MSC/M/030/2013
ADOPTED by written procedure
on 4 September 2013

Minutes
of the 30th Meeting of the Member State Committee (MSC-30)
11-14 June 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 30th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

The Executive Director of ECHA Mr Geert Dancet made a greeting address to the MSC members highlighting the high productivity and commitment of MSC in the last years and the importance of the Committee's contributions to the smooth proceedings of the REACH processes. Members were encouraged to be more active and were invited to share their views for improving the work efficiency in the light of the increasing MSC workload, in particular with regard to the substance and dossier evaluation processes.

One member made a remark on the limited capacity and competence of the smaller EU MSs comparing with the bigger ones that are able to provide more expertise and to contribute to the larger extent in all areas of the Committees' work.

Item 2 - Adoption of the Agenda

The Agenda was 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

One member declared potential conflict of interest in respect to the dossier evaluation case TPE 072/2013 based on the annual declaration as published on the ECHA website and was therefore considered not to be in a position to participate in the vote for this case.

Item 4 - Administrative issues

SECR requested the members to provide feedback from the travel and accommodation services of the new travel agency and apologised for the problems met during the organisation of the members' participation in the current meeting.

MSC was also informed of the SECR's plans regarding the preparation of the minutes of the current meeting with extension of 5 weeks for members' commenting due to the summer holiday period.

Item 5 – Adoption of the minutes of the MSC-29 meeting

The minutes of MSC-29 were adopted as provided for the meeting.

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 five dossier evaluation cases (see Section V for more detailed identification of the cases). WP was launched on 17 April and closed on 2 May 2013. For one case, the draft decision (DD) was split thus resulting in two DDs for this case and overall seven DDs for the six cases. By the closing date, responses to WP were received from 24 members with voting rights and from the Norwegian member. Unanimous agreement was reached on two DDs. For five DDs, 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-30 meeting.

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

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

TPE 049/2013 2-{N-[2,6-Diamino-4-oxo-4H-pyrimidin-(5Z)-ylidene]-hydrazino}-5-methyl-benzenesulfonic acid (List No. 700-002-8)

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 one PfA to ECHA's DD was submitted suggesting acceptance of the PNDT study proposed by the registrant (and proposed to be rejected by ECHA). The main arguments of the submitting CA for the PNDT study were as follows: (1) as no detailed information is provided on use, the most probable route cannot be identified (and consequently, solid conclusions for low toxicity from the available 28-day study cannot be drawn) (2) a 28-day study does not cover the toxic endpoints for reproductive and developmental toxicity (3) the screening study required on this tonnage level (Annex VIII) does not have any added value above the already available 28-day study (4) the production volume – 99 tpa - is very close to Annex IX level where a PNDT study would be required anyway and (5) the substance has a wide dispersive use. Therefore, there is a concern and the testing proposal should be accepted.

SECR did not modify DD for the meeting based on PfA, however, modified DD correcting a sentence that 'the registrant agreed to ECHA's DD' to 'the registrant did not object DD'.

Registrant's comments on PfAs of CAs and discussion

The Registrant did not provide any written comments on PfA. In the discussion, the MSC expert representing the CA submitting PfA repeated the arguments of the PfA and added that the Registrant indicated some relevant concerns in the dossier and accepting the proposed test would significantly improve the quality of the dossier. Another MSC member claimed that acceptance of the PNDT study would necessarily mean a data gap remaining for the reproductive/developmental toxicity screening study (OECD 421/422) which could provide in some cases added value (e.g. mating behaviour, fertility, histopathology of reproductive organs and perinatal effects are not covered by a PNDT study). Therefore, this member strongly agreed with ECHA's position to reject the PNDT study and at the same time urged launching a targeted CCH (tCCH) for the identified data gap regarding the screening study for reproductive toxicity.

SECR explained that the Registrant did not give a solid justification why the PNDT study would be needed so a rejection seems appropriate, in particular, taking into account column 2 of Annex VIII which is referring to serious concerns about the potential for adverse effects on fertility or development as a reason to propose pre-natal or 2-generation study at Annex VIII level. Concerning the consequent data gap for the screening study, on one hand, the Registrant stated in the dossier that it is not likely to add any scientifically useful information as the available 28-day study with doses up to 1000 mg/kg/d did not give any indications for effects on fertility. On the other hand, rejection of the PNDT study would make the registrant aware of the data gap for the screening study and give time to the registrant to spontaneously update the registration dossier with a suitable screening test. If the Registrant will not address this data gap within a limited time, ECHA would launch a targeted CCH, in the framework of the Areas of Concern (AoC) approach or else. Modifying the Registrant's proposal and asking for a screening study is however not possible in the current TPE process as there was no PfA on this issue and a screening study being a requirement on Annex VIII level only would be out of scope of a TPE.

A stakeholder representative advised against accepting a test which is not a minimum requirement without a strong justification. COM reminded that as this is the first time when a proposed test even if not being a minimum requirement but justified by the Registrant would be rejected, a solid justification for the rejection in the minutes of the meetings is important. SECR mentioned that in future similar cases ECHA could already note in DD sent to registrants the potential data gap and its potential consequences.

Session 2 (closed)

Based on the above considerations, MSC concluded not to amend DD and agreed to reject the testing proposal.

MSC found unanimous agreement on ECHA's DD as provided for the meeting. Two MSC members submitted a joint written statement to ECHA attached to the minutes of the current meeting (see it in section VI) regarding the data gap for the screening study and

the urgent need to launch a tCCH on it by ECHA, and with particular concern to an earlier agreement of MSC and workshop on dossier evaluation to normally not open a CCH for incompliances identified in a TPE process.

TPE 055/2013 Tricobalt tetraoxide (EC No. 215-157-2)
TPE 056/2013 Cobalt dichloride (EC No. 231-589-4)
TPE 057/2013 Cobalt di(acetate) (EC No. 200-755-8)
TPE 058/2013 Cobalt carbonate (EC No. 208-169-4)
TPE 059/2013 Cobalt sulphate (EC No. 233-334-2)
TPE 060/2013 Cobalt dinitrate (EC No. 233-402-1)
TPE 061/2013 Cobalt oxide (EC No.215-154-6)
TPE 062/2013 Cobalt bis(2-ethylhexanoate) (EC No. 205-250-6)
TPE 063/2013 Cobalt hydroxide oxide (EC No. 234-614-7)
TPE 064/2013 Cobalt dihydroxide (EC No. 244-166-4)
TPE 065/2013 Cobalt (EC No. 231-158-0)
TPE 066/2013 Cobalt, borate neodecanoate complexes (EC No. 270-601-2)

Session 1 (open)

Three representatives of the Registrants participated in the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

ECHA explained that all of the above substances are members of a category proposed by the Registrant and consisting of the above 12 cobalt compounds. The read-across (RA) rationale is based on toxicity of cobalt-ion. PfAs and comments of the Registrants on them are addressing all category members even though some of them were not submitted individually for all category members. Therefore, all category members were discussed in the same session.

Two substances, tricobalt tetraoxide and cobalt dichloride were proposed to be tested by the Registrant via oral route for 90-day RDT, pre-natal developmental toxicity and reproductive toxicity (2-generation study) so that the results would be read across to other members of the category. Tricobalt tetraoxide and cobalt dichloride has been chosen for testing based on its lowest and highest water solubility and bioaccessability within the category, respectively.

ECHA further explained that nine PfAs to ECHA's DD were submitted. First PfA suggested recommending the Registrant to analyse the exact composition of the tested substances (sample). Concerning the RA approach according to the second PfA one CA had the view that in general TPs on analogue substances belonging to the category should be considered as inadmissible (for pragmatic reasons this CA can now accept the proposed approach). This PfA also suggested addressing the RA rationale in DD. Regarding ECHA's judgement on the plausibility of the RA in DD, the same PfA suggested giving more details on the underlying rationale for RA discussing the hypothesis based on bioaccessibility derived from *in vitro* solubility tests and release rate in gastric fluid and validation of the hypothesis based on seven 28-day RDT tests. The same PfA continues asking for more discussion and conclusion on how the test results of the two selected cobalt category members with very high and very low gastric fluid solubility may be used for RA to untested cobalt category substances taking into account the needs for hazard classification and labelling and for risk assessment. The third PfA suggested reflecting in DD the significance of particle size of the tested samples in relation to the gastric fluid release rate as the latter is one of the central components of the proposed RA concept.

The fourth PfA regarding requirement for the 90-day RDT study disagreed with DD challenging the statement (and asking to remove it) that there is a data gap for a 90-day study as in the view of this CA, there is sufficient information available in the dossiers on sub-chronic toxicity, both via oral and inhalation route. Furthermore, inhalation seems the most appropriate route of exposure, five of the soluble substances in the proposed category are already classified as Carc. 1B (inhalation) and the NOAEL for oral systemic effects will not change the obligation to minimize exposure. Because inhalation route seems to be the most critical and relevant exposure route for soluble cobalt compounds,

for RA the same route should be taken into account for the insoluble cobalt compounds. For the above reasons, the proposal for a 90-day oral sub-chronic toxicity study does not seem justified. The same PfA also suggests further discussion on the need for 90-day study at MSC-30.

Concerning the 'generation study', according to the fifth PfA, a CA has the view that there is no data gap for Annex X, 8.6.3 and that the dossiers contain reliable information from studies of cobalt substances that indicate the adverse effects on reproduction. Some of the category members, like cobalt dichloride have already been classified as *Repr. 1B*, thus there is no data gap for cobalt dichloride and thus RA could be applied to those cobalt substances that are considered soluble or show high bioavailability. For 'insoluble' cobalt substances like tricobalt tetraoxide a two generation study should be carried out in the most appropriate route of administration. The same CA suggested that there are no arguments to state that inhalation is not the most appropriate route of exposure. Thus, requesting a study via the oral route does not seem appropriate. The same CA reminded that testing the two selected substances will generate information on the category members and provide evidence for the full category justification. This is the reason why testing is required or allowed, otherwise the overall RA for the cobalt category is not acceptable. The same PfA also suggested further discussion on the need for a reproductive toxicity study at MSC-30.

The sixth and seventh PfAs suggested requesting an EOGRTS for Annex X, 8.7.3 only instead of ECHA's proposal to give two options for the Registrant either to perform the two-generation reproductive toxicity test (EU B.35) or EOGRTS (OECD 443) with the second generation. The eighth PfA suggested keeping the two options but excluding from the optional request for EOGRTS the extension of cohort 1B (production of F2 generation).

The ninth PfA was related only to TPE-066 a CA considered that the rationale for accepting the RA for this substance was not sufficiently explained in the draft decision. The decision should address the contribution of the counter-ions to toxicity.

SECR modified DDs for the meeting based only on the PfA concerning the significance of particle size and the ninth PfA.

SECR also split DDs into part A and B where part A addressed the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity) and part B addressed the information requirement for a 90-day repeated dose toxicity study and a PNDT study. ECHA Secretariat modified due to splitting of the requirements the deadlines to be given to the Registrant to submit the required test results.

The split DDs modified and updated with procedural steps were provided to MSC for finding unanimous agreement.

Registrant's comments on PfAs of CAs and discussion

The Registrants in the written comments on PfAs preferred the OECD 416 (two-generation) study to EOGRTS. They claimed that available data are insufficient for establishing a DNEL for male reproduction and that there are no data at all on the effects on female reproductive organs. They also noted that effect levels can drastically differ in males and females. Concerning route of administration, they claimed that according to public data oral exposure of cobalt compounds can target other tissues than lung and reproductive organs and there is no DNEL for related systemic toxicity. Furthermore, they gave more details on the rationale of the RA approach proposed explaining that the result of the proposed testing should justify the establishment of two RA (sub)categories with unlimited RA within both of them. The Registrants anticipate case-by-case decisions for those substances that appear to fall "outside" the boundaries of these RA subcategories. In such a case, a "conservative" approach is envisaged whereby such a substance would be placed into the more stringent (i.e. more bioavailable, more toxic) (sub)category. The Registrants also asked for advice as to which additional parameters could be used to clarify the composition of the test sample.

The representatives of the Registrants in the discussion mainly repeated the argumentation of their written comments on PfAs highlighting the following points. First, they stressed that the RA strategy focuses on systemic concerns and is based on the concept of bioaccessibility. Second, due to systemic concerns, the tests were proposed via

oral route to ensure sufficiently high blood levels for studying potential systemic effects. Inhalation effects had already been extensively and sufficiently covered in other available studies on several cobalt compounds. Third, one of the reasons to propose a two-generation study instead of EOGRTS was that so far no metal compounds have been tested with EOGRTS, i.e. there is not much experience in this field. The Registrant pointed out that the review performed by Piersma et al (2011), which recommends the EOGRTS over 2-generation study is based on 498 chemicals of which only two chemicals are metals. Fourth, in case of 'cobalt, borate neodecanoate complexes', in the view of the Registrants', it is sufficiently demonstrated that counter-ions are less potent systemic toxicants than the cobalt ions and therefore, the proposed RA strategy should be feasible also in the case of this substance.

Several MSC members raised the concerns mainly expressed also in PfAs. Most of them addressed the issue of whether or not studies for systemic toxicity are needed particularly with soluble cobalt compounds when several (five) of them have already a harmonised classification as carcinogen, Cat 1B (inhalation), mutagen Cat 2 and reprotoxic Cat 1B. One CA argued that for non-threshold carcinogens, DNELs would not affect the risk management measures requiring minimisation of exposure. This is already required for these substances by workers' protection legislation.

Replying to these and further questions, representatives of the Registrants explained that bioaccessibility as a basis for RA was used as recent data showed that systemic effects seem to correlate well with the gastric fluid release rate. They also clarified their intention to correct substance specific DNELs within the members of the read across category based on molecular weight. Based on available data they feel confident that results will fall into two categories with one order of magnitude being the boundary for one subcategory. Recent NOAELs indicate that there is no continuum to be expected between these subcategories. Instead of testing a third substance to improve this way the basis of the RA approach, they proposed that substances with results not clarifying clearly for any of the two categories will be assigned to the worst case (soluble) subcategory.

They further justified their choice for cobalt dichloride as one substance to be tested with the arguments that there will be no potentially interfering counter-ion in the gastric fluid (as it would be the case with e.g. cobalt dinitrate) and that cobalt dichloride is already extensively tested for other routes and endpoints which makes the evaluation of the results easier and the conclusions drawn more robust.

Concerning the testing strategy they mentioned to use as range finders the results of already available 28-d studies for the 90-day study and those of the proposed 90-d study for the two-generation study.

Concerning carcinogenicity and mutagenicity, they expressed their view that in the literature there is no *in vivo* evidence of carcinogenicity for insoluble cobalt compounds and even soluble cobalt compounds cause cancer only locally (lung). The Registrants assume that this local carcinogenicity is a result of a secondary effect (e.g. chronic inflammation caused by cobalt). Therefore many cobalt compounds not causing even inflammation in lungs should not be classified as carcinogens. They confirmed they are currently conducting and have conducted studies according to GLP and recent guidelines to decide whether or not cobalt compounds should be considered as mutagens. Currently available public database on cobalt compounds show genotoxicity and mutagenicity but they are related to soluble cobalt compounds and based on not up-to-date *in vitro* studies. They mentioned that their own guideline compliant, GLP studies are negative for in vitro mutagenicity, as well as for in vivo clastogenicity for all tested compounds. The registrants mentioned that they may collaborate with a MS and launch the process for re-classification.

Addressing these discussion points, SECR was of the opinion that DD could explicitly state that the testing strategy is based on systemic concerns and on oral toxicity testing adequately addressing these concerns. SECR also reminded that scope of the current decision-making process is to decide on the proposed tests and underlying justification but not to discuss harmonised classification and labelling. Although the proposed testing strategy might not be justified for the safe use and/or classification of the substances to be tested, but will provide data needed for the RA strategy and consequently the other substances of the category to fulfil information requirements of REACH. SECR also stressed

that a CCH was not carried out on the dossiers concerned for mutagenicity, carcinogenicity and sub-chronic toxicity via inhalation.

MSC concluded based on the above discussion that DDs shall be amended with the following considerations:

- DDs concern the testing plan based on RA/grouping approach; the working hypothesis is the cobalt ion toxicity and the fact that in vitro bioaccessibility in artificial gastric fluid is a better estimate for bioavailability than water solubility,
- estimations of internal systemic exposure is subject to some uncertainties if based solely on an in vitro bioaccessibility; the read-across adaptation based on the results of the proposed tests shall ensure that these uncertainties are analysed, minimized to the extent practicable or feasible, and taken into account for the purpose of classification and labelling and/or risk assessment,
- ECHA has not performed a compliance check on endpoints such as mutagenicity, carcinogenicity and sub-chronic toxicity via inhalation and may do so at any time at its own discretion,
- the Registrants have not explained how the results of the proposed tests will be used to reach conclusions on classification, in particular for reproductive toxicity; the information provided in the comments of PfAs and at the meeting by the registrants indicating that they intend to set up two sub-categories on the basis of the test results was not available in the registration dossiers and consequence of this approach needs to be further considered; therefore, the acceptance of the testing proposals does not imply that the application of the read-across strategy in its current form is fully conclusive and acceptable,
- in case the proposed tests would not confirm the read-across hypothesis relied upon by the Registrants, this outcome shall not alter the obligation of the Registrant to meet the standard information requirements. Should the read-across strategy be inadequate, it is the responsibility of the Registrant to ultimately submit reliable information or adaptations which should not underestimate the hazards of the registered substances in relation to the relevant endpoints; if the proposed approach does not satisfy the conditions set out in Annex XI, ECHA reserves the right to request the information necessary to fulfil the information requirements for the substances subject to the present decisions,
- the total surface area of the particles (i.e. not exclusively particle size) is an important factor to be considered for all substances in the category as it will affect the rate of solubilisation; the Registrant needs to take into consideration factors the particle size, i.e. rate of cobalt-ions release from the particles,
- concerning 'Cobalt, borate neodecanoate complexes', the issue of counter-ions should be adequately addressed by the Registrants; this issue was however not discussed in-depth at the meeting.

Session 2 (closed)

MSC found unanimous agreement on ECHA's 12 DDs addressing the testing proposals for a 90-day RDT and PNDT study as amended for Section III reflecting the above uncertainties and conclusions.

The Chair recognised the results of voting on 12 DDs relating to TP for a two-generation reproductive toxicity study, as amended as appropriate based on the above conclusions. As MSC did not reach a unanimous agreement on these 12 DDs at the vote, the Chair invited the disagreeing MSC members to provide written justifications for their disagreement if the justification were different to those provided for previous similar cases (otherwise SECR would use the justification provided in previous similar cases). ECHA will refer the 12 DDs to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

TPE 069/2013 bis(2,3-epoxypropyl) terephthalate (EC No. 230-565-0)

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 to ECHA's DD were submitted. One PfA suggested rejecting the 'generation study' and recommending the registrant to consider resubmitting a TP once the results of the 90-day study are known as in the view of the submitting CA there are currently no sufficient triggers for the 'generation study' at the Annex IX level. Two other PfAs suggested requesting an extended one generation reproductive toxicity study (EOGRTS) for Annex X, 8.7.3 only instead of ECHA's proposal to give two options for the Registrant either to perform the two-generation reproductive toxicity test (EU B.35) or EOGRTS (OECD 443) with the second generation. A fourth PfA suggested keeping the two options but excluding from the optional request for EOGRTS the extension of cohort 1B (production of F2 generation).

SECR did not modify DD for the meeting based on any PfA.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs agreed with the PfA concerning insufficient triggers for the 'generation study' but disagreed with the other PfAs requesting EOGRTS instead of the two-generation study.

The expert and the MSC member representing the CA submitting the PfA concerning insufficient triggers for the 'generation study' repeated the arguments in PfA. They added that although the registered substance is a phthalate potentially referring to effects on reproduction/endocrine disruption, its structure is considerably different to other phthalates consequently its toxicological profile could also be different. They also proposed that the issues on triggers in general should be further discussed or an expert group should be established to discuss issues related to a validity of triggers in similar cases.

SECR reconfirmed that in its view a slight to moderate change seen in a 28-day study in the weight of reproductive organs particularly for a phthalate which is a member of phthalate group of substances suspected causing endocrine disrupting (ED) effects should be considered as a trigger for a 'generation study' and consequently, TP for a 'generation study' should be accepted. SECR explained that change in the weight of reproductive organs is typically an effect for EDs and no further effects may be seen in the repeated dose toxicity tests. SECR also indicated that results of a 90-day study could reproduce similar effects and would lead to the same discussion on relevance of the triggers and thus results of the 90 day study would not resolve the issue. Several MSC members supported ECHA's view as expressed in DD. Furthermore, SECR suggested first to deal with similar cases on a case-by-case basis to gain experience and to establish group later to consider the triggers in general. One MSC member suggested collecting similar cases for the Manual of Decision of MSC. Two MSC members highlighted that considering the potential ED properties; EOGRTS would definitely be a better option than the two-generation study.

MSC concluded to split DD into TPE-069A and TPE-069B where TPE-069A addressed the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity) and TPE-069B addressed the information requirement for a 90-day RDT and a PNDT study. Furthermore, MSC concluded to add to TPE-069A an additional explanation on the results seen in 28-day study as a trigger for the 'generation study', with a caveat that its conduct be re-evaluated in light of the results of the 90-day study. Due to splitting of the requirements, MSC also concluded to modify the deadlines to submit the required test results to be given to the Registrant in both split DDs.

Session 2 (closed)

MSC found unanimous agreement on ECHA's DD addressing the testing proposals for a 90-day RDT and PNDT study (TPE-069B/2013) as split and amended based on the above conclusions.

The Chair recognised the results of voting on DD (TPE-069A/2013) relating to TP for a two-generation reproductive toxicity study, as split and amended based on the above conclusions. As MSC did not reach a unanimous agreement on DD at the vote, the Chair invited the disagreeing MSC members to provide written justifications for their disagreement if the justification were different to those provided for previous similar cases

(otherwise SECR would use the justification provided in previous similar cases). One MSC member submitted his modification to his disagreement used in earlier cases reflecting the special concern of potential ED properties.

ECHA will refer the case (TPE-069A/2013) to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

TPE 070/2013 Trichloroacetic acid (EC No. 200-927-2)

TPE 071/2013 Sodium trichloroacetate (EC No. 211-479-2)

Session 1 (open)

As the two cases had the same Registrant with the same test proposed, received the same comments and PfAs and as ECHA requested the Registrant to test sodium trichloroacetate in both cases, the discussion of the two cases is described in the same section as follows.

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

SECR explained that five PfAs to ECHA's DDs were submitted. Part one of the first PfA suggested not-requesting the 'generation study' proposed only by ECHA (as an additional test under Article 40(3)(c) but not by the registrant) as in the view of the submitting CA the triggers based on spermatogenesis effects in the dog are not directly relevant for the rat and so a 'generation study' at Annex IX level in this species would not be useful. Part two of the first PfA and two other PfAs suggested requesting an EOGRTS for Annex X, 8.7.3 only instead of ECHA's proposal to give two options for the Registrant either to perform the two-generation reproductive toxicity test (EU B.35) or EOGRTS (OECD 443) with the second generation. The fifth PfA suggested keeping the two options but excluding from the optional request for EOGRTS the extension of cohort 1B (production of F2 generation). A fifth PfA suggested removing a sentence referring to a premature conclusion made by ECHA on the developmental toxicity potential of the registered substance based on available information.

SECR modified DDs based on PfA concerning the premature conclusion on developmental toxicity potential of the registered substances but not on the other PfAs.

Registrant's comments on PfAs of CAs and discussion

The Registrant in the written comments on PfAs accepted ECHA's request for a 'generation study' and expressed the intention to perform the OECD 416 (two-generation) study. The Registrant also indicated intention to possibly classify the substances as Reprotoxic, cat. 1 or 2 based on the results of the PNDT study and waive the two-generation study using this classification.

The expert and the MSC member representing the CA submitting the PfA with the suggestion of not requesting the 'generation study' repeated the arguments in PfA. They added that the referred 90-day low-dose dog study is indicating concerns for spermatogenesis whereas the 90-day and lifetime high-dose rat studies are showing no adverse effects in reproductive organs; those studies had been performed in the same lab approximately in the same years. Although these studies performed with sodium trichloroacetate are historic, they are likely to have been conducted with the same method that makes their results conclusive and comparable. For the submitting CA the conclusion is that the rat is likely to be highly insensitive to (sodium) trichloroacetate. This concern was shared by some other members suggesting that requesting a 'generation study' on rat as an insensitive species may not produce relevant results. ECHA emphasised that the Registrant indicated a concern for fertility based on impaired spermatogenesis seen in dogs which he wanted to follow. A 'fertility study' cannot be requested with dogs; therefore, ECHA requested a 'fertility study' with the standard species rats. ECHA agrees that the available data indicate that rats are less sensitive than dogs but the data are not sufficiently robust to conclude that the rats are insensitive because sperm parameters were obviously not examined in rats and the fixative used at that time for reproductive organs is known to be less suitable. Generally, toxicokinetic studies to clarify interspecies differences could be helpful but cannot be requested in this case for procedural reasons as there was no PfA suggesting a toxicokinetic study.

MSC concluded based on the above considerations that the 'generation study' on rats should not be requested. However, as the concern for spermatogenesis without a 'generation study' will remain, the Registrant needs to be reminded to address this concern either via appropriate risk management measures (RMMs) or developing and implementing a new testing strategy. If none of these options will be applied by the Registrant, ECHA still can launch a CCH or Member States can consider the substances for substance evaluation ensuring that the concern is addressed properly.

MSC also concluded to explain the Registrant why the 'generation study' is no longer requested and to change the deadline to submit the required test result to be given to the Registrant from 30 to 12 months.

Session 2 (closed)

Based on the above conclusions, MSC found unanimous agreement on ECHA's DDs as amended in the meeting by removing the requirement for a 'generation study' on rat and by providing an explanation on the remaining concern.

TPE 052/2013 3,6-bis(4-tert-butylphenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione (EC No. 416-250-2)

Session 1 (open)

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

SECR explained that two PfAs to ECHA's DD were submitted. Part 1 of the first PfA suggested rejecting EOGRTS on this tonnage level (Annex VIII) as in the view of the submitting CA there is no sufficiently convincing evidence of adverse effects on reproduction provided and an EOGRTS is unlikely to provide any information necessary to conduct a robust risk assessment on this tonnage level. Part 2 of the first PfA suggested – if EOGRTS will be eventually requested in DD – to delete a sentence referring to the necessity of inclusion of F2 generation in EOGRTS for fulfilling REACH requirements if the tonnage level for Annex IX/X is reached. The second PfA suggested deleting the whole paragraph referring to inclusion of F2 generation in EOGRTS and related REACH requirements at Annex IX/X level.

SECR did not modify DD for the meeting based on any PfA.

Registrant's comments on PfAs of CAs and discussion

The Registrant did not provide any comments on PfAs. The expert and the MSC member representing the CA submitting the PfA with the suggestion not accepting the Registrant's proposal for the 'generation study' maintained their proposal based on the arguments in PfA. No support was expressed for this PfA by other MSC members as it was considered to be justified by the Registrant. The other PfA referring to the requirements at Annex IX/X level was supported by some MSC members. SECR maintained its view that the Registrant should explicitly be reminded what the current REACH requirements of the next tonnage levels (Annex IX/X) for reproductive toxicity are to make sure that the Registrant is aware of those requirements before deciding to implement the current testing strategy (i.e. why an EOGRTS without further conditions set is acceptable at Annex VIII level).

Session 2 (closed)

Based on the above considerations, MSC concluded not to change the testing requirements (i.e. accepted the Registrant's testing proposal for EOGRTS) but to modify the paragraph referring to the relation between EOGRTS and Annex IX/X level requirements.

Based on the above conclusions, MSC found unanimous agreement on ECHA's DD as amended in the meeting based on the above conclusion. Two MSC members submitted a joint written statement to ECHA attached to the minutes of the current meeting (see it in section VI) regarding the lack of explicit indication from the Registrant of his intention to include the developmental neurotoxicity (DNT) and developmental immunotoxicity (DIT) cohorts in his testing proposal for EOGRTS.

TPE 053/2013 3,6-bis-biphenyl-4-yl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione (EC No. 413-920-6)

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 more explicit formulation (i.e. exact reference to Annex I, 0.5) why EOGRTS proposed by the Registrant at Annex VIII level was rejected. MSC concluded to refine the formulation even further than suggested in WP citing the text of Annex I, 0.5.

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

TPE 067/2013 Reaction mass of 2-methylpent-2-ene and diisopropyl ether (List No. 906-484-8)

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 four MSC members. One MSC member suggested to remind the Registrant that the composition of the tested substance (sample) should be better described particularly because it is an UVCB substance. MSC concluded to add to DD the standard paragraph used for this purpose.

The other three MSC members questioned why DD including a 'generation study' and other studies had not been split and suggested to address the Registrant's proposed weight-of-evidence (WoE) approach more precisely in DD. SECR explained the Registrant's detailed testing strategy which explains why DD shall not be split: (1) if results of a 'generation study' with one of the components of the registered substance (DIPE) is positive, the Registrant would classify the substance and would not conduct any further studies with the registered substance (2) if results of the study with DIPE are negative, the Registrant would perform a combined 90-day/'generation study'; in case of positive results of this combined study, the Registrant would classify the substance and would not conduct any further studies with the registered substance (3) only if results of the combined study are negative, the Registrant would perform the PNDT study with the registered substance. SECR also stressed that there was no PfA for splitting.

MSC concluded not to split DD and to refine the paragraph referring to how the Registrant's proposed WoE approach could potentially be considered to fulfil the relevant information requirements.

The Chair recognised the results of voting on DD as amended based on the above conclusions. As MSC did not reach a unanimous agreement on DD at the vote due to conflicting views on the method of choice for the 'generation study' (two-generation reproductive toxicity test (EU B.35) or EOGRTS (OECD 443) without F2), the Chair invited the disagreeing MSC members to provide written justifications for their disagreement if the justification were different to those provided for previous similar cases (otherwise SECR would use the justification provided in previous 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. SECR will inform the Registrant about the outcome of the current discussions without undue delay.

TPE 068A/2013 and TPE 068B/2013 Reaction mass of 2,2'-oxydibutane and 2-methylpropan-2-ol and butan-2-ol and 2,2'-oxydipropane (List No. 903-919-3)

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 one MSC member suggesting to remind the Registrant that the composition of the tested substance (sample) should be better described particularly because it is an UVCB substance. MSC concluded not to amend DD as the standard paragraph which is already in DD is sufficient for this purpose.

Based on the above conclusion, MSC found unanimous agreement on ECHA's DD addressing the testing proposal for a 90-day RDT (TPE-068B/2013) as provided for the meeting.

The Chair recognised the results of voting on DD (TPE-068A/2013) relating to TP for a two-generation reproductive toxicity study and PNDT study as provided for the meeting

(the studies were kept together due to the Registrant's testing strategy). As MSC did not reach a unanimous agreement on DD at the vote, the Chair invited the disagreeing MSC members to provide written justifications for their disagreement if the justification were different to those provided for previous similar cases (otherwise SECR would use the justification provided in previous similar cases).

ECHA will refer the case (TPE-068A/2013) to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

TPE 072/2013 Cyclohexyldimethoxymethylsilane (EC No. 402-140-1)
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 one MSC member suggesting to refine the paragraph explaining to the Registrant why in general the absence of severe effects in RDT studies cannot be used as an evidence of absence of prenatal developmental effects caused by the substance. MSC concluded to refine the paragraph concerned.

Based on the above conclusion, MSC found unanimous agreement on ECHA's DD as amended in the meeting. One MSC member did not participate in the vote due to her declared conflict of interest.

d. Update on appeal cases *(Partly closed session)*
SECR gave a presentation on the outcome on the appeal case (case A-005-2011) concerning an ECHA compliance check decision imposing a 90-day inhalation study on rabbits under section 8.6.4. of Annex X. It was explained that the BoA decision is based on the following elements: insufficient justification in ECHA's decision why the contested test was needed (in particular, not clearly explaining the objective of the study) and the fact that the contested study has been rarely conducted. According to ECHA SECR the key elements of the Board of Appeal (BoA) decision are: the margin of discretion for ECHA under Annex X 8.6.4., alleged infringement of Article 25(1) of REACH, because it had not clearly explained why the test was needed and why a test involving less animals was not sufficient to meet the specific concern, and the disproportionality of the ECHA's decision as ECHA had not clearly defined the objective of the decision and therefore could not justify that the 90 day inhalation study on rabbit was the least onerous test to meet the objective in question.
The representative of the Board of Appeal emphasised the need to read the whole decision and explained that he is not in a position to provide any further explanations on the issued BoA decision. In the following brief discussion, several members and STO observers exchanged views on the lack of historical data in this specific case and on the need to validate the new TGs for the purpose of historical control. Also the extent of possible reflections of the ruling to other cases and processes were raised for discussion. It was stressed by SECR that the BoA decision applies to the present case and naturally ECHA has to take the lessons from the case for other similar cases. Regarding the present case for which the ECHA decision was annulled by BoA, SECR explained that the compliance check process on the present registration dossier as updated in the meantime will be restarted and all steps of the normal decision making process will follow.

e. General topics

1) Introduction to issues to be considered in the context of a complex category evaluation (*Closed session*)

SECR gave a status report on the on-going preparations of DDs for two big categories (alkanes, crude oils) and stressed that lessons from the cobalt category will be taken into account. MSC took note of the report.

2) Status report on on-going evaluation work

SECR gave detailed statistics and update on the status of evaluation work. MSC took note of the report.

Item 7 – SVHC identification

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

SECR gave a brief report on the outcome of the written procedure for SVHC agreement seeking on the identification of dipentyl phthalate (DPP) proposed to be identified as SVHC based on Article 57 (c) as toxic to reproduction 1B. It was explained that MSC agreed unanimously on identification of this substance as an SVHC in the written procedure launched on 21 May 2013 and closed on 31 May 2013. 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

The members were reminded that they should resist from contacts with stakeholders during the MSC involvement in the authorisation process as in the document 'General principles and guidance for the Committee members of ECHA' it is stated '*Committee members should refrain from communicating with stakeholders on dossiers that are currently on-going with the Committee without the involvement of the ECHA Secretariat'.* It was underlined that in case such contact cannot be avoided the MSC Secretariat should be informed and involved in the communication exchange as soon as possible.

Cadmium (Cd) (EC No. 231-152-8)

Cadmium oxide (CdO) (EC No. 215-146-2)

The dossier submitter (DS) representative from the Swedish CA presented to MSC the two Annex XV proposals for Cd and CdO based on Article 57 (a) (carcinogen 1B) and 57 (f) (equivalent level of concern based on kidney and bone effects). She indicated that the substances have harmonised classification as carcinogen 1B and STOT RE 1 (Specific target organ toxicity - repeated exposure) in Annex VI of the CLP Regulation. Majority of the comments in the public consultation were on exposure, uses, alternatives and risks which are not considered at this stage but only at the next stage of the authorisation process. Some comments were addressing the issues related to the equivalent level of concern conclusion.

The Chair concluded with agreement of MSC that there was no reason to discuss the 57 (a) as the basis for identification of Cd and CdO as SVHCs because the substance has a harmonised classification as carcinogen 1B. Therefore further discussion took place on the reasons for the proposal to use Article 57(f) as the basis for SVHC identification. It was recognised that there is sufficient evidence on kidney and bone effects which are serious effects and comparable to those of Article 57(a) to 57(c) indicating equivalent level of concern.

One stakeholder observer strongly questioned whether the substances indeed are of equivalent level of concern as there seems to be no causal relationship between exposure and bone effects at population level. The kidney effects seen at population level and in workers are not at a level of equivalent level of concern in his view as exposure is well controlled.

DS in her response further elaborated on bone fractures as a high risk factor at population level and emphasised that until now no trend of decrease in urinary cadmium over the past 20 years has been detected. In the response by SECR members were reminded that SVHC identification is based on the intrinsic properties (which have been confirmed already by harmonised classification as STOT RE 1) and that there is no need to demonstrate causality for CMRs and thus no such need exists for proposals under Article 57(f).

Other issues which are outside the scope of Article 57 (the basis for identification as SVHC) were raised for discussion. One member expressed her view that authorisation is not the most relevant option to reduce the risks associated with these substances but given the hazard properties, inclusion in the candidate list can be supported. Regarding authorisation as a risk management measure it was stated that exposure to Cd should be minimised but

that substitution has to great extent already taken place based on the restrictions on marketing and use of Cd and Cd compounds. Therefore, it was questioned what benefit from subjecting the substances for authorisation would be gained.

In conclusion MSC unanimously supported the proposal that Cd and CdO should be identified as a SVHC under Article 57(a) due to their harmonised classification as carcinogen and under Article 57(f) due to the adverse effects to bones and kidneys that give rise to equivalent level of concern to those of other substances listed in points (a) to (c) of Article 57 of REACH. MSC unanimously agreed on the support documents and agreements for both cadmium and cadmium oxide as provided for the meeting.

The Chair thanked the dossier submitters for providing the proposals to the SVHC identification process and MSC for the unanimous agreement.

4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]

The DS representative from the German CA presented to MSC the Annex XV proposal for the above-mentioned substance pointing out that the proposal is made based on the degradation of 4-nonylphenol ethoxylates to 4-nonylphenols in the similar way as described already for 4-tert-octylphenol ethoxylates that have been identified SVHCs due to their degradation to 4-tert-octylphenol. It was also explained that 4-nonylphenol ethoxylates primarily degrade to 4-nonylphenol and they are expected to be a long-term source for 4-nonylphenol. In the overview made on the main comments received in the public consultation, the dossier submitter highlighted that commenting member states had no detailed comments but supported the proposal while the comments received from industry were very similar to the ones submitted in the previous round on the SVHC proposals for 4-octylphenol ethoxylates and on 4-nonylphenol mainly challenging the ED hazard.

The Commission observer (DG ENTR) mentioned that the legal text/guidance does not specify exact provisions for considering ED hazards of the transformation/degradation products of a substance as evidence for an SVHC. The COM observer further informed MSC of a draft COM paper on the use of Article 57(f) of REACH Regulation for identification of SVHCs when transformed/degraded to substances meeting CMR criteria according to Article 57 (a) to (c) that was presented and discussed in the last RiME meeting. In response, the MSC Chair reminded members that the relevance of the transformation products has been considered by MSC already and substances have been included in the candidate list based on these arguments.

MSC unanimously agreed to identify 4-nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof] as SVHCs in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because (through their degradation) they are substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH. MSC unanimously agreed on the support document and agreement as provided for the meeting.

2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) (EC No. 253-037-1)

2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) (EC No. 247-384-8)

2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327) (EC No.223-383-8)

2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) (EC No. 223-346-6)

The DS representative from the German CA presented to MSC the Annex XV proposals for the above-mentioned four substances explaining the rationale for choosing these four phenolic benzotriazoles among the others based on their structural similarities and read across (R-A) between the four substances. It was further mentioned that all four substances are proposed for SVHC identification due to their vPvB properties under Art 57 (e) of REACH and UV-320 and UV-328 are also proposed for identification as PBT substances under Article 57 (d) as these substances would meet also the T-criterion due to their specific target organ toxicity after repeated exposure. The Weight of Evidence (WoE) approach applied in the persistence (P) assessment was further elaborated based on the comments received in the public consultation and the information from a registrant who recently submitted registration of UV-328 concluding that the substance should be considered as PBT. As regards the bioaccumulation of these substances, the dossier submitter clarified that the assessment was done based on the available data from screening, QSARs and BCF studies (with BCFs>5 000).

In the comments of the public consultation in particular the conclusion on persistence was challenged and comments were provided also on bioaccumulation and procedural aspects regarding assessment for meeting the T criterion.

MSC considered first whether the evidence provided in the dossiers is sufficient to conclude on persistency (P) of these substances. According to DS the rationale for WoE on persistence was employed as there were no simulation studies for degradation on the four proposed substances to be evaluated. Therefore R-A approach in accordance with REACH Annex XI, 1.2 was applied and assessment information for WoE was used in accordance with Annex XIII, 3.2.1 (c) referring to results from simulation testing on degradation in sediment and with 3.2.1 (d) referring to other information such as information from field studies or monitoring studies (provided that its suitability and reliability can be reasonably demonstrated).

According to DS WoE justification was based on results of screening tests indicating low potential for biodegradation, high log Koc indicating strong binding to soil/sediment making the substances partially not available for degradation, monitoring studies detecting the transformation products in a variety of compartments around the world, longevity in the environment based on field studies where two of the UV-substances were found decades after production ceased, common (complex) degradation pathways for all considered phenolic benzotriazoles, R-A from a simulation study on EC 407-000-3 (a fifth UV-substance with a similar chemical structure) specifying dissipation half-lives in aerobic and anaerobic conditions which would give basis to estimate that the degradation half-lives for the four substances as well as R-A information on 1H-benzotriazole for which the primary aerobic and anaerobic degradation half-lives would be over the cut-offs.

In the absence of simulation studies for degradation of the four proposed substances the main issue was how to use the dissipation half-life information from the simulation tests on EC 407-000-3 to produce sufficient evidence on degradation half-lives for the four proposed substances. It was questioned whether there is sufficient information available on the mass balance and kinetic estimation of the degradation and dissipation process taking place in the test. The test was not designed for following degradation of the first metabolite (M1) (which was measured in the dissipation exercise). This complicates the evaluation of the degradation kinetics of M1. The major uncertainty lies in the continuous formation of M1 from EC 407-000-3, which may lead to overestimation of the degradation half-life. The degree of this overestimation will depend on the amount of the parent left at the given point of time. It was mentioned that uncertainty remains whether the data can be used to support the assumption that degradation in aerobic conditions could exceed (i.e. be slower than) the threshold values for persistence. However, there seem to be indications that the main first metabolite (M1) could be persistent in anaerobic conditions in sediment but uncertainties remain for the reasons stated above. There is little experience how to use data from anaerobic conditions for persistence assessment and guidance in this respect is missing. It was indicated that the draft SD should be further

strengthened for the R-A rationale and degradation trends. The graphs presented were proposed to be re-formulated to better reflect the main outcome of the test results and comparing the measured results with the modelling results. The half-life times were proposed to be temperature corrected. Further the question was raised how to distinguish between P and vP in a WoE-approach.

Also improvements on the part regarding the field studies were proposed. Based on the discussion and requests by MSC, several amendments of the draft Support Document were made by DS during the meeting on the basis of the available information in the original Annex XV proposal. However, also a high number of further assumptions, reflections of uncertainties brought up in the discussion and re-calculations were included in the document by the representative of the DS. The revised document suggested vP and P conclusion based on ready biodegradability tests, R-A assessment from EC 407-000-3 and its first metabolite (M1) on the basis of dissipation half-lives, partially re-calculated for temperature adjustment, new graphs comparing modelling results with the measured dissipation values and monitoring studies with new model calculations.

Because of the extensive and complex modifications of the draft SD during the meeting and in the absence of any guidance how to consider such information in a WoE approach, MSC felt that it would not be possible to conclude persistence of the substance on the basis of the information presented. It was suggested that further consultation of PBT experts would be useful before drawing final conclusions.

The bioaccumulation part of the draft SD was not reflected in depth at the meeting. However, the tentative conclusion by the DS is that the substances meet the criterion for vB.

As there is no harmonised classification on specific target organ toxicity in Annex VI of CLP, ECHA had asked the Risk Assessment Committee (RAC) to provide its opinion on whether the information provided by the DS shows that the substance meets the criteria for classification for specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) under CLP. Without further discussion, MSC unanimously supported the conclusions of RAC on these substances' specific target organ toxicity that was annexed to their support documents.

In this regard, the SECR made some procedural remarks pointing out that a detailed assessment and data comparison with the requirements of Annex XIII for the PBT/vPvB substances should be done by the dossier submitter when preparing an Annex XV proposal for a substance. It was noted that the ECHA Executive Director had requested for the RAC opinion for the classification of these two substances on an exceptional basis in order to support the MSC agreement seeking for these SVHC proposals. MSs were strongly encouraged not to use this way when making proposals related to substance identification as SVHCs due to the serious practical consequences to the RAC workload, resource implications, uncertainties regarding the outcome and further confusing consequences to the companies. SECR recommended making first a C&L proposal, concluding that and only then proceeding with SVHC identification.

SECR underlined the importance of having a solid basis for MSC conclusions on the SVHC proposals in form of a documentation that is fit for purpose in the substances' support documents, e.g. with clear comparison of the information presented with the criteria of Annex XIII of REACH for the sake of transparency and prevention of potential future challenges in Court.

In conclusion, MSC unanimously agreed that it is currently not possible to conclude on the identification as SVHCs of UV-320, UV-327, UV-328 and UV-350 under Article 57 (d) and/or under Article 57(e) due to the need for further consideration of the documentation provided by the dossier submitter and the updates provided during the meeting. Two MSC members deliberately abstained from voting on the four Annex XV proposals. One of them provided a statement that is attached to these minutes (in section VII).

The substances will not be included in the candidate list but the MSC agreement and the draft SD as modified in the meeting will be published on ECHA's website. It is possible to

revise the proposals and to restart the SVHC identification process again with the revised proposals. The representative of the DS explained that their intention would be to consult further the PBT experts and then to decide on how to proceed with the SVHC proposals.

The Chair thanked the DS for the hard work during the meeting and for bringing up an interesting case which added up to the experience and knowledge of MSC in handling of PBT/vPvB proposals. The Chair also thanked MSC for unanimous agreement giving a possibility to close the current process on the substances but leaving the door open for possible future actions as necessary.

Ammonium pentadecafluorooctanoate (APFO) (EC No. 223-320-4)

Pentadecafluorooctanoic acid (PFOA) (EC No. 206-397-9)

The DS representative from the German CA presented to MSC the proposals for PFOA and APFO together with the representative of the Norwegian CA (joint work by these CAs) and the modifications introduced in their SDs based on the comments received in the public consultation. The SVHC proposals are based on Article 57 (c) (toxic to reproduction 1B) and (d) (PBT). It was explained that there is a RAC opinion in favour of the proposed CLH of both substances as toxic for reproduction 1B and STOT RE1 (according to the CLP Regulation) and their inclusion in Annex VI of the CLP Regulation is envisaged in the near future. DS explained that strong evidence exists that PFOA and APFO meet the P criterion based on their persistency in abiotic degradation tests as well as in biotic degradation, screening and simulation tests. It was explained that although these substances do not fulfil the numerical B criterion of Annex XIII, PFOA and APFO are considered by DS as bioaccumulative substances using a weight of evidence (WoE) approach ~~that included~~ and based on further information, e.g. on the different bioaccumulation mechanism (binding to proteins), results from bioaccumulation in terrestrial species, detection of elevated levels in biota, in particular in endangered species or in vulnerable populations compared to levels in their surrounding environment as well as data from scientific analysis of human body fluids and tissues.

Based on comments received during public consultation, the WoE presentation regarding bioaccumulation was strengthened in the draft SDs, following the structure of Annex XIII, section 3.2 (Assessment information) by improving argumentation, data presentation and reflection of the uncertainties.

It was considered by MSC members that the presentation of the data and comparison of the information with the Annex XIII criteria using a WoE approach had been much improved, taking account of comments provided in the public consultation, and that as presented now in the draft SDs, it provides a good basis for considering identification of the substances as SVHCs.

The members considered first whether the provided evidence is sufficient to identify PFOA and APFO as SVHCs according to Article 57 (c) because of their toxic for reproduction properties. MSC concluded that the T criterion as specified in Annex XIII, 1.1.3 (b) and (c) can be considered as being met based on the RAC opinion on the harmonised classification of PFOA and APFO as Repr. 1B and STOT RE1 and the favourable vote on inclusion of the substances in Annex VI of CLP by the Commission's REACH Committee.

Concerning the persistency of PFOA and APFO, based on the evidence provided in the Support documents, the members supported the conclusions of the dossier submitter that these substances can be considered as persistent (P) and very persistent (vP).

As regards bioaccumulation (B) of PFOA and APFO, it was stated by some members that the proposals presented in the comments to use Article 57 (f) as the legal basis for identification would no longer seem to be necessary after improvement of the documentation of application of a WoE approach and other improvements and clarifications in the dossier.

MSC agreed with the dossier submitter's conclusion that the substances do not meet the numerical B criterion of Annex XIII based on BCF values. The conclusion of the DS was

supported that there are indications raising concern on bioaccumulation in terrestrial species and elevated levels in biota based on findings in herring gull eggs and in tawny owl eggs, in liver of polar bear and accumulation in terrestrial food webs. There is further supporting evidence from scientific analysis of human body fluids and tissues. PFOA is detected in human blood and breast milk, being persistent and not metabolised and having a long elimination half-life in humans.

The PFOA/APFO body distribution volumes and elimination pathways, were considered by the Committee and it was concluded that although differences between different species might be found in the elimination rates, there seems to be evidence available that these substances go to body organs (lungs, kidney and liver), blood and milk and that there are clear indications causing concern that the main elimination route in breastfeeding mothers is via breast milk. It was also concluded that the current dataset allows a robust decision-making for these substances.

An industry expert accompanying a MSC observer reminded that SVHC proposals for which a weight of evidence approach is used for the PBT determination should follow the same guidance provided to registrants on the preparation of Weight of Evidence outlined in the relevant ECHA guidance documents. He presented concerns related to the selective use of data from all available information, only supporting the proposal made. He further raised a multitude of issues related to the quality of data that are neglected or ignored in the dossier, a lack of discussion of the uncertainties around the use of disconnected data and with respect to use and calculation of magnification factors, in particular the lack of contemporaneous data for well-characterized, multi-level food chains. In addition, he criticised negligence of uncertainties associated with extrapolation from organ to organ across species, organ to whole body across species, cold-blooded species to warm-blooded species, lack of whole body residues and the in his opinion inadequately characterised exposures of the relevant species in field studies. Some issues regarding the consistency/adequacy of the data and the nature and severity of effects were also raised. In his view, the selected data taken together are inconclusive and the dossiers suggest that the justification for organ to organ extrapolation of bioaccumulation across species is based on the potential for "organ-specific toxicity" although there are no demonstrated effects on the organisms (e.g., toxicity) or their organs in these studies based on e.g., histopathological assessment of the organs from which the residue measurements were derived. The DS confirmed that different studies and arguments have been considered in the applied WoE approach for the bioaccumulation assessment, and that within these different studies different criteria had been followed when assessing the bioaccumulation potential within these studies made in Canada, EU or other countries. The draft Support Document tries to address these comments and provide answers.

The MSC Chair noted that MSC should assess whether the SVHC criteria are met in these SVHC cases and whether the implemented WoE approach allows drawing the necessary conclusions for the MSC agreement seeking.

Following this discussion, the support documents and the respective agreements for PFOA and APFO were updated to further clarify the bioaccumulation/elimination mechanisms and to better accommodate the uncertainties in the WoE approach applied.

In conclusion, MSC unanimously agreed to identify PFOA and APFO as SVHCs in accordance with Articles 57 (c) and (d) of Regulation (EC) 1907/2006 (REACH) due to their toxic for reproduction and PBT properties. MSC unanimously agreed on their support documents and agreements as amended during the meeting.

The Chair thanked the dossier submitters, the German CA as well as the Norwegian CA, for preparing the proposals and for bringing up interesting new cases where the revised Annex XIII criteria could be applied in practice.

Item 8 – Prioritisation of Candidate List substances for inclusion in Annex XIV

a. Discussion on ECHA's 5th draft recommendation for inclusion of priority substances in Annex XIV

MSC took note of the further work carried out for the 5th draft recommendation for inclusion on substances for the authorisation list (Annex XIV). In the presentation SECR also provided responses to the written comments submitted by members after the MSC-29 meeting. In its updated meeting document which was provided as a room document SECR proposed to not include decaBDE in the 5th draft recommendation following the proposal by Norway to list the substance in the Stockholm Convention on Persistent Organic Pollutants (POPs) and following the information from the Commission services that a request for ECHA to prepare a restriction proposal for that substance is soon to be submitted. Commission observer further explained that it is recommended to refrain from recommending decaBDE in order to avoid legislative divergence and that restriction would be a clearer regulatory approach supporting inclusion in Stockholm convention.

However, MSC unanimously opposed the view not to include deca-BDE in the draft recommendation for the public consultation. Firstly, because the process to include deca-BDE under the Stockholm convention is very long and the outcome at this stage is very uncertain and secondly, as there was no information available on the planned scope of the restriction and its time-schedule, nor any confirmed intention for such Annex XV proposal. Therefore it was felt that delaying the public consultation was associated with a risk of no action. MSC could not see a reason why the substance could not be removed from the draft recommendation after the public consultation or even from Annex XIV in the same way as from Annex XVII if inclusion in Stockholm convention would one day take place.

Secretariat promised to report on the view of MSC to the ECHA management which will then decide whether to include the substance decaBDE in the draft recommendation for the public consultation or not.

As regards the inclusion of substances for public consultation and the reasoning provided at MSC-29 seven members had submitted written comments on 4-tert-OPnEO, RCFs, decaBDE, ADCA and DMF. In the discussion those views were partly repeated and the comments on ADCA and DMF were further supported. Several members suggested reconsidering inclusion of DMF. Some members indicated that it is not proportionate to add those substances (i.e. DMF and ADCA) to Annex XIV. However, they acknowledged that ECHA's arguments for prioritising these substances followed the agreed approach and that based on this approach these substances go to the public consultation. Some members felt that ECHA is maybe too constrained by the prioritisation criteria and the uncertainties should still be further reflected. As regards RCFs some members felt the wide dispersive use had been overestimated. Consistency and balance of the scoring for those substances was also called for by one Stakeholder observer, also reminding about the complexity of the organisation of the downstream users in that sector which needs to be counted for when considering the latest application dates. When discussing the comments of MSC on substances proposed to be included in the draft recommendation SECR indicated that these were mostly not exactly in the scope of the prioritisation criteria as defined in Article 58(3) and further elaborated in the generic approach document and thus it is difficult for SECR to take them into account.

It was concluded that all five proposed substances and possibly decaBDE will be included in the draft recommendation for the public consultation by ECHA but MSC will reflect the comments already received at this stage in its opinion. SECR informed that it plans to launch public consultation of its 5th draft recommendation for Annex XIV priority substances on approximately 24 June.

b. Review of the general priority setting approach – first discussion

SECR presented a proposal for an approach to review the priority setting approach for inclusion of substances from the candidate list to the authorisation list and some of its initial findings that came up during testing of some of the aspects, such as considering use descriptors like SU/PROC/ERC for assessment of wide-dispersiveness of use, refinement of intrinsic properties, use of information on occurrence of industrial/professional/consumer use as indication for wide-dispersiveness. As main reasons for the revision it was explained that the current prioritisation approach was developed before the first registration deadline

and that SECR has recognised some difficulties in keeping the assessment at an appropriate level keeping in mind the role of prioritisation in the authorisation process. The review aims also to contribute to the workability, and increase the predictability and transparency of the process, in particular for industry. It was emphasised that the purpose of the prioritisation work is not expected to be a list of substances with a correct order but rather to identify the most relevant substances for inclusion in Annex XIV first. Similarly, the starting point for the work will remain the criteria in Article 58(3), as assessed per substance and not per use or per individual company.

MSC supported the proposal to consider a simplified approach for prioritisation and welcomed the idea that the main focus of the revision was in assessment criteria of wide dispersiveness of use. Many members welcomed the ideas presented. Some meeting participants were stating that more evaluation of the testing and results of those are needed for further discussion. While supporting the use and importance of use descriptors, one member noted that these may not be consistently used in the registration dossiers and that Stakeholder Observers of MSC could play a role in communicating this further to the registrants. A further suggestion from one of them was to consider also the physical form of the substance as this is currently not factored in but may be critical for exposure considerations.

MSC was invited to provide written comments based on the presentation. SECR explained that it will further test different models for prioritisation approach and report back to MSC in September. Following a proposal from SECR it was decided that a special back-to-back meeting with MSC-31 meeting in September will be organised to give an opportunity for an in depth discussion on this topic.

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. Task of the Rapporteur in drafting the opinion of the MSC

b. Appointment of Rapporteur

c. Establishment of a MSC 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 5th draft recommendation of ECHA.

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

Item 10 – Substance evaluation

a. Request to provide an opinion on addition of a substance in the Community Rolling Action Plan (CoRAP) in accordance with Article 45(5) of REACH

Following a request from Germany in May to add one substance, 1,4-benzenediamine, N,N'-mixed phenyl and tolyl derivatives, to the CoRAP using the procedure described in Article 45(5) of REACH and requesting to add the substance to CoRAP outside the annual update of CoRAP, MSC was requested to provide its opinion on this possible addition. The Rapporteur, as mandated by MSC for this task already in September last year in the context of the Rapporteur appointment for the first CoRAP update, introduced the draft opinion and how it was developed using the same criteria as was used for the MSC opinion on the first update of the CoRAP in February. After a brief discussion MSC adopted the opinion on the proposal to add this substance to the CoRAP to be evaluated still this year.

After the formal adoption of the opinion SECR reminded about the additional administrative burden this type of urgent request creates and how any addition of substances to the CoRAP, even though may well serve a purpose, requires also budgetary resources from ECHA which might be difficult to organise at short notice, and inevitably will lack confirmation about the substance identity or a possibility to carry out a

compliance check in advance if required. With this in mind SECR suggested that addition of substances to the CoRAP during the year, outside the regular annual CoRAP update, should be reserved for exceptional situations and always include substantiation for the urgency. Appreciation about the proactive role of Germany was indicated by one Stakeholder Observer. For possible future cases development of some criteria/justification of urgency was proposed during the discussion.

b. Report from the ECHA workshop on Substance Evaluation (23-24 May 2013) and update by ECHA on the work on the next CoRAP update

SECR provided a report on the main outcome from the discussions that took place on the substance evaluation workshop in May. No discussion took place but one Stakeholder Observer expressed their appreciation for the possibility to attend such a workshop for the first time, and the possibility for interactions that it offered.

MSC also heard an update on the progress made in the development of the next CoRAP update with MSs and ECHA Secretariat. Based on the work until now, a compilation of a preliminary draft CoRAP update is on-going, and allocation of evaluating MSs and substances should be done by mid-August. The plan is to publish draft CoRAP update in November and final one in March.

The Chair encouraged members to consider volunteering for rapporteurship and as members of the working group that are planned to be established for drafting the MSC opinion on the next CoRAP update in the September meeting of MSC.

c. Processing of draft decisions for substance evaluation - short update by the Secretariat

SECR informed MSC about the plans of MSCAs about when they intend to address their substance evaluation draft decisions for MSCA consultation and consequently in MSC meetings in the autumn and beginning of next year. Based on the available plans, the first draft decision on substances placed on the CoRAP for evaluation in 2012 is likely to be targeted to the September MSC meeting, and a few more planned for November and December meetings. As not all plans were yet communicated to ECHA, SECR encouraged the remaining MSCAs to try to plan their work ahead as far as possible, and then indicate those plans to SECR. It was reminded that a booking table is available for that purpose in Evaluation CIRCABC. SECR also suggested that the procedural deadlines are strictly followed and informed the participants about further detailed guidance being prepared on the decision making process for substance evaluation which will soon be available in CIRCABC.

Item 11 – Report from other ECHA bodies and activities

The MSC Chair informed MSC of the report prepared by the Committees' Secretariat on the basis of a request from the ECHA's Management Board on the Committees' functioning with regard to the increasing workload. It was noted that the main option considered in the document refers to the potential co-opting of members in the Committees for Risk Assessment and for Socio-economic analyses, as this is not seen necessary for MSC at this stage.

Item 12 – Any other business

No suggestions have been received by members under this agenda item.

Item 13– Adoption of conclusions and action points

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

SIGNED

Anna-Liisa SUNDQUIST
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
BIWER, Arno (LU)
CONWAY, Louise (IE)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)

ECHA staff
ANDERSSON, Niklas
BALLESTER CASALS, Juan
BALOGH, Attila
BELL, David
BIGI, Elena
BROERE, William

FINDENEGG, Helene (DE)	CARLON, Claudio
FLODSTRÖM, Sten (SE)	CLENAGHAN, Conor
GAIDUKOVS, Sergejs (LV)	DANCET, Geert
HUMAR-JURIC, Tatjana (SI)	DE COEN, Wim
KOUTSODIMOU, Aglaia (EL)	DELOFF-BIALEK, Anna
KULHANKOVA, Pavlina(CZ)	DEMATTIO, Silvia
LULEVA, Parvoleta (BG)	DE WOLF, Watze
MARTIN, Esther (ES)	FASEY, Andrew
MIHALCEA-UDREA, Mariana (RO)	FEEHAN, Margaret
PALEOMILITOU, Maria (CY)	HAUTAMÄKI, Anne
PISTOLESE, Pietro (IT)	HEIKKILÄ, Minna
REIERSON, Linda (NO)	HUUSKONEN, Hannele
STESSEL, Helmut (AT)	JACQUET, Cyril
TALASNIEMI, Petteri (FI)	KARHU, Elina
TYLE, Henrik (DK)	KORJUS, Pia
VANDERSTEEN, Kelly (BE)	KOULOUMPOS, Vasileios
VESKIMÄE, Enda (EE)	KREUZER Paul
WIJMENGA, Jan (NL)	LEHTILÄ, Reko
Representatives of the Commission	LOUEKARI, Kimmo
KOBE, Andrej (DG ENV)	LUOTAMO, Marita
STRECK, Georg (DG ENTR)	MÜLLER, Birgit
Observers	NAUR, Liina
ANNYS, Erwin (CEFIC)	NYGREEN, Beryl
BASTIJANCIC-KOKIC, Biserka (HR)	O'FARRELL, Norah
BUONSANTE, Vito (ClientEarth)	PELTOLA-THIES, Johanna
DROHMANN, Dieter (ORO)	REUTER, Ulrike
LIGTHART, Jerker (ChemSec)	RAHKONEN, Olli
SCHUBERT, Kai-Volker (expert accompanying Erwin ANNYS for PFOA/APFO discussion under item 7	RIBEIRO, Lucie
STAIRS, Kevin (Greenpeace)	RUOSS, Jürgen
TAYLOR, Katy (ECEAE)	RÖNTY, Kaisu
VAN VLIET, Lisette (HEAL)	SOBANSKA, Marta
WAETERSCHOOT, Hugo (Eurometaux)	SUNDQUIST, Anna-Liisa
	TARAZONA, José
	TISSIER, Chrystèle
	VAHTERISTO, Liisa
	VASILEVA, Katya

Proxies

- KULHANKOVA, Pavlina (CZ) also acting as proxy of RUSNAK, Peter (SK)
- MICHALCEA-UDREA, Mariana (RO) also acting as proxy of CRUZ, Ana Lúcia (PT)
- PISTOLESE, Pietro (IT) also acting as proxy of CAMILLERI, Tristan (MT)
- STESSEL, Helmut (AT) also acting as proxy of ANDRIJEWSKI, Michal (PL)
- STESSEL, Helmut (AT) also acting as proxy of HUMAR-JURIC, Tatiana (SI) on Thursday and Friday

Experts and advisers to MSC members

ALMEIDA, Inês (PT) (expert to CRUZ, Ana Lúcia)
ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
DOBRAK-VAN BRELO, Agnieszka (BE) (expert to VANDERSTEEN, Kelly)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
GUTZKOW, Kristine Bjerve (NO) (expert to REIERSON, Linda)
INDANS, Ian (UK) (expert to DOUGHERTY, Gary)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)

MALKIEWICZ,Katarzyna (SE) (expert to FLODSTRÖM, Sten)
MORKA, Heidi (NO) (adviser to REIERSON, Linda)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
PIPIRAITE-VALISKIENE, Donata (LT) (expert to DUNAUSKIENE, Lina)
RÜHL, Dana (DE), (expert to FINDENEGG, Helene)
TRAAS, Theo (NL) (expert to WIJMENGA, Jan)

SVHC dossier submitter representatives:
BRANDT, Marc (DE) for four phenolic benzotriazoles
STOCK, Frauke (DE) for 4-nonylphenol ethoxylates
VIERKE, Lena (DE) for PFOA and APFO
WARHOLM, Margareta (SE) for Cd and CdO

By WEBEX-phone connection:
HAKKERT Betty (NL) and GOMEZ Jeannette (NL) during agenda items 1-9; STAUDE Claudia (DE), JÖHNCKE Ulrich (DE), BECKER Eva (DE), DUNGEY Steve (UK), CORRELL MYHRE Ingunn (NO), KOPANGEN Marit (NO), BLOM Cécile (NO), HUSA Stine (NO), HAUG Line Småstuen (NO) and BAUMBUSCH Angelica (NO) during agenda item 7; GARCÍA-JOHN Enrique, BERTATO Valentina, LUVARÀ Giuseppina, BORRAS HERRERO Anna, ROZWADOWSKI Jacek, FERNANDES DE BARROS Mariana, POPOVA Temenuzhka and LUNGU Marilena from EC during agenda items 6-10.

Case owners:
Representatives of the Registrant were attending under agenda item 6b for cobalts category.

Apologies:
ANDRIJEWSKI, Michal (PL)
CAMILLERI, Tristan (MT)
COSGRAVE, Majella (IE)
CRUZ, Ana Lúcia (PT)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
RUSNAK, Peter (SK)

III. Final Agenda

ECHA/MSC-30/2013/A/30

Agenda
30th meeting of the Member State Committee

11-14 June 2013
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

11 June: **starts at 9:00**
14 June: **ends at 13:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/030/2013
For adoption

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

Item 4 – Administrative issues

For information

Item 5 – Adoption of minutes of the MSC-29

- Adoption of draft minutes of MSC-29

MSC/M/29/2013
For adoption

Item 6 – Dossier evaluation

Closed session for 6c, 6d(partly) and 6e1
Indicative time plan for 6b is Day 1, for 6c Day 2-4

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

ECHA/MSC-30/2013/081
For information

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

For discussion followed by agreement seeking under 6c:

ECHA/MSC-29/2013/084

Testing proposals

TPE 049/2013 2-{N-[2,6-Diamino-4-oxo-4H-pyrimidin-(5Z)-ylidene]-hydrazino}-5-methyl-benzenesulfonic acid (List No. 700-002-8)
ECHA/MSC-30/2013/002-003

TPE 055/2013 Tricobalt tetraoxide (EC No. 215-157-2)
ECHA/MSC-30/2013/006-008

TPE 056/2013 Cobalt dichloride (EC No. 231-589-4)
ECHA/MSC-30/2013/009-011

TPE 057/2013 Cobalt di(acetate) (EC No. 200-755-8)
ECHA/MSC-30/2013/012-014

TPE 058/2013 Cobalt carbonate (EC No. 208-169-4)
ECHA/MSC-30/2013/015-017

TPE 059/2013 Cobalt sulphate (EC No. 233-334-2)
ECHA/MSC-30/2013/018-020

TPE 060/2013 Cobalt dinitrate (EC No. 233-402-1)
ECHA/MSC-30/2013/021-023

TPE 061/2013 Cobalt oxide (EC No.215-154-6)
ECHA/MSC-30/2013/024-026

TPE 062/2013 Cobalt bis(2-ethylhexanoate) (EC No. 205-250-6)
ECHA/MSC-30/2013/027-029

TPE 063/2013 Cobalt hydroxide oxide (EC No. 234-614-7)
ECHA/MSC-30/2013/030-032

TPE 064/2013 Cobalt dihydroxide (EC No. 244-166-4)
ECHA/MSC-30/2013/033-035

TPE 065/2013 Cobalt (EC No. 231-158-0)
ECHA/MSC-30/2013/036-038

TPE 066/2013 Cobalt, borate neodecanoate complexes (EC No. 270-601-2)
ECHA/MSC-30/2013/039-041

TPE 069/2013 bis(2,3-epoxypropyl) terephthalate (EC No. 230-565-0)
ECHA/MSC-30/2013/042&044

TPE 070/2013 Trichloroacetic acid (EC No. 200-927-2)
ECHA/MSC-30/2013/045&047

TPE 071/2013 Sodium trichloroacetate (EC No. 211-479-2)
ECHA/MSC-30/2013/048&050

TPE 052/2013 3,6-bis(4-tert-butylphenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione (EC No. 416-250-2)
ECHA/MSC-30/2013/004-005

For information and discussion

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

As listed above under **6b** and cases returned from written procedure for agreement seeking in the meeting:

TPE 053/2013 3,6-bis-biphenyl-4-yl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione (EC No. 413-920-6)
ECHA/MSC/D/2013/0107-8

TPE 067/2013 Reaction mass of 2-methylpent-2-ene and diisopropyl ether (List No. 906-484-8)

ECHA/MSC/D/2013/0109-110

TPE 068/2013 Reaction mass of 2,2'-oxydibutane and 2-methylpropan-2-ol and butan-2-ol and 2,2'-oxydipropane (List No. 903-919-3)

ECHA/MSC/D/2013/0111-3

TPE 072/2013[1] Cyclohexyldimethoxymethylsilane (EC No. 402-140-1)

ECHA/MSC/D/2013/0114-5

For agreement

d. Update on appeal cases *(Partly closed session)*

ECHA/MSC-30/2013/001
For information

e. General topics

1) Introduction to issues to be considered in the context of a complex category evaluation **(*Closed session*)**

For information and discussion

2) Status report on on-going evaluation work

For information

Item 7 – SVHC identification

Indicative time plan: Start on Day 2

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

Room document
For information

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

- Cadmium (EC No. 231-152-8)

  ECHA/MSC-30/2013/051-053

- Cadmium oxide (EC No. 215-146-2)

  ECHA/MSC-30/2013/054-056

- 4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]

  ECHA/MSC-30/2013/057-059

- 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) (EC No. 253-037-1)

  ECHA/MSC-30/2013/060-062

- 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) (EC No. 247-384-8)

  ECHA/MSC-30/2013/063-065

- 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327) (EC No. 223-383-8)

  ECHA/MSC-30/2013/069-071

- 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) (EC No. 223-346-6)

  ECHA/MSC-30/2013/072-074

- Ammonium pentadecafluorooctanoate (APFO) (EC No. 223-320-4)

ECHA/MSC-30/2013/075-077

- Pentadecafluorooctanoic acid (PFOA) (EC No. 206-397-9)

ECHA/MSC-30/2013/078-080

For agreement

Item 8 – Prioritisation of Candidate List substances for inclusion in Annex XIV

a. Discussion on ECHA's 5th 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 (2nd discussion)

ECHA/MSC-30/2013/086-094

For discussion

b. Review of the general priority setting approach – first discussion

For information and 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. Task of the Rapporteur in drafting the opinion of the MSC

ECHA/MSC-30/2013/082

For discussion & decision

b. Appointment of Rapporteur

For decision

c. Establishment of a MSC Working Group to support the Rapporteur

ECHA/MSC-30/2013/083

For decision

Item 10 – Substance evaluation

a. Request to provide an opinion on addition of a substance on the CoRAP in accordance with Article 45(5) of REACH

ECHA/MSC-30/2013/067-068

- Draft opinion from the Rapporteur

ECHA/MSC-30/2013/085

For discussion and possible adoption

b. Report from the ECHA workshop on Substance Evaluation (23-24 May 2013) and update by ECHA on the work on the next CoRAP update

For information and discussion

c. Processing of draft decisions for substance evaluation - short update by the Secretariat

For information

Item 11 – Report from other ECHA bodies and activities

For information

Item 12 – Any other business

- Suggestions from members

For information

Item 13– Adoption of conclusions and action points

- Table with conclusions and action points from MSC-30

For adoption

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-30, 11-14 June 2013
(adopted in written procedure on **21 June 2013**)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 - Administrative issues	
	MSC to provide further feedback to the SECR on the new travel agency's services provided when organising their travel and accommodation arrangements for MSC-30 after the meeting
Item 5 – Adoption of minutes of the MSC-29	
MSC adopted the draft minutes without further changes made in the meeting.	MSC-S to upload final version of the minutes on MSC CIRCABC by 17 June 2013.
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-30/2013/081.
6b. Introduction to and preliminary discussion on draft decisions on testing proposals after MS-CA reactions (*Session 1, open*) **6c. Seeking agreement on draft decisions on testing proposals 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: • TPE 049/2013 2-{N-[2,6-Diamino-4-oxo-4H-pyrimidin-(5Z)-ylidene]-hydrazino}-5-methyl-benzenesulfonic acid (List No. 700-002-8) • TPE 052/2013 3,6-bis(4-tert-butylphenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione (EC No. 416-250-2) • TPE 053/2013 3,6-bis-biphenyl-4-yl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione (EC No. 413-920-6) • TPE 055B/2013 Tricobalt tetraoxide (EC No. 215-157-2) • TPE 056B/2013 Cobalt dichloride (EC No. 231-589-4) • TPE 057B/2013 Cobalt di(acetate) (EC No. 200-755-8) • TPE 058B/2013 Cobalt carbonate (EC No. 208-169-4) • TPE 059B/2013 Cobalt sulphate (EC No. 233-334-2) • TPE 060B/2013 Cobalt dinitrate (EC No. 233-402-1)	MSC-S to upload on MSC CIRCABC the final ECHA decisions/cover letters of the agreed cases.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
• TPE 061B/2013 Cobalt oxide (EC No.215-154-6) • TPE 062B/2013 Cobalt bis(2-ethylhexanoate) (EC No. 205-250-6) • TPE 063B/2013 Cobalt hydroxide oxide (EC No. 234-614-7) • TPE 064B/2013 Cobalt dihydroxide (EC No. 244-166-4) • TPE 065B/2013 Cobalt (EC No. 231-158-0) • TPE 066B/2013 Cobalt, borate neodecanoate complexes (EC No. 270-601-2) • TPE 068B/2013 Reaction mass of 2,2'-oxydibutane and 2-methylpropan-2-ol and butan-2-ol and 2,2'-oxydipropane (List No. 903-919-3) • TPE 069B/2013 Bis(2,3-epoxypropyl) terephthalate (EC No. 230-565-0) • TPE 070/2013 Trichloroacetic acid (EC No. 200-927-2) • TPE 071/2013 Sodium trichloroacetate (EC No. 211-479-2) • TPE 072/2013 Cyclohexyldimethoxymethylsilane (EC No. 402-140-1)	
MSC could not reach unanimous agreement on the following draft decisions as modified in the meeting where appropriate: • TPE 055A/2013 Tricobalt tetraoxide (EC No. 215-157-2) • TPE 056A/2013 Cobalt dichloride (EC No. 231-589-4) • TPE 057A/2013 Cobalt di(acetate) (EC No. 200-755-8) • TPE 058A/2013 Cobalt carbonate (EC No. 208-169-4) • TPE 059A/2013 Cobalt sulphate (EC No. 233-334-2) • TPE 060A/2013 Cobalt dinitrate (EC No. 233-402-1) • TPE 061A/2013 Cobalt oxide (EC No.215-154-6) • TPE 062A/2013 Cobalt bis(2-ethylhexanoate) (EC No. 205-250-6) • TPE 063A/2013 Cobalt hydroxide oxide (EC No. 234-614-7) • TPE 064A/2013 Cobalt dihydroxide (EC No. 244-166-4) • TPE 065A/2013 Cobalt (EC No. 231-158-0) • TPE 066A/2013 Cobalt, borate neodecanoate complexes (EC No. 270-601-2) • TPE 067/2013 Reaction mass of 2-methylpent-2-ene and diisopropyl ether (List No. 906-484-8) • TPE 068A/2013 Reaction mass of 2,2'-oxydibutane and 2-methylpropan-2-ol and butan-2-ol and 2,2'-oxydipropane (List No. 903-919-3) • TPE 069A/2013 Bis(2,3-epoxypropyl) terephthalate (EC No. 230-565-0)	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).
Item 7 – SVHC identification **a) Written procedure report on seeking agreement on identification of SVHCs**	
MSC unanimously agreed to identify the following substance as an SVHC in written procedure (and unanimously agreed on its SD and agreement as presented in the respective documents): • Dipentyl phthalate (DPP) (EC No. 205-017-9)	SECR to add the newly identified SVHC (in written procedure) to the Candidate List. SECR to upload the

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	agreement and support document on MSC CIRCABC and to publish them, as well as the RCOM, on the MSC section of the ECHA website.
7b) Seeking agreement on Annex XV proposals for identification of SVHC	
MSC unanimously agreed to identify the following substances as SVHCs (and unanimously agreed on their SDs and agreements as presented in the respective documents): • Cadmium (EC No. 231-152-8) • Cadmium oxide (EC No. 215-146-2) • 4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof] • Ammonium pentadecafluorooctanoate (APFO) (EC No. 223-320-4) • Pentadecafluorooctanoic acid (PFOA) (EC No. 206-397-9) With regard to the Annex XV dossiers proposing SVHC identification of PhBTAs under Article 57 (d) and/or under Article 57(e) and following the discussion at the meeting, MSC unanimously agreed that it is currently not possible to conclude on SVHC identification of the following substances: • 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) (EC No. 253-037-1) • 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328) (EC No. 247-384-8) • 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327) (EC No. 223-383-8) • 2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320) (EC No. 223-346-6)	SECR to add the newly identified SVHCs to the Candidate List (update foreseen by 20 June 2013). SECR to upload the agreements and support documents on MSC CIRCABC and to publish them, as well as the RCOMs, on the MSC section of the ECHA website. SECR to upload on MSC CIRCABC and ECHA website the MSC agreements that it was not possible to conclude on the identification of the four substances as SVHCs.
Item 8 – Prioritisation of Candidate List substances for inclusion in Annex XIV **c. Discussion on ECHA's 5th 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 (2nd discussion)	
MSC took note of the further work carried out for the 5th draft recommendation for inclusion of priority substances in Annex XIV and the responses of SECR to the written comments submitted. SECR had proposed to not include decaBDE following the proposal by NO to list the substance in the Stockholm Convention on Persistant Organic Pollutants. However, MSC supported inclusion of decaBDE in the draft recommendation at this stage.	SECR to consider further the MSC input on all the substances that are under consideration to be recommended. SECR to launch public consultation of its 5th draft recommendation for Annex XIV priority substances on 24 June.
8b. Review of the general priority setting approach – first discussion	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
MSC acknowledged the initial work to review the priority setting approach and welcomed the plan to discuss it further in September.	MSC to provide comments and views on the initial plans for the review to the Secretariat by 5 July 2013. SECR to organise a back-to-back meeting (with MSC-31) to discuss with interested MSC participants the results from testing new approaches for setting priority with the available data.
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 **d. Task of the Rapporteur in drafting the opinion of the MSC** **e. Appointment of Rapporteur** **f. Establishment of a MSC Working Group to support the Rapporteur**	
MSC adopted the mandate and the tasks of the rapporteur, and appointed one member as a Rapporteur for drafting the MSC opinion on ECHA's 5th draft recommendation. MSC established a working group to support the Rapporteur and appointed volunteering members to it.	
Item 10 – Substance evaluation **d. Request to provide an opinion on addition of a substance on the CoRAP in accordance with Article 45(5) of REACH**	
Draft opinion from the Rapporteur was adopted by MSC.	MSC opinion to be published with the CoRAP update with this one substance.
Item 10 – Substance evaluation **b. Report from the ECHA workshop on Substance Evaluation (23-24 May 2013) and update by ECHA on the work on the next CoRAP update**	
MSC took note of the report.	MSC members to consider possibilities to volunteer for next Rapportership for MSC opinion development on the next CoRAP update.
Item 10 – Substance evaluation **c. Processing of draft decisions for substance evaluation - short update by the Secretariat**	
MSC took note of the status report.	Members/Evaluating MSCAs to indicate their plans in terms of decision making process for the 2012 CoRAP substances in a booking table that is available on Evaluation CIRCABC.
Item 13 – Adoption of conclusions and action points	
MSC to adopt the conclusions and action points of MSC-30 in written procedure.	MSC-S to upload the conclusions and action points on MSC CIRCABC by 17 June 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 040/2013	Nectaryl	404-240-0
TPE 048/2013	Reaction mass of 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched and 1,3-Propanediamine, N-[3-(tridecyloxy)propyl]-, branched acetate	To be defined

Draft decisions that written procedure was terminated for:

MSC ID number	Substance name used in draft decision	EC No
TPE 053/2013	3,6-bis-biphenyl-4-yl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	413-920-6
TPE 067/2013	Reaction mass of 2-methylpent-2-ene and diisopropyl ether	906-484-8
TPE 068A/2013	Reaction mass of 2,2'-oxydibutane and 2-methylpropan-2-ol and butan-2-ol and 2,2'-oxydipropane	903-919-3
TPE 068B/2013	Reaction mass of 2,2'-oxydibutane and 2-methylpropan-2-ol and butan-2-ol and 2,2'-oxydipropane	903-919-3
TPE 072/2013	Cyclohexyldimethoxymethylsilane	402-140-1

VI. Statements of the Danish MSC member and Dutch MSC alternate member on dossier evaluation cases TPE 049 and TPE 052

TPE 049

The Netherlands and Danish MSC members strongly encourage ECHA to make contact with the registrant immediately after issuing the decision on testing proposal 049. This would be with the purpose to point out that as a result of rejecting his testing proposal on a prenatal developmental toxicity test, a data gap exists for the standard information requirement at Annex VIII concerning the prenatal development/ reproductive toxicity screening test. The Netherlands and Danish MSC members propose to ECHA to initiate a targeted compliance check on this endpoint if the registrant does not supply the information in accordance with REACH requirements of his own accord within a reasonable time frame.

TPE 052

The Netherlands and Danish MSC members have noted that the registrant has not explicitly indicated that he will include the developmental neurotoxicity (DNT) and developmental immunotoxicity (DIT) cohorts in his testing proposal for the Extended One Generation Reproductive Toxicity Study (EOGRTS). The Netherlands and Danish MSC members assume that this will be the case because inclusion of these two cohorts was supported by the Reproductive Toxicity Expert Group established by the Commission, except in cases where specific information is available that renders inclusion of these cohorts scientifically unnecessary. Developmental neurotoxicity and developmental immunotoxicity furthermore are important aspects of modern higher tier reproductive toxicity studies.

VII. Statement of the German MSC member made with regard to the agreement seeking on the SVHC identification of UV-320, UV-327, UV-328 and UV-350

DE is of the opinion that it was possible to conclude on the SVHC properties of the four Benzotriazoles (UV 350, UV 328, UV 327, UV 320) based on the Annex XV dossiers and the discussions during the meeting.

Therefore I could not agree to the conclusion. As we wanted to avoid non-unanimous agreement DE decided to abstain from vote in this case.

We plan to discuss the dossier again in the PBT WG and to submit Annex XV dossiers afterwards.