment simulation test (OECD 307 and 308) which were originally proposed by the Registrant in the registration dossier.

Session 2 (closed)

MSC concluded based on the above discussions that biodegradation simulation testing should be required in surface water, soil and sediment (guidelines OECD 309, 307 and 308) and an explanation regarding the order of testing and adaptation possibilities of the three tests should be provided in section III of DD. MSC agreed that SECR should introduce the appropriate deadline for submission of the test results taking into account the modifications made in DD. No other modifications were introduced to DD which was already modified for the MSC meeting based on the other PfAs (see above).

MSC found unanimous agreement on ECHA's DDs as amended in the meeting based on the above conclusions.

TPE 004/2013 3-hydroxy-1,1-dimethylbutyl 2-ethyl-2-methylheptaneperoxoate (EC No. 413-910-1)

Session 1 (open)

One representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

SECR explained that four PfAs to ECHA's DD were submitted. One PfA suggested providing the Registrant also with the option of the OECD 309 test (simulation biodegradation test in surface water) as the hydrolysis data in the dossier are contradictory (i.e. no clear conclusion can be drawn now which test method will be most suitable). Another PfA suggested advising the Registrant to make sure that the environmentally relevant components are assessed in the fish early-life stage (FELS) test and therefore to perform the FELS test only when the results of the soil and sediment simulation tests are available. The third PfA suggested modifying the test requirements for terrestrial organisms (giving to the Registrant four options (OECD 207, OECD 222, OECD 220, OECD 232) to test terrestrial invertebrates instead of two and modifying the wording of requirements for tests on terrestrial plants and micro-organisms). The fourth PfA suggested requesting the 90-day repeated dose toxicity (RDT) study via inhalation route instead of oral route (as proposed by the Registrant).

SECR modified DD for MSC consideration based on all PfAs but the one concerning the 90-day study.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs disagreed with PfA of NL-CA and still wished to perform the 90-day study via the oral route. The Registrant agreed with PfA of UK-CA that the OECD 309 test is more relevant than OECD 307 and 308 and considers a new hydrolysis test necessary. Based on this PfA of UK-CA, the Registrant intended to "remove" the testing proposals for OECD 307 and 308 and after the hydrolysis test perform the OECD 309 test only. The Registrant also agreed with the modified test requirements for terrestrial testing as proposed by DK-CA.

The representative of Registrant at the meeting mainly repeated the arguments why the oral route is the most appropriate route for the 90-day study. She gave detailed explanation why there is no significant exposure via inhalation during manufacture and handling by downstream users. She also stated that the pure substance is skin irritant but not corrosive, not eye irritant or stomach irritant so irritation to the respiratory tract is unlikely. She also repeated the argument that vapour pressure of the substance is considerably low despite the presence of impurities with high vapour pressure that could significantly increase vapour pressure. An inhalation study would be very difficult also because the substance would decompose very soon in higher temperatures needed to generate vapours.

Based particularly on the arguments of the Registrant in the dossier and confirmed at the meeting indicating low exposure, the MSC member representing the MSCA that submitted the PfA for the inhalation route agreed to the oral route as the most appropriate route of administration.

Based on the written comments of the Registrant on the PfA SECR wished to clarify to the Registrant that the current DD is based on the registration dossier containing TPs for OECD 307/308. The relevant PfA proposed to add OECD 309 but not to replace with it the OECD 307/308 studies. Therefore, the only discussion point in this regard is whether or not to add OECD 309 as an optional requirement but not whether or not the OECD 307/308 studies should be required. It was concluded that the relationship and requirements for simulation testing in surface water (OECD 309) and in soil and sediment (OECD 307 and OECD 308) need to be further clarified in the text of the DD.

Session 2 (closed)

MSC concluded to add a sentence concerning the right order of studies in section II and to refine the arguments for requesting optionally simulation tests OECD 307, 308 and 309 in section III of DD. MSC also concluded to explicitly remind the Registrant in section III of DD that adaptation of the requirements for the OECD 307, 308, 309 studies is possible with proper justification.

MSC found unanimous agreement on ECHA's DD (which was already modified for the meeting on the basis of the PfAs as indicated above) as amended in the meeting based on the above conclusions. MSC agreed that the dead line for submission of the data can be introduced to the DD by SECR when having considered the potential effect of addition of OECD 309 in DD. No further modifications were made.

TPE 029B/2013 2-piperazin-1-ylethylamine (EC No. 205-411-0)

Session 1 (open)

One representative of the Registrant participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

ECHA explained that earlier in the decision making process, ECHA split the DD into TPE-029A and TPE-029B where TPE-029A addresses the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity) and TPE-029B addresses the other information requirements. As TPE-029A/2013 had been agreed upon in WP on 8 April 2013, it and the four PfAs related only to the two-generation study is not addressed here.

Besides these four PfAs, another two PfAs to ECHA's DD (TPE-029B) were submitted by two CAs. Regarding long-term toxicity on terrestrial invertebrates, Earthworm reproduction test (OECD 222) proposed by the Registrant, one PfA proposed to use the following three options: Earthworm reproduction test (OECD 222), or Enchytraeid reproduction test (OECD 220) or Collembolan reproduction test (OECD 232). Alignment of Section III accordingly is also proposed by the same PfA. The other PfA proposed to conduct the 90-day repeated dose toxicity study by inhalation instead of oral administration because of the corrosive properties of the substance susceptible of producing critical local effects in the respiratory tract, possible inhalation exposure according to various exposure scenarios and the possible first-pass effects via the oral route.

SECR modified DD for MSC consideration based on the PfA concerning the route of administration in RDT study but not on the other PfA.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs disagreed with the PfA to conduct the 90-day study via inhalation instead of drinking water for animal welfare reasons (first, it is a corrosive substance, second, range finding studies are already available for drinking water but not for inhalation). The Registrant's comments relating only to the two-generation study are not addressed here. The Registrant also criticised DD regarding testing on effects to terrestrial organisms although no PfAs were provided on this part of DD.

The representative of the Registrant explained at the meeting that the Registrant is aware of that the local inhalation DNEL derived from a sub-chronic inhalation study may be lower than the derived systemic DNEL from the oral route. Furthermore, he stated that the substance is not used in pure form but in a formulation and that inhalation exposure is less relevant for consumers than dermal exposure is. Moreover, the Registrant indicated that proper risk management measures (RMMs) are already in place in industrial setting and the substance is handled with special care. Also exposure situations may have been overestimated when preparing the exposure assessment due to limited available information on real exposures. Therefore, instead of the complete 90-day inhalation study he proposed as a compromise to perform the 2-week dose-range finder study via inhalation which would provide the necessary dose descriptor to derive a local inhalation DNEL. In his view as already stated in the written comments on PfAs, the 90-day study via the oral route would be more appropriate to give indications for reproductive effects which the Registrant could use for deciding whether higher tier

reproductive studies (two-generation or EOGRTS) would be needed. He also mentioned that the Registrant could consider exposure based waiving of reproductive toxicity studies, based on the results from the oral sub-chronic study and the available exposure data.

SECR and the MSC member representing MSCA that submitted the PfA proposing inhalation route were of the view that CSR shows a significantly high inhalation exposure. SECR added that although the registration dossier can be updated any time, based on the current exposure data in CSR exposure based waiving would not be likely to be accepted by ECHA. SECR also highlighted that first, a reproductive toxicity screening study is already available that could be used as a dose range finder, second, the substance is corrosive and this is the major concern. Local effects related to the corrosivity cannot be properly evaluated via the oral route. Exposure assessment is currently based on oral data with RCRs being relatively high (up to 0.81). Therefore SECR is also convinced that a 90-day inhalation study is needed.

The representative of the Registrant claimed that performing a range finder study via inhalation and the 90-day study via the oral route would give the systemic NOAEL and the local DNEL at the same time. Furthermore, exposure data in CSR based on more recent information from downstream users should be updated reflecting lower inhalation exposure. Based on the above, he maintained his position for the 90-day study via oral route and the range finder study via inhalation. He also referred to TPE-002/2012 where according to his view a similar scenario was seen.

The representative of the Registrant expressed the wish to get a preliminary feedback from ECHA on his exposure based-waiving approach once it is established. SECR indicated that the provision of a preliminary assessment of information requested by means of a dossier evaluation decision is not part of ECHA's current practice and did not see grounds for deviating from this practice in this case.

Session 2 (closed)

ECHA explained that DDs are based on registration dossiers as of the date of the start of the MSCA consultation. Later updates cannot be taken into account for an already launched decision making process. MSC agreed that the hearing of registrants in Session 1 shall not be used for providing key information which would change the approach for the DD and that was not available in the registration dossier at the start of the MSCA consultation nor was part of the PfAs. Consequently, as in this case the Registrant's proposal for the 2-week range finding study via inhalation and the information on low inhalation exposure were neither available in the registration dossier nor mentioned in the written comments on the PfA but were only mentioned orally at the MSC meeting, MSC shall not consider this information in the current decision making and agreement seeking procedure. MSC also agreed that based on the above argumentation the Registrant's contribution in the discussion shall be properly recorded in the minutes but not reflected in the final decision.

The Chair noted that hearing of the representatives of registrants is not part of the formal decision making process as specified by the legal text. As the hearing option is provided only in those cases where a DD is discussed in Session 1 of the MSC meeting and a similar option is not available in those cases where DD is addressed in a WP, MSC has to take good care of equal treatment of registrants and not to let the oral contributions at the meeting to influence significantly the content of DD. The objective of the informal hearing is to give a possibility to MSC members and experts to ask further questions of clarification to understand better the basis for the final decision making.

MSC concluded that the 90-day repeated dose toxicity study shall be required via the inhalation route as proposed in a PfA but the argumentation in DD for the inhalation route shall be strengthened. MSC concluded that no amendment of the DD on the basis of the PfA on long-term toxicity on terrestrial invertebrates was necessary.

MSC found unanimous agreement on ECHA's DD as amended in the meeting based on the above conclusion.

TPE 028/2013 Hydrazine (EC No. 206-114-9)

Session 1 (open)

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

SECR explained that three PfAs were submitted to ECHA's DD. All of them suggest rejecting the 28-day repeated dose toxicity (RDT) study, mainly because the substance already has a harmonised classification as carcinogen cat 1B and corrosive. Therefore the results of the 28-day study would not affect risk management measures. One PfA also suggests adding a reminder to section III that the 28-day study may be omitted based on the CSR.

SECR responded to PfAs and did not modify the DD in advance of the meeting.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs agrees with them and confirms that he does not want to perform the 28-day study any longer.

In the introduction of the case, the SECR noted that this TP concerns an Annex X dossier, however the Registrant wants to use the 28-day RDT study for examining the most sensitive local effects and defining a lowest NOAEC.

The members from the MSCAs who made these PfAs further clarified the rationale behind the proposed TP rejection by specifying that the required information is already available and the test does not appear to be scientifically justified. They also pointed out that the CSR examination suggests that the exposure with the substance is well-controlled and the risk-driven testing does not seem necessary. The Registrant in the written comments on PfAs notes that a binding OEL under the EU worker protection legislation has recently been proposed for this substance, so there would not be a need to establish any DNEL under the REACH Regulation.

SECR noted that there is already information available on the local effects based on one year study which would be more relevant to establish the lowest concentration causing an irritation effect by inhalation than information from the proposed 28 day study by inhalation.

MSC concluded that this TP should be rejected as in this particular case, the Registrant has fulfilled the standard information requirements and no valid justification to conduct further studies based on column 2 of Annex X, 8.6.4 have been provided. SECR was requested to modify the DD according the above conclusions and to include the relevant justification for the line followed in the section III of DD.

Session 2 (closed)

MSC unanimously agreed to reject this TP based on legal and scientific justification as specified above.

MSC found unanimous agreement on ECHA's DD as amended in the meeting based on the conclusions of the discussion.

CCH 022/2013 Citronellol (EC No. 203-375-0)

Session 2 (closed)

SECR explained that agreement seeking on DD was sought in WP. However, WP was terminated by the Chair of MSC on request of a MSC member suggesting a reminder for the Registrant in DD to consider whether based on the results of the required *in vivo* micronucleus study another *in vivo* mutagenicity study addressing point mutations would be warranted (same PfA was submitted from the same MS). MSC concluded not to add the reminder to DD because it would not be relevant for a CCH DD which is only requesting information on the mutagenicity *in vitro*.

MSC found unanimous agreement on DD as provided for WP.

TPE 010/2013 Octadecanoic acid, branched and linear

TPE 011/2013 Fatty acids, C16-18 and C18-unsatd., branched and linear
TPE 012/2013 Isooctadecanoic acid
Session 2 (closed)
SECR explained that agreement seeking on these DDs part of the Fatty acids category was sought in WP. WP was terminated by the Chair of MSC on request of a MSC member. Following the member's request, the section III was further clarified explaining why the test (OECD 222) on earthworms would be the most relevant test for the substance although according to PfA of one CA three optional test species should be provided. The Registrant agreed to this PfA in the written comments. Also an editorial change was introduced based on the general MSC agreement at MSC-28 regarding the wording to be used for long term toxicity testing in aquatic environment where no difference in sensitivity between invertebrates and fish can be concluded.

MSC found unanimous agreement on these ECHA's DDs as amended in the meeting.

TPE 014/2013 Fatty acids, C18-unsaturated, dimers distillation product (EC No. 500-148-0)
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 a MSC member's proposal some editorial changes to be made in the DD (with regard to the identification of tested material composition). SECR did not agree that the proposed changes would be editorial only.

Following the SECR clarification, the MSC member from the CA proposing the modification withdrew their request for DD changes.

MSC found unanimous agreement on ECHA's DD as provided for the meeting.

TPE 026/2013 3-hydroxy-2-(hydroxymethyl)-2-methylpropionaldehyde (EC No. 242-393-3)
Session 2 (closed)
SECR explained that agreement seeking on DD was sought in WP. However, WP was terminated by the Chair of MSC on request of a MSC member suggesting a reminder for the Registrant in DD to consider whether based on the results of the required *in vivo* micronucleus study another *in vivo* mutagenicity study addressing point mutations would be warranted (same PfA was submitted from the same MS). MSC concluded to add the reminder to section III of DD.

MSC found unanimous agreement on DD as provided for WP and modified based on the above conclusion.

TPE 041A&B/2013 Reaction mass of α,α-4-trimethyl-(1S)-3-cyclohexene-1-methanol and α,α-4-trimethyl-(1R)-3-cyclohexene-1-methanol and 1-methyl-4-(1-methylethylidene)-cyclohexanol (Terpineol) (EC No. 232-268-1)
Session 2 (closed)
SECR explained that agreement seeking on these DDs was sought in WP. However, WP was terminated by the Chair of MSC on request of a MSC member suggesting a reminder for the Registrant in DD to consider whether further reproductive testing is necessary. In this member's view as expressed also in a PfA, based on available data of an OECD 422 study the Registrant could initiate a process for harmonised classification as toxic to reproduction 1B that would make further reproductive testing unnecessary. MSC concluded that a reminder for a classification-based possible adaptation of the requirement for a generation study shall be included in section III of TPE-041A/2013 only. MSC also concluded not to modify TPE-041B/2013 as provided for WP (because PfA only referred to TP for a two-generation reproductive toxicity study).

MSC found unanimous agreement on TPE-041B/2013 as provided for WP.

The Chair recognised the results of voting on TPE-041A/2013 as provided for WP and modified based on the above conclusion. As MSC did not reach a unanimous agreement on TPE-041A/2013 at the vote, ECHA will refer DD to COM which will prepare a decision

in accordance with the procedure of Article 133(3) of REACH. The Chair noted that SECR would use the justification for disagreement as provided in PfAs.

TPE 046A/2013 Slags, phosphorus-manufg (EC No. 273-732-3)
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 two MSC members from MSCAs that submitted PfAs requiring EOGRTS without the F2 generation instead of the two-generation study. One of these two members suggested that meeting discussion would be useful as in his view there is certain chance to reach a compromise agreement on DD (this member usually considers DNT/DIT cohorts necessary but not in this case). Also based on the available information on the substance it might be possible to consider that exposure to substance would be low thus giving a possibility to consider leaving out the request for F2. The other MSC member requesting the termination of WP on DD supported the idea of meeting discussion to possibly find a compromise agreement. One MSC member that submitted a PfA requesting EOGRTS without the F2 generation instead of the two-generation study made clear that a compromise agreement in her view is not possible because DNT/DIT cohorts would produce useful information and low exposure could not be confirmed for such substance.

The Chair recognised the results of voting on DD as provided for WP. As MSC did not reach a unanimous agreement on DD at the vote, ECHA will refer DD to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH. The Chair noted that SECR would use the justification for disagreement as provided in PfAs.

ECHA noted that due to an update to the registration dossier informing about cease of manufacture that is currently under further analysis with the Registrant the case TPE-046/2013 (including DD TPE-046B/2013 agreed in WP) might need to be withdrawn from the decision making procedure later on. MSC will be informed on further developments in the MSC-30 meeting at the latest.

e. Items for discussion following commenting by MSCAs (*Closed session)*
MSC was introduced with the comments submitted by some MSCAs on MSC-29 dossier evaluation cases and with the SECR's responses on them, as communicated to the commenting CA. The presentation was intended to show as an example how such comments are recorded at ECHA and how they will be taken into account later in the evaluation processes. Similar introduction to the comments submitted in the context of CA consultation will not be provided in the coming meetings. If a more generic issue is wished to be discussed at MSC a CA in the context of the CA consultation on DDs or a MSC member may propose a topic for agenda of a MSC meeting. MSC had no remarks to the approach followed.

f. Update on appeal cases *(Closed session)*
SECR provided MSC with feedback from the appeal cases on dossier evaluation decisions.

g. Status report on on-going evaluation work
SECR gave detailed statistics on the status of dossier evaluation (DEv) work until 31 March 2013. Some statistics regarding the MSC-29 round were introduced and a short analysis based on the type of the PfAs received for DDs in that round was presented. It was mentioned that 69 DDs had been referred to MSCAs and 39 DDs received PfAs. Further, the expected workload for 2013 was outlined.

SECR gave a brief overview of the compliance check evaluations and the testing proposal examinations, as well as a status update on UDS-TGR discussions and developments. MSC was informed of the publication of the report on the technical discussion session of October 2012, and on the roadmap for the update of the ECHA Guidance on IR&CSR (Chapter 7). MSC was also debriefed on the outcome of the Areas of Concern Expert meeting held prior to this MSC meeting.

MSC took note of the report. A member requested for the reasons why the initially expected number of DDs (285 DDs) for MSC-30 round was finally dropped to 43 DDs only. SECR noted that the DD numbers are outlining the expected DEv workload in the coming months and they are only provisional as a lot of elements need to be considered before the MSCA consultation on the cases can be started. With regard to the MSC-30 round, it was further explained that the big number of expected DDs was due to the large categories envisaged to be submitted to the MSCAs under this round; however, due to some difficulties encountered with the category approaches or updates to the dossiers, their submission was postponed for some of the following DEv CA consultations.

Item 7 – Substance evaluation

CoRAP and substance evaluation

- **Short update by the Secretariat**

SECR provided a short update to MSC as regards status of substance evaluation for substances listed on the CoRAP for evaluation in 2012. Out of the 36 substances that were evaluated by Member States (MSs), for 32 of them a draft decision (DD) had been issued to the Registrants. Besides the brief overview of the content of the DDs, the next steps in the process were explained to MSC. In its report on the progress in activities in substance evaluation SECR described the on-going work by MSs and ECHA for development of the CoRAP update for year 2014-2016. The presentation contained also information about the upcoming substance evaluation workshop (23-24 May 2013 in ECHA), the aims of the workshop and what type of contributions were still expected.

In the discussion some clarifying questions were made by an NGO observer about the number of PBTs and possibility for reimbursement of costs from participation to the upcoming workshop. In the response it was explained that there had been 12 substances where their PBT-ness had been marked as an additional concern, not that those were necessarily the only potential PBT substances for which a decision had been drafted. SECR clarified that the workshop is open for Accredited Stakeholder Observers of MSC but in line with other workshops no reimbursement for them was foreseen. No change to this practice is possible in a short notice. Industry observer thanked ECHA for preannouncing about the DDs to be issued as the 30 day period for commenting by possibly multiple registrants' is very tight. Consideration of special dossier updates was brought up by one member as something needing further clarification. SECR acknowledged that it is difficult to anticipate all scenarios in advance and suggested that some basic rules on dossier updates during the substance evaluation could be discussed in the upcoming workshop. One member informed MSC that her MS has approached ECHA in order to add one substance on the CoRAP based on Article 45(5) before the next full update.

Item 8 – Authorisation process

a. SVHC identification

1) Short status report by the secretariat on the on-going round

MSC Chair informed MSC of two SVHC proposals suggesting identification based on PBT/vPvB for which the "T" for identification as PBT is proposed based on STOT-RE without harmonised classification for this hazard property. As MSC has no competence in classification of the substances the ECHA Executive Director decided to request under Article 77 (3) the Committee for Risk Assessment (RAC) to prepare an opinion on whether the criteria for STOT-RE 1 or 2 are met. The RAC opinion is not meant to be used for harmonised classification of the substance but the purpose would be to help MSC in their agreement seeking on SVHC identification for these two substances.

SECR presented some statistical data on the public consultation and made a short overview on the comments received on the 10 SVHC proposals in this round.

MSC was further informed of the SECR's intention to organise a SVHC preparatory meeting on 22 May 2013 (an advance information on the potential event had been provided by e-mail already), back-to-back to the SEV Workshop in order to provide MSC

members and dossier submitters with the opportunity to exchange views based on specific SVHC proposals and to facilitate the MSC agreement seeking process at MSC-30 in June.

In the following discussion, a member whose CA submitted several SVHC proposals in the current SVHC round questioned the need and usefulness of such a meeting and suggested to ask also the dossier submitters whether they would have an interest to participate in such a meeting. It was agreed that SECR will send a message to MSC inviting the recipients to confirm to SECR in writing by 29 April 2013 their intention to participate in the potential SVHC Preparatory Meeting on 22 May 2013.

2) Update on court cases

SECR gave a short overview of SVHC Court cases T-93 to T-96/10 for which judgement decisions are available on the website of the European Court of Justice. The main considerations regarding the SVHC identification decisions were related to some procedural issues, admissibility of the actions undertaken and whether UVCB substances can be identified as PBTs on the basis of their constituents. The Court issued its judgements in these cases dismissing the actions of the Appellants as unfounded. MSC was also informed of the state of art of two other cases C-625/11 and C-626/11 on acrylamide (where in the first one the applicant challenged the MSC agreement on the SVHC identification of the substance and in the second one a question was raised whether the appellant filed action on time). Members were also informed of two new appeals recently submitted to the Court (T-134/13 and T-135/13), requesting for annulment of the SVHC identification decisions on HHPA and MHHPA. The presentation with further details on the cases has been uploaded to MSC CIRCABC.

3) Short report from ECHA workshop on implementation of the 2020 SVHC Roadmap

SECR reported briefly from the ECHA workshop on the implementation of the SVHC Roadmap 2020, held in ECHA on 17-18 April 2013. It was noted that there is wide agreement on the need for the SVHC 2020 Roadmap, on its main elements (screening, RMO analysis and communication) and on the need to share the work. The aim of the workshop was to start preparing a SVHC 2020 Roadmap Implementation Plan and the main discussions held concerned the practical work on groups of substances, streamlining RMO analyses (RMOA), as well as the need for an open and transparent communication on the Roadmap implementation.

Two MSC observers representing NGOs stated that they do not support the use of RMOAs as there are no legal requirements in REACH Regulation for preparing RMOAs. They expressed their concerns that performing such RMO analyses would further slowdown the SVHC identification process. When reporting back from the discussion if there could be overarching reasons for not wanting a substance to be substituted (not even in long term) the question was raised what nature such reasons were.

SECR stressed that the main aim of the authorisation process is substitution of SVHCs and ensuring proper control of such substances until the time substitution has taken place as well as good functioning of the internal market. According to the concept, the RMO analyses should be done by the CAs (or by ECHA if COM requested a proposal from ECHA) before the formal SVHC identification procedure starts, as it is in MSs or COM discretion to decide on how to proceed with a substance and whether to make a SVHC proposal or use other regulatory risk management instruments. Therefore there can be no question about breach of legislation as at the preparatory stage no provisions of REACH apply and making proposals is in the hands of the MSs/COM.

An MSC industry observer asked for clarification how the relevant information for deriving streamlined RMOA will be collected, as such information is not always available in the submitted registration dossier.

SECR responded that as analysing RMOs is a different, not legally binding process comparing with the formal public consultations considered under the formal REACH

processes, each MS, while analysing different RMOs, would have the right to decide whether, when and how to collect RMO-related comments.

The Roadmap implementation plan including a communication plan will be discussed in the ad-hoc CARACAL meeting in July in Helsinki.

4) Update of MSC Working Procedures on identification of SVHCs

Due to time constrains, the MSC adoption of the updated MSC working procedure on identification of SVHCs would be sought after the meeting in written procedure.

b. Prioritisation of Candidate List substances for inclusion in Annex XIV

1) Discussion on the prioritisation results of the selected substances for the next recommendation for inclusion of substances in Annex XIV and the preliminary draft recommendation (1st discussion)

2) Invitation for volunteers for Rapporteurship and membership in MSC Working Group

SECR presented the draft prioritisation results describing how and which substances had been assessed for this round. Of the 67 substances added to the Candidate List in 2012 priority has not been assessed for the 37 substances requested by the COM in August 2012 as the Annex XV reports do not include Part II. Another 12 substances for which there are no full registrations available have also not been assessed now. One further substance was assessed since - although not itself registered - relevant information could be retrieved from the registration of the reactant. In addition priority was assessed for the two consolidated entries for Refractory Ceramic Fibres (RCFs) leading to a total of 20 substances that were assessed for their priority now, following the current prioritisation approach. Substances previously assessed and not prioritised were not re-assessed this time. However, SECR made clear that substances not (re-)assessed this round will be considered in following recommendations.

SECR explained that number of substances to be recommended this year is affected by the need to ensure workability as influenced by the Agency's capacity to handle applications. However, all substances with highest scores are prioritised. Six substances with three different latest application dates were included in the draft recommendation (N,N-dimethylformamide (DMF), 4-tert-Octylphenol ethoxylates, Bis(pentabromophenyl)ether, Diazene-1,2-dicarboxamide, Aluminosilicate RCFs and Zirconia Aluminosilicate RCFs). MSC also heard about some challenges that SECR faced while assessing the priority if the registration data do not fully match the substance identity on the Candidate List as in the case of the RCFs.

Several members in their initial reactions questioned the inclusion of DMF into the draft recommendation. They claimed that authorisation is not seen as the best regulatory measure for DMF, thereby also referring to the RMOA prepared by BE. Furthermore, it was commented that exposure information used (wide-dispersiveness of use, number of sites) was not a valid measure of exposure, that risks seemed controlled in industrial settings and that it is difficult to understand why for some other solvents restrictions were proposed while this was not the case for DMF. In its response SECR justified that the starting point for the prioritisation to Annex XIV was the substances included in the Candidate List. As regards RCFs one member was concerned that it will be difficult to assess which products in the market meet the characteristics of the substances included in the authorisation list. One member noted that her MS is preparing a nomination of bis(pentabromophenyl)ether for POP's Review Committee's assessment and possible inclusion to the list of substances under the Stockholm Convention.

Some observers expressed concerns about the low number of substances proposed to be prioritised this round and ECHA using workload as an argument for not assessing priority of all the substances on the Candidate List. SECR replied that all substances will be assessed even if not in this round. Attention has to be paid also to the fact that a recommendation is required to be provided to the Commission only every second year, and ECHA has followed a practice to provide the recommendation once a year. This ensures that the legal requirements are well met. Echoing an intervention of one member SECR also assured that there will be possibility to add new substances to the

authorisation list if the process proves to be quicker than expected. One Industry Observer pointed out that given the high number of SMEs involved in the supply chain, difficulties related to identifying what is being covered by Candidate List and possibly high number of applications expected for RCFs, the latest application dates in the draft recommendation for those substances deserve still to be reviewed to avoid collation with chromates. SECR in its response promised to look at the issue from that perspective again.

The Chair concluded the discussion by inviting the participants to submit by 15 May any of their expressed concerns or still other ones based on the preliminary draft recommendation by email. Those could then be considered and analysed before the second discussion in June.

The Secretariat informed the Committee that volunteers for rapporteur and members of the working group are needed to be responsible for preparation of the MSC opinion on ECHA's draft recommendation for inclusion of substances to Annex XIV. The Secretariat will send out a request in this regard immediately after the meeting.

Item 9 – Report from other ECHA bodies and activities

- **Feedback from ECHA Management Board on MSC RoP**

The Chair informed MSC that ECHA's Management Board had approved the update of the MSC Rules of procedure in its March meeting, and the updated version is now valid and available in CIRCABC and on ECHA website.

Item 10 – Any other business

- **Commission's conclusions on the review of REACH**

The COM observer introduced MSC with the conclusions of the European Commission from the legal review of the REACH Regulation. Further, more specific conclusions and recommendations, in particular such of relevance to the work of MSC were shared.

Following some questions raised by the MSC observers, the COM observer pointed out that the REACH review was done on the basis of the progress made in last 5 years, where it is seen that all elements of REACH are working and all mechanisms developed function well. It was highlighted that it is important to investigate further the possible ways to improve efficiency, targeting and adequate use of the available resources.

- **Presentation on low toxicity substances by ECEAE**

An MSC observer from ECEAE gave a presentation on a WoE approach for justifying waiving of the 90-d RDT studies under REACH. The hypothesis is that 90-day RDT study would not bring any new useful information in the case of low toxicity substances and thus 90 day study would not be needed. The low toxicity substances are defined by information on low acute toxicity, no adverse effects in 28-day RDT study as well as negative genotoxicity, sensitisation and irritation studies. The ECHA CHEM database was used to identify substances for which data on substances (available by April 2012) on both 28- and 90-d oral toxicity studies performed with rodents were available and considering the other conditions for low toxicity of the selected substances. ECEAE ended up with 19 substances with "potential low toxicity" for which it seemed that the available 90-day RDT study did not bring any further useful toxicological information and therefore according to their view 90-day study could in these kinds of cases be waived. Based on this, ECEAE made some other proposals as indicated in their presentation (made available in MSC CIRCABC).

An MSC member shared his view on some of the data provided in the ECEAE review report, like the observations that quite low number of substances has been found in the review outcome and most of these substances with "potential low toxicity" are natural, large molecular substances. He recalled that REACH lays down the opportunity to waive from testing by using QSARs and other modelling that could be applied for these "potential low toxicity" substances. Further, the member gave a recommendation for exploring 28-day RDT studies performed with higher doses and not with a limit dose, as this would provide more conclusive sign on the relationship with the 90-d RDT study. It

was also indicated by him that 90-day study provides higher statistical power than 28-day study leading to less uncertainty.

Another member pointed out that this is not a new issue and it would be possible to take a case-by-case decision that 90-d study is not needed when good substance documentation for low toxicity is submitted. It was also noted that currently there are no general exclusion criteria for the need for 90-d RDT testing.

SECR expressed its satisfaction that the ECHA dissemination database is found valuable and is used for such projects. It was also mentioned that the REACH legislators have already included adaptation possibilities for waiving the 90-d RDT study based column 2 conditions (including available 28-d study results) of Annex IX, 8.6.2, as well as weight of evidence approach as specified in Annex XI, 1.2.

- **Suggestions from members**

No suggestions from the MSC members had been received for this Agenda item.

Item 11 – Adoption of conclusions and action points

MSC will adopt the conclusions and action points after the MSC-29 meeting in written procedure (see Section IV).

SIGNED

Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
ANASTASI Audrey Anne (MT) (alternate member)
BIWER, Arno (LU)
COSGRAVE, Majella (IE)
CRUZ, Ana Lúcia (PT)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
HUMAR-JURIC, Tatjana (SI)
KULHANKOVA, Pavlina(CZ)
LULEVA Parvoleta (BG)
MAJKA Jerzy (PL) (alternate member)
MARTIN, Esther (ES)
MIHALCEA-UDREA, Mariana (RO)
PEDERSEN Finn (DK) (alternate member)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TALASNIEMI Petteri (FI)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
WIJMENGA Jan (NL)
Representatives of the Commission
GARCÍA JOHN Enrique (DG ENTR)
KOBE, Andrej (DG ENV)
Observers
ANNYS, Erwin (CEFIC)
HIESTER Elizabeth (ClientEarth)
MUSU, Tony (ETUC)
SANTOS Tatiana (EEB)
STAIRS Kevin (Greenpeace)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
BALOGH, Attila
BONNOMET, Vincent
BRAUNSCHWEILER, Hannu
BROERE, William
CARLON, Claudio
DE COEN, Wim
DEYDIER, Laurence
DE COEN, Wim
DE WOLF, Watze
DOMINGUEZ ESTEVEZ, Manuel
FEEHAN, Margaret
HALLING Katrin
HAUTAMÄKI, Anne
HUUSKONEN, Hannele
KARJALAINEN, Anne-Mari
KARHU, Elina
MELZER, Kai
MÜLLER, Birgit
NAUR, Liina
PREVEDOUROS, Konstantinos
RAHKONEN, Olli
REUTER, Ulrike
RUOSS, Jürgen
RÖNTY, Kaisu
SIMON, Rupert
SOBANSKA, Marta
STILGENBAUER, Eric
SUNDQUIST, Anna-Liisa
TARAZONA, José
VAHTERISTO, Liisa
VASILEVA, Katya

Proxies

LULEVA, Parvoleta (BG) also acting as proxy of KOUTSODIMOU, Aglaia (EL)
LULEVA, Parvoleta (BG) also acting as proxy of KYPRIANIDOU LEONTIDOU Aglaia (CY)
MARTÍN Esther (ES) also acting as proxy of DRUGEON Sylvie (FR)
COSGRAVE Majella (IE) also acting as proxy of DOUGHERTY Gary (UK) in the afternoon of 25 April

Experts and advisers to MSC members

ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BOUWMAN Tialda (NL) (adviser to WIJMENGA, Jan)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
HERBST, Uta (DE) (adviser to FINDENEGG, Leni)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH Susan (FI) (adviser to TALASNIEMI Petteri)
LUNDBERGH, Ivar (SE) (expert to FLODSTRÖM, Sten)
MALKIEWICZ, Katarzyna (SE) (adviser to FLODSTRÖM, Sten)
MEYS Catherine (BE) (expert to VANDERSTEEN, Kelly)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)

RÜHL Dana (DE) (expert to FINDENEGG, Helene)
SMITH Helen (UK) (expert to DOUGHERTY, Gary)
TRAAS, Theo (NL) (expert to WIJMENGA Jan)
ULDUKIENE Vilma (LT) (expert to DUNAUSKIENE Lina)

By WEBEX-phone connection:
BORRAS HERRERO Anna, ROZWADOWSKI Jacek and STRECK Georg from EC during agenda items 7 and 8.

Case owners:
Representatives of the Registrant were attending under agenda item 6c for CCH-023/2013, TPE-004/2013 and TPE-029B/2013.

Apologies:
ANDRIJEWSKI Michal (PL)
CAMILLERI Tristan (MT)
DRUGEON Sylvie (FR)
KOUTSODIMOU Aglaia (EL)
KYPRIANIDOU LEONTIDOU Tasoula (CY)
TYLE Henrik (DK)

III. Final Agenda

ECHA/MSC-29/2013/A/29 Draft agenda

Final Agenda
29th meeting of the Member State Committee

24-25 April 2013
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

24 April: **starts at 9:00**
25 April: **ends at 18:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/029/2013
For adoption

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

Item 4 – Administrative issues

- Tentative MSC meeting dates for 2014

ECHA/MSC-29/2013/001
For information

Item 5 – Minutes of the MSC-28

- Minutes of MSC-28

For information

Item 6 – Dossier evaluation

Closed session for 6b3 & 6d-f
Indicative time plan for 6c is Day 1, for 6d Day 1&2

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

ECHA/MSC-29/2013/002
For information

b. General topics

1) Update on developments concerning 'generation studies' for reproduction toxicity

For information and discussion

2) Improving Consistency in the Evaluation of Terrestrial Testing Proposals - revised proposal following MSCA comments and considerations *and* Scientific Discussion paper on Terrestrial microorganisms

ECHA/MSC-29/2013/013
For information and discussion

3) Discussion on Areas of Concern-approach *(Closed session)*

For discussion

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:

ECHA/MSC-29/2013/005

Compliance checks

CCH 023/2013 Dibutyltin oxide (EC No. 212-449-1)

ECHA/MSC-29/2013/006-007

Testing proposals

TPE 001/2013 Dibenzoyl peroxide (EC No. 202-327-6)

ECHA/MSC-29/2013/003-004

TPE 004/2013 3-hydroxy-1,1-dimethylbutyl 2-ethyl-2-methylheptaneperoxoate (EC No. 413-910-1)

ECHA/MSC-29/2013/008-009 & 020

TPE 029B/2013 2-piperazin-1-ylethylamine (EC No. 205-411-0)

ECHA/MSC-29/2013/010 & ECHA/MSC/D/2013/077

TPE 028/2013 Hydrazine (EC No. 206-114-9)

ECHA/MSC-29/2013/010-011

For information and discussion

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

As listed above under **6c** and any cases returned from written procedure for agreement seeking in the meeting:[1]

- CCH 022/2013 Citronellol (EC No. 203-375-0)
  ECHA/MSC/D/2013/0025-0026
- TPE 010/2013 Octadecanoic acid, branched and linear
  ECHA/MSC/D/2013/0043-0044
- TPE 011/2013 Fatty acids, C16-18 and C18-unsatd., branched and linear
  ECHA/MSC/D/2013/0045-0046
- TPE 012/2013 Isooctadecanoic acid

[1] Note to members: The documents listed below are available in the substance specific folders in CIRCABC, as were made available for the written procedure, and are not available in the MSC-29 folders.

ECHA/MSC/D/2013/0047-0048

- TPE 014/2013 Fatty acids, C18-unsaturated, dimers distillation product (EC No. 500-148-0)

ECHA/MSC/D/2013/0051-0052

- TPE 026/2013 3-hydroxy-2-(hydroxymethyl)-2-methylpropionaldehyde (EC No. 242-393-3)

ECHA/MSC/D/2013/0071-0072

- TPE 041A&B/2013 Reaction mass of α,α-4-trimethyl-(1S)-3-cyclohexene-1-methanol and α,α-4-trimethyl-(1R)-3-cyclohexene-1-methanol and 1-methyl-4-(1-methylethylidene)-cyclohexanol (Terpineol) (EC No. 232-268-1)

ECHA/MSC/D/2013/027-028 & 097

- TPE 046A/2013 Slags, phosphorus-manufg (EC No. 273-732-3)

ECHA/MSC/D/2013/094&096

For agreement

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

Items from current cases if not addressed during 6c

For discussion

f. Update on appeal cases *(Closed session)*

For information

g. Status report on on-going evaluation work

For information

Item 7 – Substance evaluation

CoRAP and substance evaluation

- Short update by the secretariat

For information

Item 8 – Authorisation process

Tentatively closed session for 8a.3

a. **SVHC identification**

1) Short status report by the secretariat on the on-going round

For information

2) Update on court cases

For information

3) Short report from ECHA workshop on implementation of the 2020 SVHC Roadmap

For information

4) Update of MSC Working Procedures on identification of SVHCs

ECHA/MSC-29/2013/014

For discussion and possible adoption

b. Prioritisation of Candidate List substances for inclusion in Annex XIV

1) Discussion on the prioritisation results of the selected substances for the next recommendation for inclusion of substances in Annex XIV and the preliminary draft recommendation (1st discussion)

ECHA/MSC-29/2013/015-016

For discussion

2) Invitation for volunteers for Rapporteurship and membership in MSC Working Group

ECHA/MSC-29/2013/018

For discussion

Item 9 – Report from other ECHA bodies and activities

- Feedback from ECHA Management Board on MSC RoP

For information

Item 10 – Any other business

- Commission's conclusions on the review of REACH
- Presentation on low toxicity substances by ECEAE

ECHA/MSC-29/2013/019

- Suggestions from members

For information

Item 11– Adoption of conclusions and action points

- Table with conclusions and action points from MSC-29

For adoption

IV. Main Conclusions and Action Points

(adopted on 8 May 2013 in written procedure)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 - Administrative issues • Tentative MSC meeting dates for 2014	
MSC took note of the planned meetings for 2014.	MSC-S to upload the tentative meeting dates on MSC CIRCABC & ECHA website.
Item 6 - Dossier evaluation **6a. 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/cover letters on cases agreed in written procedure, as indicated in document ECHA/MSC-29/2013/002. • MSC-S to provide COM for further decision making with documents (DDs, RCOMs, extract of minutes, outcome of the vote, justifications for NO votes) of cases on which MSC did not reach agreement, as indicated in document ECHA/MSC-29/2013/002.
6b. General topics 1) Update on developments concerning 'generation studies' for reproduction toxicity	
MSC took note of COM's status report on the - planned update of the Test Methods Regulation and the relevant REACH Annexes concerning 'generation studies' - preparatory activities of a planned pilot study to evaluate particularly the relevance of the second generation in case of high exposure and low toxicity.	
6b. General topics 2) Improving Consistency in the Evaluation of Terrestrial Testing Proposals - revised proposal following MSCA comments and considerations and Scientific Discussion paper on Terrestrial microorganisms	
MSC took note of the proposed approach to be followed in the evaluation of terrestrial testing proposals.	Members to submit to SECR any remaining comments on the proposed approach on terrestrial testing evaluation and on scientific discussion paper on terrestrial microorganisms by 15 May 2013
6b. General topics Discussion on Areas of Concern - approach	
MSC took note of ECHA's implementation plans for AoC in compliance check work and the concerns expressed by DE.	MSCAs and SECR to continue discussion at CARACAL.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
6c. Introduction to and preliminary discussion on draft decisions on one compliance check and testing proposals after MS-CA reactions (*Session 1, open*) **6d. Seeking agreement on draft decisions on testing proposals and compliance checks when amendments were proposed by MS's *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting where appropriate: • CCH 022/2013 Citronellol (EC No. 203-375-0) • CCH 023/2013 Dibutyltin oxide (EC No. 212-449-1) • TPE 001/2013 Dibenzoyl peroxide (EC No. 202-327-6) • TPE 004/2013 3-hydroxy-1,1-dimethylbutyl 2-ethyl-2-methyl-heptaneperoxoate (EC No. 413-910-1) • TPE 010/2013 Octadecanoic acid, branched and linear (EC No. 269-214-1) • TPE 011/2013 Fatty acids, C16-18 and C18-unsatd., branched and linear (EC No. 273-295-9) • TPE 012/2013 Isooctadecanoic acid (EC No. 250-178-0) • TPE 014/2013 Fatty acids, C18-unsaturated, dimers distillation product (EC No. 500-148-0) • TPE 026/2013 3-hydroxy-2-(hydroxymethyl)-2-methylpropion-aldehyde (EC No. 242-393-3) • TPE 028/2013 Hydrazine (EC No. 206-114-9) • TPE 029B/2013 2-piperazin-1-ylethylamine (EC No. 205-411-0) • TPE 041B/2013 Reaction mass of α,α-4-trimethyl-(1S)-3-cyclohexene-1-methanol and α,α-4-trimethyl-(1R)-3-cyclohexene-1-methanol and 1-methyl-4-(1-methylethylidene)-cyclohexanol (Terpineol) (EC No. 232-268-1)	MSC-S to upload on MSC CIRCABC the final ECHA decisions/cover letters of the agreed cases.
MSC could not reach unanimous agreement on the following draft decisions in the meeting: • TPE 046A/2013 Slags, phosphorus-manufg (EC No. 273-732-3) • TPE 041A/2013 Reaction mass of α,α-4-trimethyl-(1S)-3-cyclohexene-1-methanol and α,α-4-trimethyl-(1R)-3-cyclohexene-1-methanol and 1-methyl-4-(1-methylethylidene)-cyclohexanol (Terpineol) (EC No. 232-268-1)	MSC-S to provide COM for further decision making with the relevant documents (DD on generation testing, RCOM, minutes, outcome of the vote, justification for the position at the vote).
6e. Items for discussion following commenting by MSCAs (*Closed session*)	
MSC took note of the SECR's proposal for dealing with the MSCA comments on dossier evaluation cases and had no further remarks to it.	
Item 7 – Substance evaluation **CoRAP and substance evaluation** • Short update by the secretariat	
MSC took note of the report on the ongoing work on the first substance evaluation draft decisions, work for the next update of the CoRAP and the planned workshop on substance evaluation on 23-24 May 2013.	• Members planning to attend the workshop to register to the event by 26 April.
Item 8 – Authorisation process **a. SVHC identification**	
1) Short status report by the secretariat on the on-going round	• SECR to request in writing members' view on the need for a Preparatory Meeting on SVHC proposals planned for 22 May 2013 and their participation interest after

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
4) MSC Working Procedures on identification of SVHCs – update	the meeting. • Members to indicate to SECR their intention to participate in the SVHC Preparatory Meeting by 15,00h (CET+1) on 29 April 2013, • SECR to launch a written procedure for adoption of the updated MSC Working procedure on SVHC identification after the meeting
Item 8 – Authorisation process **b. Prioritisation of Candidate List substances for inclusion in Annex XIV**	
1) Discussion on the prioritisation results of the selected substances for the next recommendation for inclusion of substances in Annex XIV and the preliminary draft recommendation (1st discussion) MSC took note of the work carried out for the 5th draft recommendation for inclusion of priority substances in Annex XIV. SECR took note of the oral comments for further consideration. 2) Invitation for volunteers for Rapporteurship and membership in MSC Working Group	MSC to provide written comments on the prioritisation results and draft Annex XIV entries by 15 May 2013. SECR to launch call for expression of interests for volunteers for the Rapporteur and WG members by 3 May.
Item 11 – 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.	SECR to upload the conclusions and action points on MSC CIRCABC for written adoption by 8 May 2013.

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

Draft decisions unanimously agreed by MSC in WP:

MSC ID number	Substance name used in draft decision	EC No
CCH 011/2013	Acetone	01-2119498062-37-0000
TPE 002B/2013	Sulphamidic acid	01-2119488633-28-0000
TPE 005/2013	Climbazole	01-2119615553-43-0000
TPE 006/2013	Cyanoguanidine	01-2119474914-28-0000
TPE 007B/2013	Tris (2-butoxyethyl) phosphate	01-2119485835-23-0000
TPE 008/2013	Heptanoic acid	01-2119463877-21-0000
TPE 009/2013	Oil shale, terminal processing waste	01-2119703178-42-0000
TPE 013/2013	Fatty acids, C16-18 and C-18 unsaturated	01-2119493912-29-0000
TPE 014/2013	Fatty acids, C18-unsaturated, dimers distillation product	01-2119493908-18-0000
TPE 015/2013	Fatty acids, C18-unsaturated, dimers hydrogenated	01-2119493916-21-0000
TPE 016/2013	Fatty acids, C18-unsaturated, trimers	01-2119491290-41-0000
TPE 017/2013	3-((5-(3-(Dodecanoyloxy)-2,2-dimethylpropylideneamino)-1,3,3-trimethylcyclohexyl)methylimino)-2,2-dimethylpropyl dodecanoate	01-2119880654-28-0000
TPE 019/2013	Reaction products of N,N'-ethane-1,2-diylbis(1,3-propanediamine), cyclohexane, peroxidized 4-butylamino-2,2,6,6-tetramethylpiperidine and 2,4,6-trichloro-1,3,5-triazine	01-2119921610-50-0000
TPE 020B/2013	Reaction products of N,N'-ethane-1,2-diylbis(1,3-propanediamine), cyclohexane, peroxidized 4-butylamino-2,2,6,6-tetramethylpiperidine and 2,4,6-trichloro-1,3,5-triazine	01-2119933862-33-0000
TPE 022/2013	2-ethyl-N,N-bis(2-ethylhexyl)hexylamine	01-2119896439-16-0000
TPE 023B/2013	Alkenes, C13-14, hydroformylation products, distn. residues	01-2119561659-24-0000
TPE 024/2013	Isobutyric acid, monoester with 2,2,4-trimethylpentane-1,3-diol	01-2119441305-48-0000
TPE 027/2013	Fatty acids, tall-oil, reaction products with triethanolamine	01-2119510712-51-0000
TPE 030B/2013	Octene, hydroformylation products, high-boiling	01-2119486463-31-0000
TPE 034B/2013	Barium chloride	01-2119502547-42-0000

TPE 035/2013	Silver	01-2119555669-21-0000
TPE 036/2013	Silver nitrate	01-2119513705-43-0000
TPE 037/2013	Disilver oxide	01-2119513370-54-0000
TPE 038/2013	Bis(4-chlorophenyl) sulphone	01-2119531800-49-0000
TPE 039B/2013	Calcium cyanamide	01-2119777581-29-0000
TPE 040/2013	(Z)-docos-13-enamide	01-2119519225-45-0000
TPE 046B/2013	Slags, phosphorus-manufg	01-2119489798-09-0000

Draft decisions to be referred to COM:

MSC ID number	Substance name used in draft decision	EC No
TPE 002A/2013	Sulphamidic acid	01-2119488633-28-0000
TPE 007A/2013	Tris (2-butoxyethyl) phosphate	01-2119485835-23-0000
TPE 020A/2013	Reaction products of N,N'-ethane-1,2-diylbis(1,3-propanediamine), cyclohexane, peroxidized 4-butylamino-2,2,6,6-tetramethylpiperidine and 2,4,6-trichloro-1,3,5-triazine	01-2119933862-33-0000
TPE 023A/2013	Alkenes, C13-14, hydroformylation products, distn. residues	01-2119561659-24-0000
TPE 029A/2013	2-piperazin-1-ylethylamine	01-2119471486-30-0000
TPE 030A/2013	Octene, hydroformylation products, high-boiling	01-2119486463-31-0000
TPE 034A/2013	Barium chloride	01-2119502547-42-0000
TPE 039A/2013	Calcium cyanamide	01-2119777581-29-0000

Draft decisions that written procedure was terminated for:

MSC ID number	Substance name used in draft decision	EC No
CCH 022/2013	Citronellol	01-2119453995-23-0000
TPE 010/2013	Octadecanoic acid, branched and linear	01-2119488532-32-0000
TPE 011/2013	Fatty acids, C16-18 and C18-unsatd., branched and linear	01-2119493909-16-0000
TPE 012/2013	Isooctadecanoic acid	01-2119493913-27-0000
TPE 026/2013	3-hydroxy-2-(hydroxymethyl)-2-methylpropionaldehyde	01-2119494916-20-0000
TPE 041A/2013	Reaction mass of α,α-4-trimethyl-(1S)-3-cyclohexene-1-methanol and α,α-4-trimethyl-(1R)-3-cyclohexene-1-methanol and 1-methyl-4-(1-	01-2119553062-49-0000

	methylethylidene)-cyclohexanol	
TPE 041B/2013	Reaction mass of α,α-4-trimethyl-(1S)-3-cyclohexene-1-methanol and α,α-4-trimethyl-(1R)-3-cyclohexene-1-methanol and 1-methyl-4-(1-methylethylidene)-cyclohexanol	01-2119553062-49-0000
TPE 046A/2013	Slags, phosphorus-manufg	01-2119489798-09-0000