MSC/M/027/2012
ADOPTED at MSC-28

Minutes
of the 27th Meeting of the Member State Committee (MSC-27)
10-13 December 2012

I. Summary Record of the Proceedings

Item 1 - Welcome and Apologies

The Chair of the Committee, Ms Anna-Liisa Sundquist, opened the meeting and welcomed the participants to the 27th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes).

Item 2 - Adoption of the Agenda

The Agenda was adopted as provided for the meeting by the MSC Secretariat with two inclusions - under AOB (final Agenda is attached to these minutes).

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

No conflicts of interest were declared in respect to any Agenda point of the meeting.

Item 4 - Administrative issues

No administrative issues were announced or discussed.

Item 5 – Adoption of the minutes of the MSC-26 meeting

SECR presented the revised version of the MSC-26 minutes informing MSC that written comments on the draft minutes were received by three MSC members prior to the MSC-27 meeting. Two representatives of two Registrants for two dossier evaluation cases who had participated in MSC-26 have been also consulted for the respective parts of the draft minutes. One provided comments which were included in the minutes. In conclusion, the minutes were adopted with one further change carried out at the meeting. SECR would upload the minutes on MSC CIRCABC and ECHA website.

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 seven dossier evaluation cases (see Section V for more detailed identification of the cases). WP was launched on 14 November and closed on 26 November 2012. For three cases, the draft decision (DD) was split thus resulting in two DDs for these cases and overall 10 DDs for the seven cases. By the closing date, responses to WP were received from 23 members with voting rights and from the Norwegian member. Unanimous agreement was reached on seven DDs. For three DDs involving the standard information requirement for Annex X, 8.7.3, four votes indicated disagreement, 18 votes in two cases and 17 votes in one case were in favour of the DD and two MSC members in two cases and three MSC members in one case did not vote. Thus, these three cases are to be referred to COM for further decision-making under Article 133 (3) of REACH.

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-164/2012 2,6-di-tert-butylphenol (EC No. 204-884-0)

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.

ECHA explained that one PfA to ECHA's DD was submitted suggesting to use read-across from the substance 2,4-di-tert-butylphenol instead of testing 2,6-di-tert-butylphenol for 90-day repeated dose toxicity (RDT) and long-term toxicity on Daphnia.

ECHA Secretariat did not modify DD based on the PfA. The DD updated with procedural steps was provided to MSC for finding unanimous agreement.

The Registrant in the written comments on PfAs indicated difficulties in providing sufficient evidence for building up the read-across case and therefore contemplated to generate the proposed experimental data independently for 2,6 di-tert-butylphenol itself as this in his view would form a stronger position for further hazard/risk assessment purposes.

In the discussion, the expert of the MSC member representing the MSCA that submitted the PfA accepted ECHA's argumentation for not using read-across from 2,4-di-tert-butylphenol to the registered substance. No further discussion points were raised.

Session 2 (closed)
MSC found unanimous agreement on ECHA's DD as provided for the meeting.

TPE-165/2012 2,4-di-tert-butylphenol (EC No. 202-532-0)

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.

ECHA explained that two PfAs to ECHA's DD were submitted suggesting to test the registered substance in the *Daphnia magna* reproduction study (long-term toxicity testing on aquatic invertebrates) instead of reading-across from 2,6-di-tert-butylphenol.

ECHA Secretariat modified DD based on PfAs rejecting the read-across and requesting to test the registered substance in the *Daphnia magna* reproduction study. The DD modified and updated with procedural steps was provided to MSC for finding unanimous agreement.

The Registrant in the written comments on PfAs reconfirmed the view (expressed in the comments on DD earlier) that use of 2,6-di-tert-butylphenol as a read-across substance for 2,4-di-tert-butylphenol for the 90-day sub-chronic testing is justified. There were no PfAs provided on this information requirement.

In the discussion, the MSC member from MSCA that submitted one of the PfAs based among others on QSAR data emphasised that the detailed QSAR data referred to in PfA are publicly available. However, he accepted ECHA's argumentation that as these detailed data were not in sufficient details included in PfA, the Registrant may not have been fully aware of these data. In any case the QSAR data were not to be used as the only argumentation against the proposed read-across. Consequently, a reference to these QSAR data was not included in the statement of reasons (SoR) of DD as a supporting argument for rejection of the read-across.

MSC was of the view in agreement with ECHA that it shall be ensured that all aspects of the Registrant's written comments on DD and PfAs are sufficiently reflected in SoR of DD. Similarly, MSC also supported ECHA's view that the Registrant of a substance on the Community Rolling Action Plan (CoRAP) shall be explicitly reminded that if further testing turns out to be necessary in addition to tests required in the current DD, the Registrant should approach the competent authority performing the substance evaluation (according to the current CoRAP, the substance is due for substance evaluation in 2014).

Session 2 (closed)
Based on the above discussion, MSC concluded that a paragraph to Section II of DD should be added reminding the Registrant to contact the competent authority evaluating the substance if there is a need for further testing in addition to tests required in the current DD. MSC also concluded to further reflect in the section of SoR concerning the 90-day study not only to the steric but also the electronic effects within the molecules of 2,6-di-tert-butylphenol and 2,4-di-tert-butylphenol as both were raised by the Registrant in the written comments as important elements in the justification for the proposed read-across. MSC concluded at the same time to delete the same paragraph from the section of SoR concerning the Daphnia study as the issue of steric/electronic effects is

less relevant for this endpoint. Furthermore, MSC concluded to add a paragraph into SoR emphasising the overall uncertainty in the similarity of the (eco) toxicological profiles of the registered substance and the source substance for the proposed read-across.

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

TPE-170/2012 8,9,10-trinorborn-2-ene (EC No. 207-866-0)

Session 1 (open)

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

ECHA explained that two PfAs to ECHA's DD were submitted. One of them suggested for being consistent with section III of DD, including also in section II the additional parameters of alpha2u-globulin mediated effects on kidney required for the 90-day study as indicated in section III. The other PfA suggested requiring the 90-day study via the oral route instead of inhalation route for several reasons: although the vapour pressure is high at elevated temperatures, the pungent odour would seem to lower the concern for inhalation exposure; in an acute inhalation study in rats at concentrations >27 mg/L no clear site-of-contact effects could be observed (normally the maximum concentration employed for aerosols in accordance with OECD 413 is 5mg/L); in absence of local effects, a route-to-route extrapolation from oral to inhalation route would be valid to derive a DNEL for systemic effects.

ECHA Secretariat modified section II of DD based on PfA concerning alpha2u-globulin mediated effects on kidney. The DD modified and updated with procedural steps was provided to MSC for finding unanimous agreement.

Registrant's comments on PfAs of CAs and discussion

The Registrant did not provide any written comments on PfAs. The representatives of the Registrant in the meeting emphasised that the vast majority of the substance produced (90-95%) is used as on-site intermediate. For the rest, there is only very limited workers exposure (with very small number of workers exposed only twice a year for a short time) and no consumer use. The substance is submitted by the manufacturer to a small number of downstream users. The Registrant indicated that he was not aware of the possible exposer that may occur at the level of downstream users. Consequently, in their view, there is no serious concern for long-term local effects and thus the oral route for the 90-day study should be preferred. However, they confirmed that due to the nature of the handling process of the substance (pumping a fluid from one drum to another at 70 degree Celsius), the very limited workers exposure is only possible via inhalation.

The expert of the MSC member representing the MSCA that submitted the PfA for the oral route, mainly repeated their concerns as expressed in PfA. Furthermore, he also questioned the feasibility of an inhalation study based on the derived vapour pressure for 25 degree Celsius and whether vapour pressure data extrapolated from higher temperatures can be considered as valid (i.e., the measured values are being used to extrapolate through a phase transition from liquid to solid and so may not be valid). The expert also questioned the validity of the information on the eye irritation. As a response to these concerns, ECHA showed based on available data on vapour pressure and eye irritation that, in their opinion, an inhalation study is feasible.

Session 2 (closed)

Given that there is some uncertainty concerning local irritation effects, possible exposure and how they are controlled, MSC supported ECHA's view that the 90-day study should be performed via the inhalation route. Even though the MSCA proposing the oral route still had some reservations on the inhalation study being the best option, the member from this MSCA did not object to the test being requested. Based on the above discussion, MSC concluded to request the 90-day via the inhalation route. MSC also concluded concerning the required prenatal developmental toxicity (PNDT) study that the Registrant should be given the options to perform the test either in rabbits or in rats (in

accordance with the conclusion of the MSC-25 meeting) and the reference to EU test method B.29 should be deleted from Section II as not relevant (keeping only the reference to OECD 413).

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

TPE-172/2012 Phenol, isopropylated, phosphate (3:1) (EC No. 273-066-3)

Session 1 (open)

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

ECHA explained that ten PfAs to ECHA's DD were submitted by five CAs. One PfA requested the Registrant to consider the percentage of triphenyl phosphate (TPP) of the registered UVCB substance for the selection of test substance for the aquatic toxicity tests to ensure that any hypothesis for ecotoxicity made in the chemical safety report (CSR) can be confirmed. Another PfA suggested rejecting the fish early-life stage toxicity (FELS) test based on the data available for two chronic studies on fish and Daphnia (Klimisch score 2) on the substance (which was assumed to be the same as the registered substance) and available in the UK national assessment carried out for the substance and published in 2009.

Concerning PNDT study, one PfA suggested allowing the Registrant to select the species for the first PNDT study in accordance with the agreement of the MSC-25 meeting. A further PfA suggested requiring the Registrant to consider whether data from the OECD 422 screening study are sufficient to self-classify the registered substance as toxic to reproduction category 1B for development and adequate to support a robust risk assessment. If so, in their view the PNDT study would not be needed. Another PfA recognising that potential self-classification as toxic to reproduction category 1B based on data from the OECD 422 screening study indicating severe effects on functional fertility and reproductive organs is not a column 2 argument to waive the PNDT study, and therefore considered the requirement for the PNDT study relevant.

Concerning 90-day study, one PfA recognising that the reproductive effects indicated in the OECD 422 screening study are not sufficient to reject the proposal for a 90-day study, agreed with the requirement for the study.

Concerning the generation study, one PfA suggested requesting an extended one generation reproductive toxicity study (EOGRTS) for Annex X, 8.7.3 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. Another PfA suggested keeping the two options but excluding from the optional request for EOGRTS the extension of cohort 1B (production of F2 generation). Two further PfAs expressed the view that if the Registrant based on data from the OECD 422 screening study self-classifies the registered substance as toxic to reproduction category 1B for fertility, the generation study would not be needed. If the Registrant does not self-classify the substance, in accordance with PfA of DK-CA, they suggest requesting an EOGRTS for Annex X, 8.7.3 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.

ECHA Secretariat partially modified DD based on PfAs for the meeting concerning the considerations on the identity of the substance to be tested, the species of choice for the first PNDT study and potential self-classification and its consequences for the PNDT and generation study. ECHA Secretariat also split DD into TPE-172A and TPE-172B where TPE-172A addressed the information requirement for Annex X, 8.7.3 (two-generation reproductive toxicity) and TPE-172B addressed the information requirement for a 90-day repeated dose toxicity study (RDT), a PNDT study, a long-term toxicity testing on aquatic invertebrates study, a fish early-life stage study, a bioaccumulation in aquatic species study, a soil micro-organisms study and a long-term toxicity to sediment organisms study. In addition to the PfA-based modifications (see them above), ECHA

Secretariat also 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 Registrant in the written comments on PfAs provided comments on the whole DD and actually suggested to waive the information requirements for toxicity on soil micro-organisms, long-term toxicity to sediment organisms and long-term toxicity to terrestrial invertebrates, to use read-across approach to RDT and PNDT studies as well as to use weight of evidence approach to bioaccumulation in aquatic species. The Registrant also suggested to carry out only the two-generation reproductive toxicity study (OECD 416/EU B.35) and test for long-term toxicity to aquatic invertebrates and on fish with a substance where the concentration of TPP would be <5% and utilise existing data for classification at TPP concentration >5%.

The representatives of the Registrant in the meeting discussion concerning the long-term Daphnia and fish test emphasised that the composition of the substance (including content of mono-, di- and tri-propylated components) they have tested since 1980s is the same as registered for REACH and the substance referred to in the assessment report quoted by one of the PfAs. They agreed that the amount of different propylated components can influence the toxicity of the substance. They also explained that they introduced the TPP content as a marker for effects seen in their studies as the effects correlated well with the TPP content. Also the ranges of values of TPP content used in CSR (<5%, 5-20%, >20%) were introduced as markers for breaking points seen in the effects. Furthermore they highlighted that there are chronic test data for fish and Daphnia for the substance with >5% TPP content while for the substance with <5% TPP content there are no data; that is why they would like to perform the chronic Daphnia and fish test with the substance with <5% TPP content.

ECHA reminded the representatives of the Registrant that no updates submitted after the start of MSCA consultation can be considered for this DD and thus the new testing strategy expressed in the comments due to PfAs and in the late update to the registration dossier cannot be taken into account. Concerning the long-term Daphnia and fish test ECHA also pointed out that none of the substances in the assessment report quoted by one of the PfAs can be confirmed to be exactly the same as the registered substance. The difference is mainly due to the fact that while the registration dossier refers to mono-, di- and tri-propylated components, the quoted report mentions only mono- and tri-propylated components and obviously the full composition of the tested substance was not analysed for the test. Furthermore, in ECHA's view the composition of the substance to be tested remains uncertain and variable. ECHA would like to see ensured that the substance with the composition of the highest concern will be tested.

Concerning PNDT study, ECHA highlighted that if the substance will be self-classified as toxic to reproduction, category 1B for developmental effects, the study does not need to be performed. Concerning the generation study, ECHA stressed that the decision on which the test method to use is likely to be taken by the European Commission (COM) as the Committee most likely will not be able to find unanimous agreement on the test method to be used. The representatives of the Registrant highlighted that in their view the substance qualifies only for a category 2 classification for reproductive toxicity and they do not intend to self-classify the substance as category 1B without the results of the planned two-generation study or the OECD 443 study as recommended by several Member States.

MSC generally supported ECHA's views on the topics discussed.

Session 2 (closed)

MSC concluded to require the Registrant to perform both the chronic Daphnia and fish test (FELS) with the registered substance and to update the paragraph in section III on

testing of low water soluble UVCB substances concerning both tests. MSC also concluded to add a reminder on the waiving possibility conditioned on self-classification as toxic to reproduction, category 1B based on developmental effects/effects on fertility and on available toxicity data that are adequate to support a robust risk assessment, and to include this into the split DDs concerning both PNDT and generation study. MSC further concluded to add two paragraphs in section II to both split DDs reminding that the Registrant shall as far as possible ensure that the studies are planned in a way that takes into consideration the worst-case scenario for the concerned health and environment endpoints with regard to the composition of the tested substance, since it is clear that the substance is manufactured in different compositions. Consequently, the Registrant should report the composition of the tested samples of the registered substance and shall ensure and justify that the results are appropriate for a proper classification and labelling as well as for the chemical safety assessment of the different compositions of the UVCB substance. MSC also concluded to remove a paragraph from DD TPE-172A/2012 concerning the requirement for a PNDT study to be performed in a second species, as this reuiqrement is not relevant for this case.

MSC found unanimous agreement on ECHA's DD addressing the testing proposals for a RDT study, a PNDT study, a long-term toxicity testing on aquatic invertebrates study, a fish early-life stage study, a bioaccumulation in aquatic species study, a soil micro-organisms study and a long-term toxicity to sediment organisms study (TPE-172B/2012) as provided for the meeting and amended based on the above conclusions.

The Chair recognised the results of voting on DD (TPE-172A/2012) relating to TP for a two-generation reproductive toxicity study, as provided for the current meeting 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). ECHA will refer the case (TPE-172A/2012) to COM which will prepare a decision in accordance with the procedure of Article 133(3) of REACH.

d. Items for discussion following commenting by MSCAs

Closed session

ECHA replied to a question raised by a MSCA in the MSCA consultation on dossier evaluation cases concerning ECHA's strategy to dossiers with multiple data gaps where the same substance is already registered by a lead registrant on behalf of a SIEF. ECHA explained that its main policy line in these cases is to make the Registrant outside of SIEF to contact SIEF and fill in the data gaps with the data already available in SIEF. The MSC member of the questioning Member State (MS) welcomed ECHA's reply.

As a separate discussion point, ECHA also outlined how it will slightly modify its communication policy with MSCAs in the context of the MSCA consultation on dossier evaluation cases. The change will mainly affect the way how ECHA should be notified of any concerns of MSCAs which are not meant to be a PfA to a DD.

Open session

ECHA replied to a question raised by a MSCA in the MSCA consultation on dossier evaluation cases concerning the interpretation of BioMagnification Factor (BMF) values of fish dietary exposure tests in relation to PBT (persistent- bioaccumulative-toxic) assessment. ECHA informed that its PBT Working Group started working on this very complex issue and will update MSC on ECHA's harmonised approach probably in 2014. The MSC member of the questioning MS welcomed ECHA's reply.

e. General topics

Approach for terrestrial plant toxicity – long-term and short-term studies

ECHA presented the comments received from a stakeholder organisation (STO) and experts of MSs to ECHA's Scientific Discussion Paper (SDP) on Terrestrial Plant Toxicity Testing, together with ECHA's responses to them. MSC and the representative of the concerned STO accepted the responses and generally supported ECHA's recommendation for the approach to be followed for terrestrial plant toxicity in the context of testing proposal examinations. ECHA agreed to the view of one MSC expert that the calculations and generally the way leading to ECHA's conclusions in similar papers should be transparent enough in the future to allow readers to come to the same conclusions. MSC endorsed the recommended approach as provided for the meeting without any changes. Replying to a question ECHA recognised the need to complement the relevant guidance based on the endorsed approach. However, until this update will happen, ECHA will appropriately communicate the endorsed approach to MSCAs, MSC members and registrants so that they would know what line ECHA follows in this context.

f. Status report on ongoing evaluation work

SECR gave a detailed statistics and update on the status of evaluation work until end of November 2012. Also figures for the coming year were introduced. MSC took note of the report.

ECHA also stressed that as the number of cases referred to COM due to disagreement on the test method to be used for generation study is rapidly increasing (currently 43), an urgent solution is needed. To this end, ECHA indicated its firm intention to try and find possible agreement in MSC on DDs of selected cases where based on the specific features of the case an agreement could be searched without breaking the legal conditions for the decision-making. The four MSC members supporting EOGRTS against the two-generation study stressed that they have not changed their point of view and instead of case-by-case negotiations a fundamental resolution should be found. COM highlighted its willingness to start preparing the modification of the appropriate REACH Annexes and the Test Method Regulation at the beginning of 2013 if sufficient support from MSCAs to the relevant COM approach/paper will be received. COM was of the view that until changing the legal framework, chances for case-by-case dossier-specific solutions are very limited.

Item 7 – SVHC identification

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

SECR explained that unanimous agreement was sought for thirteen substances[1] in written procedure. The written procedure started on 19 November 2012. By closing date of 29 November, 25 responses were received from the MSC members with voting rights and the Norwegian member.

For one draft agreement (DecaBDE), 23 votes were in favour, and the Norwegian member also supported the agreement, none were against the proposed agreement, one member was not able to provide a view on the proposal and three members did not vote.

For the draft agreement on Lead monoxide, the written procedure was terminated at a member's request and the substance was addressed for further discussion and agreement seeking at this MSC plenary meeting.

[1] bis(pentabromophenyl)ether [decabromodiphenyl ether; decaBDE], dibutyltin dichloride (DBT), N,N-dimethylformamide [dimethyl formamide], orange lead [lead tetroxide], lead bis(tetrafluoroborate), trilead bis(carbonate) dihydroxide [basic lead carbonate], lead titanium trioxide, lead titanium zirconium oxide, silicic acid, lead salt, silicic acid ($H_2Si_2O_5$), barium salt (1:1), lead-doped [silicic acid, barium salt, lead-doped], 1-bromopropane [n-propyl bromide], methyloxirane [propylene oxide]

For all other substances, 24 members with voting rights and the Norwegian member responded in favour of the proposed agreements and the respective support documents, none were against and three members did not vote. Thus, MSC unanimously agreed to identify the 12 substances as SVHCs in written procedure on 29 November 2012. These substances would go on the candidate list on top of 31 other substances that will automatically be included in the candidate list since there were no relevant comments challenging their identification. The candidate list would be updated and published by 21 December 2012.

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

SECR gave a brief presentation reminding MSC of the key steps in the authorisation process within the risk management framework.

Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA) (EC 204-650-8)
The dossier submitter (DS) representative from the Austrian CA introduced to MSC the Annex XV proposal for the substance, that is classified as a respiratory sensitiser in Annex VI of the CLP Regulation, focusing on the key comments received during the public consultation and the way they had been responded to/addressed in the supporting documentation (draft support document (SD) and/or response to comments table (RCOM)). The dossier proposes for the first time identification of a SVHC based on Article 57 (f) because of its respiratory sensitising properties and adverse effects to human health. Documentation provided in the dossier demonstrates that there is evidence that ADCA is a strong respiratory sensitiser causing adverse effects to human health. MSC was informed that no relevant additional data have been provided during the public consultation on the Annex XV SVHC proposal for ADCA that may lead to modifications in the SD, therefore the only changes made are related to the better-structured justification and the inclusion of some remarks on skin sensitisation and more detailed explanations on study description. The dossier submitter furthermore considered that the scientific evidence of probable serious effects to human health is sufficient to consider that the substance gives rise to equivalent level of concern to those other substances referred to in Article 57.

SECR underlined that there are no specific provisions or criteria in Article 57 allowing the identification of a respiratory sensitiser as a SVHC. Therefore under Article 57(f), the assessment should be done on a case-by-case basis and MSC should consider whether there is scientific evidence of probable serious effects to human health of ADCA which give rise to an equivalent level of concern in comparison to those other effects addressed under Art 57 (a-e).

Concerning whether ADCA gives rise to an equivalent level of concern, it was argued by some members that the current proposal covers very general points which would be applicable to many sensitisers and would not be sufficiently specific for identification of ADCA as SVHC. Thus, MSC agreed that substance-specific argumentation would be needed for each individual case.

The high prevalence of cases in exposed workers (high incidence of respiratory sensitisation at work) was suggested to be considered as the argumentation combined with the information on the exposure levels which seemed to be relevant for triggering the respiratory sensitisation. This information was proposed to be used as surrogate information for potency which cannot be further explored because the evidence on the effects is based on empirical data from humans. Furthermore the evidence shows that the ADCA effects are severe and long-lasting and could be compared to CMR effects and that safe exposure limits cannot be derived. It was also indicated that the other elements listed in the general approach paper on SVHC identification of respiratory sensitisers were also explored and documented in the dossier.

Some members expressed doubt whether sufficient information was available to come to a conclusion that the substance could be considered as a SVHC. However, it was not possible to specify information which was missing to make the dossier more complete.

A few members pointed out that the prevalence cannot be considered as evidence for potency. In response, the dossier submitter clarified that the dossier includes a reference to a reliable study that provides information on the quite low exposure levels at the work place where cases of respiratory sensitisation had been identified. Further, three other studies show significant indications supporting the study conclusions. There are companies in EU still using ADCA although the number of exposed workers is significantly reduced, but exposure cannot be excluded. The dossier submitter stressed that also consumer exposure via articles may be possible.

It was noted that outside the MSC agreement seeking process on SVHC identification a risk management option analysis (RMOA) had been carried out by the DS, concluding that authorisation would be the proper regulatory measure to take. Although a member expressed the view that historically a restriction seemed to be the best route for regulating/controlling the risks arising from skin (and respectively respiratory) sensitisers, it was concluded that discussion on the risk management options is not part of the MSC agreement seeking process on SVHC identification and therefore such discussion should not take place in the MSC context. ECHA pointed out that identification of SVHCs has to be based on hazard-related argumentation as indicated in Article 57. One participant expressed however the view that it was in addition also the competence of MSC participants to consider whether the scope of application of Article 57 is fulfilled, i.e. whether it is appropriate to consider a substance for phase out in accordance with Article 55 defining the aim of the authorisation scheme.

It was concluded that ADCA is a strong respiratory sensitiser based on information on the prevalence of cases among exposed workers and information on relatively low exposure levels at work places. There is scientific evidence that ADCA induces occupational asthma with a possible delay of symptoms up to years. Prolonged exposure to ADCA may result in persistent symptoms of bronchial hyperresponsiveness lasting for years. Furthermore, although the irreversibility of the ADCA effects is not the same as for the CMRs (as the respiratory sensitisation symptoms can disappear when exposure is removed), the sensitisation reaction (elicitation) remains irreversible; therefore, it still arises a serious concern as no full recovery is possible even after cessation of exposure. Moreover, derivation of safe exposure limits is not possible and the severity of the effects is well-proven in the dossier and is equivalent to effects of substances identified as SVHCs under Article 57 (a)-(e). Therefore ADCA should be identified as a SVHC.

Following this discussion the support document and the respective agreement for ADCA were re-structured to further emphasise the scientific evidence as to why the substance is considered to probably elicit serious effects on human health due to its strong respiratory sensitising properties, which are of equivalent level of concern to those other effects referred to in Article 57.

Two MSC members pointed out that the identification of this respiratory sensitiser as a SVHC does not set a precedent for respiratory sensitisers in general, as the MSC agreement in accordance with Article 57 (f) is to be sought on a case-by-case basis considering the substance-specific justification and the scientific evidence provided in the Annex XV dossier.

One MSC member made a statement (provided in Annex VI to the current minutes) with regard to his vote on ADCA and the following two SVHC proposals on substances with respiratory sensitising properties. This statement was supported by the UK.

In conclusion, MSC unanimously agreed on its support document and agreement as amended during the meeting and identified ADCA as SVHC in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because it is a substance with respiratory sensitising properties for which there is scientific evidence of probable serious effects to human health which gives rise to an equivalent level of concern to effects of other substances listed in points (a) to (e) of Article 57 of REACH. The UK MSC member was deliberately absent for the vote.

Cyclohexane-1,2-dicarboxylic anhydride (HHPA) (EC 201-604-9), Cis-cyclohexane-1,2-dicarboxylic anhydride (EC 236-086-3), Trans-cyclohexane-1,2-dicarboxylic anhydride (EC 238-009-9)

Hexahydromethylphthalic anhydride (MHHPA) (EC 247-094-1), Hexahydro-4-methylphathalic anhydride (EC 243-072-0), Hexahydro-1-methylphathalic anhydride (EC 256-356-4), Hexahydro-3-methylphathalic anhydride (EC 260-566-1)

The DS representative from the Dutch CA presented to MSC the two Annex XV proposals for the above-mentioned substances, focusing on the responses to the comments received during the public consultation on the Annex XV proposals for HHPA and MHHPA that are classified respiratory sensitisers in Annex VI of the CLP Regulation. It was pointed out that defining of in quantitative terms safe concentration levels for these substances is not possible. Instead, in the Netherlands reference values corresponding to an additional risk for sensitisation of 10 % have been calculated. According to the dossier submitter irreversibility of adverse effects to the human health and indications of high potency in inducing respiratory sensitisation are well documented for HHPA and MHHPA.

Three members expressed general concerns similar to the ones brought forward for ADCA on the possibility that the cases would be seen as setting a precedent for other respiratory sensitisers. It was recognised that a substantial amount of information is available on these substances.

The potency for respiratory sensitisation was again considered to be a key factor for considering the substances to meet Article 57 (f). One member questioned the reliability of the human data as the basis of the potency considerations. According to his view animal data would provide a firmer basis to understand the potency. Both the DS and many members underlined that the human data cannot be considered insignificant and irrelevant. Requesting more experimental data is no option because no animal test method exists for examination of respiratory sensitisation and may as well be considered unacceptable from an animal welfare perspective. The DS indicated that the information on prevalence of the cases among the exposed workers as well as on the exposure levels that seemed to have triggered the respiratory sensitisation can be used as surrogate information for potency.

A STO observer made a remark on the difference between potency and prevalence in these cases, as the high potency for sensitisation does not necessarily lead to the high prevalence.

It was concluded that HHPA and MHHPA should be identified as SVHCs because high prevalence of respiratory sensitisation cases among exposed workers at low workplace exposure levels and this information was considered to provide sufficient evidence that the substances are strong sensitisers. Furthermore, there is scientific evidence that these substances can induce occupational asthma with a possible delay of symptoms of up to several years, which may result in persistent symptoms of respiratory hyper-sensitivity after prolonged exposure. Also, setting of safe concentration limits is not possible as no safe levels of exposure have been identified that would fully prevent the risk of sensitisation. The irreversibility of elicitation is similar to the effects of CMRs whereas the respiratory sensitisation symptoms may at some instances disappear when exposure is removed or in other instances remain long-lasting although exposure has been stopped. The severity of the effects is well documented in the dossiers and is equivalent to the effects of substances addressed under Article 57 (a)-(e).

The support documents and the respective agreements for HHPA and for MHHPA were re-structured to further emphasise the scientific evidence as to why the substances are considered to probably elicit serious effects on human health, which give rise to an equivalent level of concern to effects of other substances referred to in Article 57.

Similarly to the ADCA agreement seeking, two MSC members made a remark that the identification of these respiratory sensitisers as SVHCs does not set a precedent for respiratory sensitisers in general, as the identification of SVHCs under Article 57 (f) has to be carried out on a case-by-case basis.

With regard to his vote on the HHPA and MHHPA proposals, the MSC member who made a statement (provided in Annex VI to the current minutes) under ADCA agreement seeking pointed out that his statement concerns also these two SVHC proposals. Again the UK supported this statement

In conclusion, MSC unanimously agreed on their support documents and agreements as amended during the meeting and identified HHPA and MHHPA as SVHCs in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because they are substances with respiratory sensitising properties for which there is scientific evidence of probable serious effects to human health which gives rise to an equivalent level of concern to effects of other substances listed in points (a) to (e) of Article 57 of REACH. The UK MSC member was deliberately absent for the vote on both the HHPA and MHHPA Annex XV proposals.

Methoxyacetic acid (EC 210-894-6)

The DS representative from the Swedish CA presented to the MSC the arguments for the Swedish proposal for identification of the substance as a SVHC under Article 57 (f) due to its endocrine disrupting properties causing probable serious effects to human health and to the environment, and to the SVHC proposal under Article 57 (c) due to the classification as toxic for reproduction category 1B. DS made an overview of the comments received in the public consultation on the Annex XV proposals for MAA and presented the responses provided in the RCOM and the modifications made in this regard in the SD. It was indicated that MAA already has a harmonised classification in Annex VI of the CLP Regulation as Repr. 1B. However, the DS had proposed MAA to be identified as a SVHC also under Article 57 (f) taking into account evidence on the endocrine disrupting properties of MAA which would give rise to the equivalent level of concern to other properties addressed under Article 57. Identification of the substance also under Article 57 (f) would cover the remaining additional concerns related to the uncertainty that it may not be possible to determine thresholds for effects caused by the endocrine mode of action contrary to other MoA-triggered reproductive effects, for which normally a threshold for the effect can be established. The missing identification as endocrine disruptor (ED) could lead to incorrect assessment of risk posed by the uses of the substance.

The DS pointed out that specific provisions concerning the route of granting authorisation may later on apply for substances identified under Article 57 (f) as having ED properties– c.f. REACH Article 138.7 (Commission review).

Some further remarks were made on the added value of the 57 (f) proposal with regard to regulatory consistency in endocrine disruptors' identification, indirect consequences for authorisation of related substances (e.g. metabolites) and environmental risk assessment due to the endocrine disrupting properties is not covered by Article 57(c) identification. The DS also indicated that the default classification limit of 0.5%/0.3% should not apply to an ED substance but the classification concentration limit should rather be 0.1 % as specified for non-threshold substances (carcinogens, mutagens).

Regarding the Article 57 (c) proposal for SVHC identification due to MAA toxic for reproduction properties, MSC unanimously supported the proposal that MAA should be identified as a SVHC due to its harmonised classification as toxic for reproduction.

With regard to the proposed '57 (f)' identification because of probable serious effects caused by the ED properties to the environment, SECR expressed the view that no evidence is provided in the dossier that such effects in the environment could have an impact on animals at the population level. This was however challenged by some participants. It was also noted that the dossier could not be complemented with new

data at this point in time of the process as such data were not part of the documentation in the public consultation. The DS responded that the concern for the environment introduced in Annex XV dossier comes from their CA's general position to whenever appropriate consider adverse effects of endocrine disruptors as relevant for both human health and the environment. The members expressed different views on this aspect some supporting and some disagreeing with the DS.

It was considered whether in this particular dossier, sufficient evidence is provided to meet the requirements for Article 57 (f) identification as the toxic effects elicited by the endocrine disrupting mode of action have been taken into account for the harmonised classification of the substance as toxic for reproduction.

As regards the MAA identification under Article 57 (f), different views were shared with regard to the added value of having a "double" identification basis for the substances meeting several of the Article 57 (a)-(e) criteria, e.g. endocrine disruptors having also CMR properties. It was pointed out that 'multiple' basis of identification has already been considered possible e.g. in the context of PBT substances where the T-property may refer to CMR hazards. Also identification as both PBT and CMR has been seen as appropriate.

Several members shared the view that as the endocrine mode of action causes the toxic for reproduction effects that led to the harmonised classification of the substance, there is not sufficient evidence in the dossier supporting the MAA additional "equivalent level of concern" identification. Furthermore some participants had the view that there is no need for a "double" identification in this particular case, therefore they had difficulties to follow both proposals for MAA under Article 57 (c) and under 57(f).

The Commission observer further recommended to the DS to consider going ahead with either one of the proposals under Article 57 (c), or under Article 57 (f), but not with both.

Many of the members agreed with the concept that endocrine disruptors could be identified as substances of "equivalent level of concern", based on case-by-case evidence, even if the substance is already classified as CMR.

Taking into account the different views of the members expressed on the proposal, the Chair asked the DS to consider how they would like to proceed with the proposal. The DS then decided to withdraw the proposal based on Article 57(f).

The basis of the withdrawal was a discussion on the merits and potential problems of aiming at identification of all applicable grounds according to Article 57 (a)-(f) when identifying SVHC substances for inclusion in the candidate list. This discussion revealed the necessity for a general discussion on a number of general issues related to the concomitant identification of substances as SVHC under several subparagraphs of Article 57, before any substance specific SVHC issues of MAA could be further discussed.

- One outstanding question is if the adverse effect/intrinsic property mentioned under Article 57 (f) (the *probable serious effect*) may be the same adverse effect already applicable to identify the substance as SVHC under other Article 57 criteria, e.g. 57 (c) (toxic for reproduction).
- Another issue requiring more analysis and general discussion is whether the identification of endocrine disruptors under Article 57 (f) should consider the identification for effects on human health and the environment together or separately in cases where the endocrine mode of action is relevant for human health as well as for organisms in the environment.
- The need for elaboration of the justification for an equivalent/equal/ additional level of concern in case of endocrine disrupting mode of action is the additional concern.

It was also noted that a new SVHC dossier may be submitted for MAA at a later point in time with a proposal for complementing a '57 (c)' candidate list entry with an additional SVHC identification under 57 (f).

The Chair and MSC expressed their gratitude to the DS for raising an important issue for discussion and it was recognised that further discussions on the topic will need to be initiated.

After the DS had withdrawn the proposal based on Article 57 (f) the MSC agreement was sought solely on the proposed SVHC identification of MAA on the basis of Article 57 (c) and its classification as toxic for reproduction category 1B. MSC unanimously agreed to its support document and agreement and identified MAA as a SVHC meeting the criteria set out in Article 57 (c).

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated *(covering well-defined substances and UVCB substances, polymers and homologues)*

The DS representative from German CA introduced to MSC the Annex XV proposal for the substance and explained the reason why the substance is proposed for identification as SVHC under Article 57 (f) (equivalent level of concern due to probable serious effects to environment) based on degradation to an identified SVHC (4-(1,1,3,3-tetramethylbutyl)phenol, in the following referred to as 4-tert-octylphenol, i.e. 4-tert-OP), an endocrine disrupter for environment. DS made an overview of the comments received in the public consultation on the Annex XV proposal and presented the responses provided in the RCOM and the modifications made in this regard in the SD. It was explained that following the public consultation, further information was added to the documentation to substantiate the read across from nonylphenol to 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, to add more information on the degradation pathways and to clarify further the conclusions.

It was discussed whether sufficient evidence is provided in the dossier to conclude that both the long chain and short chain ethoxylates degrade to 4-tert-octylphenol and thus are a relevant source of the SVHC 4-tert-octylphenol for the environment, since most of the data presented in the dossier was for up to 20 ethoxy groups.

Following this discussion the support document and the respective MSC agreement on identification of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as SVHC were updated to further clarify the degradation of the long chain and short chain ethoxylates into 4-tert-octylphenol and concluded that although data are mainly available for ethoxylates with a chain length up to 20 ethoxy groups, enough evidence is available to conclude that the degradation pathway is the same for longer chain ethoxylates.

In conclusion, MSC unanimously agreed to the support document and MSC agreement as amended at the meeting and identified 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] as SVHC in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because due to the degradation of the substance, it is a relevant source in the environment of a substance of very high concern 4-(1,1,3,3-tetramethylbutyl)phenol. Therefore, there is scientific evidence of probable serious effects to the environment from 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, through degradation to 4-tert-OP, the endocrine disrupting properties of which give rise to an equivalent level of concern to those properties of other substances listed in points (a) to (e) of Article 57 of REACH.

4-Nonylphenol, branched and linear *(substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof)*

The DS representative from the German CA introduced the Annex XV proposal for the substance and explained the reason why the substance is proposed for identification as SVHC under Article 57 (f) (equivalent level of concern due to probable serious effects to environment) based on its endocrine disrupting properties. Due to its estrogen agonist mode of action fish studies show that with increasing concentration the sex ratio of offspring changed drastically, even leading to the absence of males at all. DS made an overview of the comments received in the public consultation on the Annex XV proposal and presented the responses provided in the RCOM and the modifications made in this regard in the SD.

It was explained that following the public consultation, the validity of the fish species studies was properly reassessed and overall conclusions were based on Klimisch 2 studies. Evidence for amphibians and invertebrates was considered not strong enough to conclude on endocrine disrupting properties so this information was used in the support document as supporting evidence to the fish species studies. It was also explained in relation to a comment in the public consultation to include the endocrine effects on humans for this substance that this would be regarded as a new element in the dossier. Such addition is not considered possible at this late stage of the process as the new element would not have been subject to public consultation.

One member stressed that there is limited evidence for the endocrine disrupting properties of the linear substances due to lack of in vivo data for linear compounds, even though the in vitro data show that they are endocrine active.

Following this discussion the support document for 4-Nonylphenol, branched and linear was complemented to further clarify the link between the branched nonylphenols *in vivo* data and the linear nonylphenols mode of action *in vivo*. Available data on metabolic pathways do not indicate any difference in the pathway for the linear and the branched nonylphenols and thus it can be concluded that based on the available information, it can be reasonably expected that the *in vivo* data available for the branched nonylphenols describe the adverse effects of the linear nonylphenols too.

In conclusion, MSC unanimously agreed to the support document and MSC agreement as modified at the meeting and identified 4-Nonylphenol, branched and linear as SVHC in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because of its 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 properties of other substances listed in points (a) to (e) of Article 57 of REACH.

Heptacosafluorotetradecanoic acid *(C_{14}-PFCA)* (EC 206-803-4)

Henicosafluoroundecanoic acid *(C_{11}-PFCA)* (EC 218-165-4)

Pentacosafluorotridecanoic acid *(C_{13}-PFCA)* (EC 276-745-2)

Tricosafluorododecanoic acid *(C_{12}-PFCA)* (EC 206-203-2)

The DS representative from the German CA introduced the Annex XV proposals for the four substances and explained that the substances are proposed for identification as SVHC under Article 57 (e) due to their vPvB properties. DS made an overview of the comments received in the public consultation on the Annex XV proposal and presented the responses provided in the RCOM and the modifications made in this regard in the SD.

The proposed SVHC identification of the four substances using read-across based on analogue and category approach within the group of the four substances and including C_8-PFCA and Weight of Evidence (WoE) was supported as this approach is in line with the revised Annex XIII. General support was declared for the SVHC identification of $C_{12\text{-}14}$-PFCAs as being vP and vB and for the identification of C_{11}-PFCA as being vP. However, the identification of C_{11}-PFCA as being vB was seen as a less clear-cut case, where more critical analyses and further clarification for the justification were needed.

The latter was improved in the SD of Henicosalfuoroundecanoic acid (C_{11}-PFCA) during the meeting, among other modifications already introduced in the SD before the meeting based on the comments of the public consultation. More details on the field data and more explicit WoE argumentation on the bioaccumulation criterion were made for C_{11}-PFCA. These changes further improved the justification and validity of the approach to use field studies on biomagnification, trophic transfer and bioaccumulation covering various species and trophic levels from different studies of C_{11}-PFCA as evidence on such a bioaccumulation behaviour which could be considered analogous to a Bioconcentration Factor (BCF) greater than 5000.

The SDs and the respective agreements of all four PFCAs were changed during the meeting to reflect the outcome of the discussions, emphasising the final conclusions by comparing the relevant data with the Annex XIII criteria. For Heptacosafluorotetradecanoic acid *(C_{14}-PFCA),* Henicosafluoroundecanoic acid *(C_{11}-PFCA),* Pentacosafluorotridecanoic acid *(C_{13}-PFCA),* Tricosafluorododecanoic acid *(C_{12}-PFCA*) the same minor changes on the persistency of the substances were reflected in both the SDs and the respective agreements. On the other hand for Henicosafluoroundecanoic acid *(C_{11}-PFCA*) additional changes were made to the bioaccumulation argumentation to reflect what is explained above.

In conclusion, MSC unanimously agreed to the SDs and respective agreements as modified at the meeting and identified Heptacosafluorotetradecanoic acid *(C_{14}-PFCA),* Pentacosafluorotridecanoic acid *(C_{13}-PFCA), T*ricosafluorododecanoic acid *(C_{12}-PFCA*) and Henicosafluoroundecanoic acid *(C_{11}-PFCA)* as SVHCs in accordance with Article 57 (e) of Regulation (EC) 1907/2006 (REACH) because of their very persistent and very bioaccumulative properties. This conclusion was reached on the basis ofthe application of a weight of evidence approach by taking into account all available relevant information in accordance with Annex XIII of REACH.

Lead monoxide [Lead oxide] (EC 215-267-0)

The member who had asked for the termination of the written agreement seeking on this substance explained that no clear conclusions about the best regulatory risk management option had been drawn in the analysis of the different risk management options for lead monoxide. It was then explained that consideration of other risk management options than authorisation was still feasible. As response to the observation of STO representatives the SECR explained that SECR together with the COM and MSs are working on the challenge to improve transparency and predicatability of the SVHC process.

In conclusion, MSC unanimously agreed to the SD and the agreement document as presented for the meeting and identified Lead monoxide as a SVHC in accordance with Article 57 (c) of Regulation (EC) 1907/2006 (REACH) due to its classification as toxic for reproduction category 1A.

Item 8 – ECHA's draft recommendation of priority substances to be included in Annex XIV

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

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

SECR reported on the slight updates that were introduced since the last meeting into the response to comments documents (RCOMs), in order to improve their accuracy and to

harmonise responses to similar comments, and into the background documents to take into account the new information received.

SECR explained that the outcome of the REACH Committee meeting in November regarding the latest application dates (LADs) for the chromium(VI)-compounds of last year's 3rd recommendation is now reflected in the actual draft of this year's 4th recommendation. With the anticipated entry into force (EiF) of the inclusion in Annex XIV of the chromium (VI)-substances of the 4th recommendation in February 2014, ECHA's proposal for the LADs of these four substances has been set to 24 months after EiF. Hence, the date of the suggested LADs would be February 2016 and thus coincide with the LADs of the chromium(VI) substances of the 3rd recommendation, for which the REACH Committee agreed 35 months after EiF (anticipated EiF for inclusion in Annex XIV for the substances on the 3rd recommendation is March 2013). That modification then impacted the LADs of four other substances (DMAC, EDC, MOCA from 24 to 21 months and Diglyme from 21 to 18 months) so as to distribute more evenly the possible future workload with authorisation applications of ECHA and its Risk Assessment and Socio-Economic Analysis Committees.

In the short discussion following SECR's reporting, one STO highlighted that having the LADs of all chromium(VI) substances at one date might impose a too heavy task on enterprises, in particular SMEs, and easily overstretch their resources to simultaneously contribute to authorisation applications for so many substances.

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

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

b. Adoption of the MSC opinion

The Rapporteur presented the draft opinion to MSC. The opinion on the draft fourth recommendation on priority substances to be included in Annex XIV covered the following substances: Formaldehyde, oligomeric reaction products with aniline (technical MDA), Arsenic acid, Dichromium tris (chromate), Strontium chromate, Potassium hydroxyoctaoxodizincatedichromate, Pentazinc chromate octahydroxide, Bis(2-methoxyethyl) ether (Diglyme), N,N-Dimethylacetamide (DMAC), 1,2-Dichloroethane (EDC) and 2,2-dichloro-4,4'-methylenedianiline (MOCA).

In the general discussion MSC supported ECHA's draft recommendation for Annex XIV and thus the opinion as drafted by the Rapporteur jointly with the Working Group. During the detailed discussion on chromates one member and one industry representative suggested that in setting of the transitional arrangements one should take into account that in particular SMEs are likely to face difficulties in preparing many applications for authorisation at the same time (with the same latest application date (LAD)). Therefore they both considered coinciding LADs for all the chromate(VI)-substances as not ideal.

As regards the text about arsenic acid there was some discussion whether the opinion could take any stand on the claims regarding the uses of arsenic acid as intermediate uses and if some uses at least can be assumed to be within the scope of authorisation. In this regard some minor editing of the opinion text was thus carried out. As a follow-up to the numerous comments on the topic of activities similar to traditional scientific research and development, one member suggested that ECHA should provide some further clarification, e.g. in the form of FAQ or something similar, that when e.g. a use of a substance as a calibration standard could be considered as exempted from authorisation requirements. During the discussion on two solvents, Diglyme and EDC,

view of one member was that prioritisation scores for them were likely overestimated and that the information in the registration dossiers was not necessarily sufficient to carry out the prioritisation.

One member did not consider authorisation as the most suitable risk management option for N,N-Dimethylacetamide (DMAC) although that substance appears to meet the criteria for prioritisation. SECR explained that such a statement, if included in the MSC opinion, could not be taken into account by ECHA in the finalisation of the recommendation because ECHA has no other option than to propose Candidate List substances with identified priority for inclusion in Annex XIV. Consequently, a separate statement on that concern was provided by that member for notification of the Commission (see Annex VII) as in his view the Commission should consider other options for risk management. Another member, although supporting the MSC opinion, expressed the view that the arguments presented above by the other member are worth considering.

Following on from that discussion and given the importance of the step on prioritising and recommending substances for Annex XIV in the authorisation process some members proposed to revisit the MSC involvement in this process before ECHA submits the next (i.e. 5th) draft recommendation for public consultation.

After some further editing of the final text at the meeting MSC adopted by consensus the opinion on ECHA's draft 4th recommendation.

Item 10 – Substance evaluation

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

- **Report by the Rapporteur and discussion on the first draft opinion of MSC followed by exchange of views on the draft opinion**

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

Whilst going through the justification documents and filling in the Annex to the opinion, the WG came up with a list of questions which were then discussed at the meeting. The discussion focused mostly on three main issues.

Firstly, on how to define the term aggregated tonnage and whether it should be published or not since there is already information on the tonnage of the substances in the dissemination website of ECHA. Whilst some stakeholders and members agreed that there is no problem in repeating information in different parts of the ECHA website, another stakeholder stressed that tonnage is not a good indicator for exposure. Finally it was agreed that a non-confidential version of the tonnage band will be published in the CoRAP opinion Annex even though the tonnages are already found on ECHA website and will also be published in the public version of the justification documentsSecondly, when to use the term CMR or suspected CMR (and Sensitiser or suspected Sensitiser) in the CoRAP opinion Annex was also discussed. Finally it was concluded that independent whether it is harmonised classification, self-classification from the lead in the registration dossier or self-classification from the inventory, the term CMR would be used whenever the substance is classified as category 1A, 1B or 2 (and the term Sensitiser would be used whenever the substance is classified as category 1 or 2). The justification documents would then again need to be checked and updated for consistency.

Thirdly, harmonisation between some columns of the draft CoRAP already published on ECHA website with the work of the WG was also discussed. It was agreed that harmonisation between the two is necessary. It was also agreed to add "aggregated tonnage" as a concern, if not already there, for all the substances with a total tonnage of 1000 tpa or more, except where the tonnage is claimed confidential. ECHA will need to harmonise this with the ticked concerns in the justification documents.The MSC then was reminded what was published in the CoRAP opinion Annex in February 2012 and it was agreed that the same line would be followed for February 2013.

MSC was invited to send comments on the Annex and draft opinion by 9 January 2013.

Following the CoRAP discussion the Chair invited MSC to raise any questions if any related to substance evaluation (SEv). The questions focused on the consistency screening of the draft substance evaluation decisions that is currently on-going in ECHA. SECR explained how feedback on the SEv DD is being given by highlighting comments in bubbles in the DD itself without giving precise text. Policies that might affect the SEv DDs are also highlighted in an Annex to the DD. Unfortunately at this stage for some cases there are still no standard text blocks to be used in the SEv DD. However this will be developed slowly with time and experience.

The Chair reminded MSC to indicate in the table found on CIRCABC the intended start of the MSCA consultation of SEv DDs which would then determine to which MSC meeting such DD could potentially be discussed.

One member highlighted the type of concerns they are having whilst drafting the SEv DD and requested to have some informal discussions with ECHA to clarify their thoughts. SECR explained that these same type of concerns are raised by ECHA when commenting on SEv DD during the consistency screening. For example comments are made whether a sound justification for the required information is provided, whether the information required is linked to the concern identified etc.

Another concern raised during this discussion was how to know when one process starts and the other one finishes in terms of what to request during a compliance check of a substance that is listed for substance evaluation in the public CoRAP, i.e what can ECHA request and what can the evaluating MS request. Thus an informal discussion on this issue was requested. SECR explained that this would be discussed in detail in the substance evaluation workshop planned for May 2013.

Item 11 - MSC Work plan for 2013

SECR presented the statistics of the work for 2012 and the estimates for the workload for 2013 for MSC. The MSC was complimented and thanked for the hard work done in 2012 which resulted in exceeding the targets for 2012. Thanks to the hard work, efforts and interesting discussions, MSC was able of reaching unanimous agreement on 81% of the cases. Overall the workload for MSC in 2013 is going to be much higher than 2012, together with some challenges the new SEv process might bring with its more complicated cases and a very high number of TPE DD cases. A peak in the workload for MSC seems to be towards the end of 2013, i.e. for November and December MSC meetings.

Item 12 – Any other business

- **Registrations and audit report by Client Earth and European Environmental Bureau (EEB)**

The representative of Client Earth presented the screening of 40 substances listed in the ChemSec SIN list. These were endocrine disruptors and PBT substances. The data used was the one published in the dissemination portal. Elements audited are classification,

labelling and packaging, safe exposure thresholds for environment (PNEC) and workers (DNEL, DMEL), occupational exposure limits (OELs), Guidance on safe use, endocrine disruption and toxicity studies.

Following the presentation the Chair explained that MSC has not very much focused on compliance checks so far since ECHA had to deal with testing proposal examinations of those substances that were registered in the first registration deadline. Also she reminded that even though the presentation highlighted the importance of MSC role in compliance check, yet draft decisions come to MSC only when there are proposals for amendment from the MSCAs.

Since the presentation is also highlighting the importance to deal with inconsistencies in the submitted dossiers, the Chair highlighted that one of ECHA's strategic aims is to improve the quality of the registration dossiers and that is the goal that ECHA is working towards, together with industry and interested parties.

One of the stakeholder representatives explained that even for them the quality of the dossiers is of a critical nature. REACH was a learning process for everybody, so many are improving their assessments.

- **Introduction to a topical scientific workshop on risk assessment of the sediment compartment**

SECR explained that from next year ECHA would start to have a new type of activity as part of Strategic Aim regarding scientific developments. This would enhance the dialogue between academia, regulators and business parties on broad scientific issues of regulatory relevance.

The first of such topical workshops is going to be on environment, on risk assessment on sediment compartment. This would be held in ECHA on 7-8 May 2013. It would have the format of a scientific workshop with an international scientific committee whose members are from academia, business sector, regulators and MSC.

Participation would be by invitation only. In early January MSC would receive a link for further distribution to those that might be interested. There is a possibility of reimbursement but only for a limited number of participants once proper justification is provided. After the workshop the outcome of the workshop would be presented and this would be the background for the update of the guidance document in 2014.

Item 13 – Adoption of conclusions and action points

MSC adopted the conclusions and action points of MSC-27 at the meeting (see Section IV).

Signed
Anna-Liisa Sundquist
Chair of the Member State Committee

II. List of attendees

Members/Alternate members
COSGRAVE, Majella (IE)
CRUZ, Ana Lúcia (PT)
DEIM, Szilvia (HU)
DOUGHERTY, Gary (UK)
DRUGEON, Sylvie (FR)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FLODSTRÖM, Sten (SE)
HUMAR-JURIC, Tatjana (SI)
KORENROMP, Rene (NL)
KOUTSODIMOU, Aglaia (EL)
KULHANKOVA, Pavlina(CZ)
KYPRIANIDOU-LEONTIDOU, Tasoula (CY)
LUDBORZS, Arnis (LV)
LULEVA, Parvoleta (BG)
MARTIN, Esther (ES)
MIHALCEA-UDREA, Mariana (RO)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TALASNIEMI, Petteri (FI)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
Representatives of the Commission
BERTATO, Valentina (DG ENTR)
BINTEIN, Sylvain (DG ENV)
POPOVA, Temenuzhka (DG ENTR)
Observers
ANNYS, Erwin (CEFIC)
BUONSANTE, Vito (ClientEarth)
FRANCHIOLI, Luigi (UEAPME)
LIGTHART, Jerker (ChemSec)
MUSU, Tony (ETUC)
STAIRS, Kevin (Greenpeace)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
BALOGH, Attila
BELL, David
BROERE, William
CARLON, Claudio
CLENAGHAN, Conor
DE WOLF, Watze
FABERGA CLEMENT, Julia
FEEHAN, Margaret
HIRVONEN, Tero
KARHU, Elina
KORJUS, Pia
LE CURIEUX, Frank
LEPPER, Peter
LUOTAMO, Marita
NAUR, Liina
O'FARRELL, Norah
PELTOLA-THIES, Johanna
REUTER, Ulrike
RUOSS, Jürgen
RÖCKE, Timo
RÖNTY, Kaisu
SUNDQUIST, Anna-Liisa
TARAZONA, José
VAHTERISTO, Liisa
VASILEVA, Katya

Proxies

- PISTOLESE, Pietro (IT) also acting as proxy of CAMILLERI, Tristan (MT)
- RUSNAK, Peter (SK) also acting as proxy of ANDRIJEWSKI, Michal (PL)
- VANDERSTEEN, Kelly (BE) also acting as proxy of BIWER, Arno (LU)
- DUNAUSKIENE, Lina (LT) also acting as proxy of LUDBORZS, Arnis (LV) on Thursday morning
- KORENROMP, René (NL) also acting as proxy of TYLE, Henrik (DK) from Thursday at 15:45 onwards

Experts and advisers to MSC members

ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BUDASOVA, Jana (EE) (expert to VESKIMÄE, Enda)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
INDANS, Ian (UK) (expert to DOUGHERTY, Gary)

KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LONDESBOROUGH, Susan (FI) (adviser to TALASNIEMI, Petteri)
LUNDBERGH, Ivar (SE) (expert to FLODSTRÖM, Sten)
MOLDOV, Raili (EE) (adviser to VESKIMÄE, Enda)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
PIPIRAITE-VALISKIENE, Donata (LT) (expert to DUNAUSKIENE, Lina)
SÄLL, Liselott (NO) (adviser to REIERSON, Linda)
TRAAS, Theo (NL) (expert to KORENROMP, René)
WIMMER, Martin (AT) (expert to STESSEL, Helmut)
WODLI, Jordane (FR) (expert to DRUGEON, Sylvie)

SVHC dossier experts
GOMEZ, Jeannette (NL)
MALKIEWICZ, Katarzyna (SE)
MAURITZ, Ilse (AT)
STOCK, Frauke (DE)
VIERKE, Lena (DE)

By WEBEX-phone connection:
GARCÍA-JOHN Enrique, LUVARÀ Giuseppina, BORRAS HERRERO Anna, ROZWADOWSKI Jacek and STRECK Georg from DG ENTR during agenda items 6, 7, 8, 9 and 10; JUFFERNHOLZ Tanja (DE) during agenda item 7b; BIWER Arno (LU) and MOELLER Ruth (LU) during agenda items 7 and 9; DUNGEY Steve (UK) during agenda item 7; DOYLE Ian (UK) during the discussion on TPE-172/2012

Case owners:
Representatives of the Registrant were attending under agenda item 6b for TPE-170/2012 and TPE-172/2012.

Apologies:
ANDRIJEWSKI, Michal (PL)
BIWER, Arno (LU)
CAMILLERI, Tristan (MT)

III. Final Agenda

ECHA/MSC-27/2012/A/27 FINAL

Agenda
27th meeting of the Member State Committee

10-13 December 2012
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

10 December: **starts at 14:00**
13 December**: ends at 18:00**

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/027/2012
For adoption

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

Item 4 – Administrative issues

For information

Item 5 – Adoption of the draft minutes of the MSC-26

MSC/M/26/2012
For adoption

Item 6 – Dossier evaluation

Closed session for 6c
Indicative time plan for 6b is Day 1, for 6c Day 2 to 5

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

ECHA/MSC-27/2012/001
For information

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

ECHA/MSC-27/2012/011

For discussion followed by agreement seeking under 6c:

Testing proposals

- TPE-164/2012 2,6-di-tert-butylphenol (EC No. 204-884-0)

  ECHA/MSC-27/2012/002-003
- TPE-165/2012 2,4-di-tert-butylphenol (EC No. 202-532-0)

  ECHA/MSC-27/2012/004-005
- TPE-170/2012 8,9,10-trinorborn-2-ene (EC No. 207-866-0)

  ECHA/MSC-27/2012/006-007
- TPE-172/2012 Phenol, isopropylated, phosphate (3:1) (EC No. 273-066-3)

  ECHA/MSC-27/2012/008-010

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**

For agreement

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

Items from current cases if not addressed during 6b

For discussion

e. General topics

ECHA/MSC-27/2012/064
For information

ECHA/MSC-27/2012/062
For discussion and endorsement

f. Status report on ongoing evaluation work

For information

Item 7 – SVHC identification

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

ROOM DOCUMENT
For information

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

Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA) (EC 204-650-8) ECHA/MSC-27/2012/012-14

Cyclohexane-1,2-dicarboxylic anhydride (HHPA) (EC 201-604-9), cis-cyclohexane-1,2-dicarboxylic anhydride (EC 236-086-3), trans-cyclohexane-1,2-dicarboxylic anhydride (EC 238-009-9)	ECHA/MSC-27/2012/015-17
Hexahydromethylphthalic anhydride (EC 247-094-1), Hexahydro-4-methylphathalic anhydride (EC 243-072-0), Hexahydro-1-methylphathalic anhydride (EC 256-356-4), Hexahydro-3-methylphathalic anhydride (EC 260-566-1)	ECHA/MSC-27/2012/018-020
Methoxyacetic acid (EC 210-894-6)	ECHA/MSC-27/2012/021-023
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated *(covering well-defined substances and UVCB substances, polymers and homologues)*	ECHA/MSC-27/2012/024-026
4-Nonylphenol, branched and linear *(substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof)*	ECHA/MSC-27/2012/027-029
Heptacosafluorotetradecanoic acid (EC 206-803-4)	ECHA/MSC-27/2012/030-032
Henicosafluoroundecanoic acid (EC 218-165-4)	ECHA/MSC-27/2012/033-035
Pentacosafluorotridecanoic acid (EC 276-745-2)	ECHA/MSC-27/2012/036-038
Tricosafluorododecanoic acid (EC 206-203-2)	ECHA/MSC-27/2012/039-041
Lead monoxide [Lead oxide] (EC 215-267-0)	ECHA/MSC/D/2012/0339-341

For discussion and agreement

Item 8 – (Updated) ECHA's draft recommendation of priority substances to be included in Annex XIV

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

ECHA/MSC-27/2012/043-049

For information

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

ECHA/MSC-27/2012/050-060

For information and discussion

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

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

b. **Adoption of the MSC opinion**

ECHA/MSC-27/2012/061
For discussion and adoption

Item 10 – Substance evaluation

CoRAP:

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

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

ECHA/MSC-27/2012/063
For discussion

Item 11 – MSC Work plan for 2013

ECHA/MSC-27/2012/042
For information

Item 12 – Any other business

- **Registrations and audit report by Client Earth and European Environmental Bureau (EEB)**
- **Introduction to a thematic workshop on risk assessment of the sediment compartment**

For information

Item 13 – Adoption of conclusions and action points

- Table with conclusions and action points from MSC-27

For adoption

IV. Main Conclusions and Action Points (adopted at the MSC-27 meeting)

Main conclusions and action points
MSC-27, 10-13 December 2012
(adopted at the MSC-27 meeting)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 5 - Adoption of the draft minutes of the MSC-26	
MSC adopted the draft minutes with modifications proposed by members in writing before the meeting and one slight modification in the meeting.	MSC-S to upload final version of the minutes on MSC CIRCABC by 17 December 2012.
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-27/2012/001. MSC-S to provide COM for further decision making with documents (DDs, RCOMs, extract of minutes, outcome of the vote, justifications for NO votes) of cases on which MSC did not reach agreement, as indicated in document ECHA/MSC-27/2012/001.
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 (DD) on testing proposals when amendments were proposed by MSCAs *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting where appropriate of: - *TPE-164/2012 2,6-di-tert-butylphenol (EC No. 204-884-0)* - *TPE-165/2012 2,4-di-tert-butylphenol (EC No. 202-532-0)* - *TPE-170/2012 8,9,10-trinorborn-2-ene (EC No. 207-866-0)* - *TPE-172B/2012 Phenol, isopropylated, phosphate (3:1) (EC No. 273-066-3)* MSC could not reach unanimous agreement on the following draft decisions as modified in the meeting: - *TPE-172A/2012 Phenol, isopropylated, phosphate (3:1) (EC No. 273-066-3)* on the information requirements for Annex X, 8.7.3 due to different views of MSC members on the most appropriate generation test (B.35 (TG 416) or OECD TG 443) to be requested for fulfilling the standard REACH information requirements for this endpoint.	MSC-S to upload on MSC CIRCABC the final ECHA decisions/cover letters of the agreed cases. MSC-S to provide COM for further decision making with documents (DD on generation testing, RCOM, minutes, outcome of the vote, justification for the position at the vote) of cases on which MSC did not reach agreement.
6e. General topics - Approach for terrestrial plant toxicity - long and short term studies	
MSC endorsed ECHA's recommended approach to be applied for terrestrial	ECHA to find appropriate ways to

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
plant toxicity (long- and short-term studies) in testing proposal examinations as provided for MSC-27.	communicate the endorsed approach to MSCAs and registrants.
6f. Status report on ongoing evaluation work	
MSC took note of the report including plans for dossier evaluation in 2013 and dossier evaluation statistics from 2012. MSC urged COM to find a resolution concerning test methods to be used to fulfil the standard information requirements of Annex X, 8.7.3.	
7 – SVHC identification **7a. Written procedure report on seeking agreement on identification of SVHC**	
MSC unanimously agreed to identify the following twelve substances as SVHCs in written procedure (and unanimously agreed on their SDs and agreements as presented in the respective documents) : • bis(pentabromophenyl)ether [decabromodiphenyl ether; decaBDE] *[under Art. 57 (d)&(e) due to its PBT/vPvB properties]*, • dibutyltin dichloride [DBT] *[under Art. 57 (c) due to its toxic for reproduction properties],* • N,N-dimethylformamide [dimethyl formamide] *[under Art. 57 (c) due to its toxic for reproduction properties]* • orange lead [lead tetroxide] *[under Art. 57 (c) due to its toxic for reproduction properties],* • lead bis(tetrafluoroborate) *[under Art. 57 (c) due to its toxic for reproduction properties],* • trilead bis(carbonate) dihydroxide [basic lead carbonate] *[under Art. 57 (c) due to its toxic for reproduction properties],* • lead titanium trioxide *[under Art. 57 (c) due to its toxic for reproduction properties],* • lead titanium zirconium oxide *[under Art. 57 (c) due to its toxic for reproduction properties],* • silicic acid, lead salt *[under Art. 57 (c) due to its toxic for reproduction properties],* • silicic acid ($H_2Si_2O_5$), barium salt (1:1), lead-doped [silicic acid, barium salt, lead-doped] *[under Art. 57 (c) due to its toxic for reproduction properties],* • 1-bromopropane [n-propyl bromide] *[under Art. 57 (c) due to its toxic for reproduction properties],* • methyloxirane [propylene oxide] *[under Art. 57 (a)&(b) due to its carcinogenic and mutagenic properties]*.	SECR to add the newly identified SVHCs (in written procedure) to the Candidate List (update foreseen by 21 December 2012). SECR to upload the agreements and support documents on MSC CIRCABC and on the MSC webpage of the ECHA website after final editing. SECR to publish also RCOMs on the MSC webpage of the ECHA website.
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): • Diazene-1,2-dicarboxamide [C,C'-azodi(formamide), ADCA] (EC 204-650-8) *[under Art. 57 (f) due to its respiratory sensitising properties causing probable serious effects to the human health]* • Cyclohexane-1,2-dicarboxylic anhydride (HHPA) (EC 201-604-9), cis-cyclohexane-1,2-dicarboxylic anhydride (EC 236-086-3), trans-cyclohexane-1,2-dicarboxylic anhydride (EC 238-009-9) *[under Art. 57 (f) due to their respiratory sensitising properties causing probable serious effects to the human health]* • Hexahydromethylphthalic anhydride (EC 247-094-1), Hexahydro-4-methylphathalic anhydride (EC 243-072-0), Hexahydro-1-	SECR to add the newly identified SVHCs at the meeting to the Candidate List (update foreseen by 21 December 2012). SECR to upload the agreements and support documents on MSC CIRCABC and on the MSC webpage of the ECHA website after final editing. SECR to publish also RCOMs on the MSC webpage of the ECHA website.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
methylphathalic anhydride (EC 256-356-4), Hexahydro-3-methylphathalic anhydride (EC 260-566-1) *[under Art. 57 (f) due to their respiratory sensitising properties causing probable serious effects to the human health]* • Methoxyacetic acid (EC 210-894-6) *[under Art. 57 (c) due to its toxic for reproduction properties]* • 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated *(covering well-defined substances and UVCB substances, polymers and homologues) [under Art. 57 (f) due to its endocrine disrupting properties causing probable serious effects to the environment]* • 4-Nonylphenol, branched and linear *(substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof) [under Art. 57 (f) due to its endocrine disrupting properties causing probable serious effects to the environment]* • Heptacosafluorotetradecanoic acid (EC 206-803-4) *[under Art. 57 (e) due to its vPvB properties]* • Henicosafluoroundecanoic acid (EC 218-165-4) *[under Art. 57 (e) due to its vPvB properties]* • Pentacosafluorotridecanoic acid (EC 276-745-2) *[under Art. 57 (e) due to its vPvB properties]* • Tricosafluorododecanoic acid (EC 206-203-2) *[under Art. 57 (e) due to its vPvB properties]* • Lead monoxide [Lead oxide] (EC 215-267-0) *[under Art. 57 (c) due to its toxic for reproduction properties]* With regard to the Annex XV dossier proposing SVHC identification of MAA under Article 57 (c) and under Article 57(f) and following the MSC discussion at the meeting, the dossier submitter withdrew the part of the Annex XV proposal concerning the identification of the substance as SVHC due to its endocrine disrupting properties. The withdrawal was motivated by the MSC discussion indicating that at this point in time there seems to be a need for a general discussion on issues related to the identification of SVHCs under Article 57 (f) concomitant with other criteria set out in points (a) to (e) of Article 57. Therefore, the above-mentioned MSC agreement was reached solely on the proposed SVHC identification of MAA due to its toxic for reproduction properties.	
Item 8 – (Updated) ECHA's draft recommendation of priority substances to be included in Annex XIV **8a. Responses of ECHA to the comments received in the public consultation on ECHA's draft recommendation** **8b. Introduction of any changes to the draft recommendation documentation following the consultation outcome**	
MSC took note of: - the SECR report on the slight updates that were introduced to the response to comments-documents and the background documents since the last meeting. - on how the outcome of the REACH Committee meeting in November had been reflected in the draft recommendation for chromium(VI)-compounds as regards the latest application dates (LADs), and how that modification then impacted the LADs of four other substances (DMAC, EDC, MOCA and Diglyme).	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 9 - Opinion on the draft recommendation of priority substances to be included in Annex XIV **9a. Discussion on the draft opinion based on the (updated) draft recommendation of priority substances to be included in Annex XIV** **9b. Adoption of the MSC opinion**	
MSC took note of the draft opinion presented by the rapporteur. MSC supported ECHA's draft recommendation for Annex XIV. One member did not consider authorisation as the most suitable risk management option for DMAC and hence a statement on that view will be provided to the Commission. The opinion on the draft fourth recommendation on priority substances to be included in Annex XIV covers the following substances: - Formaldehyde, oligomeric reaction products with aniline (technical MDA) - Arsenic acid - Dichromium tris (chromate) - Strontium chromate - Potassium hydroxyoctaoxodizincatedichromate - Pentazinc chromate octahydroxide - Bis(2-methoxyethyl) ether (Diglyme) - N,N-Dimethylacetamide (DMAC) - 1,2-Dichloroethane (EDC) - 2,2-dichloro-4,4'-methylenedianiline (MOCA) MSC adopted the opinion on ECHA's draft 4th recommendation. Given the importance of the Annex XIV Recommendation step in the authorisation process some members suggested to revisit the MSC involvement before ECHA submits the draft recommendation for public consultation	ECHA to take into account MSC opinion for finalisation of the recommendation for inclusion of substances in Annex XIV and to submit it to Commission in January 2013. MSC-S to publish the final MSC opinion on ECHA website and in MSC CIRCABC. Members to provide items/proposals to be further discussed with regard to the prioritisation approach and MSC involvement prior to public consultation by 18 January 2013 to support discussion on the topic in MSC-28.
Item 10 - Substance evaluation	
CoRAP: **Preparations for the MSC opinion on the draft Community Rolling Action Plan (CoRAP)** • **Report by the Rapporteur and discussion on the first draft opinion of MSC followed by exchange of views on the draft opinion** MSC took note of the work of the working group and supported the drafting of the opinion so far.	MSC to send comments to the Rapportuer copying MSC functional mailbox on draft opinion and its Annex by 9 January 2013.
Item 13 – Adoption of conclusions and action points	
MSC adopted the conclusions and action points of MSC-27.	MSC-S to upload the conclusions and action points on MSC CIRCABC by 17 December 2012.

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

Cases unanimously agreed by MSC in WP:

MSC ID number	Substance name used in draft decision	EC No
TPE-163/2012	O,O,O-tris(2(or 4)-C9-10-isoalkylphenyl) phosphorothioate	406-940-1
TPE-166/2012	Reaction mass of 1-phenyloctadecane-1,3-dione and phenylicosane-1,3-dione	915-316-2
TPE-167/2012	Polysulfides, di-tert-Bu	273-103-3
TPE-169B/2012	Ethanol, 2-methoxy-, manufacture of, by-products from, esters with boric acid	310-290-3
TPE-171/2012	2-oxepanone, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol	500-099-5
TPE-173B/2012	Tetrapropylenebenzene	246-772-4
TPE-174B/2012	4-tert-butylpyrocatechol	202-653-9

Cases to be referred to COM:

MSC ID number	Substance name used in draft decision	EC No
TPE-169A/2012	Ethanol, 2-methoxy-, manufacture of, by-products from, esters with boric acid	310-290-3
TPE-173A/2012	Tetrapropylenebenzene	246-772-4
TPE-174A/2012	4-tert-butylpyrocatechol	202-653-9

VI. Statement of a MSC member made with regard to the agreement seeking on the SVHC identification of ADCA, HHPA and MHHPA in accordance with Article 57 (f) of the REACH Regulation

Article 55 sets the aim of the authorisation provision to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.

Thus one of the aims of the authorisation provisions of REACH is clearly to progressively replace substances of very high concern with suitable alternatives. Therefore, Denmark is of the view that only substances with uses that should be phased-out should be included in the candidate list.

Denmark recognises that respiratory sensitizers have the potential to cause very serious health effects and such substances, therefore, need to be strictly controlled. This is, in particular, the case when such substances are present in a form that is respirable. When respiratory sensitizers are present only in non-respirable forms and when products containing them are only used as prescribed which avoids bringing them into a respirable form, then the potential for causing respiratory allergic reactions is absent.

Denmark notes that probably all enzymes are respiratory sensitizers and that some of them are included in Annex VI to the CLP Regulation with the classification "H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled". However, many enzymes have significant technologically and environmental beneficial uses, e.g. in food additives and laundry detergents and for production of biofuels. It is the opinion of Denmark that when such enzymes are marketed and used in non-respirable forms and in accordance with appropriate use instructions avoiding creation of respirable forms, they would not qualify for inclusion in the candidate list as replacement is not warranted for these substances. The manufacturing process for such enzymes of course still needs to be strictly controlled to avoid inhalation.

VII. Statement of a MSC member for Dimethylacetamide submitted to the Secretariat of the Member State Committee of ECHA on 20 December 2012 to be forwarded to the European Commission (Ref. Opinion of MSC on ECHA's draft 4th Recommendation of Priority Substances)

UK Statement for Dimethylacetamide:

The UK are of the opinion that the recommendation for Dimethylacetamide (DMAc) to be taken forward for addition to Annex XIV may be flawed. In line with the emerging themes in the roadmap for 2020, we would encourage the Commission to investigate whether alternative risk management options may be more effective.

During the public consultation on the ECHA recommendation, various stakeholders suggested that a restriction on those uses that led to higher exposures would be a better risk management option than authorisation. There would appear to be merit in this line of thought. The idea of using restriction as a risk management option was not considered as part of the original Risk Management Options Analysis (RMOA) performed for DMAc (the RMOA was performed before registration). As the existing RMOA looked at a limited number of options, it would seem prudent to re-open it so that full consideration can be given to the various control options available, in line with the developing roadmap for SVHC assessment and identification.

For some of the reported uses, it can be reasonably anticipated that exposures will be well controlled (e.g., use as a solvent in fibre production & in industrial installations). For other uses, exposure may be higher and more difficult to control (e.g., as a solvent in formulated products). This would suggest that a targeted restriction along similar lines to the existing restriction for dichloromethane may be more effective at reducing exposure and managing any risks. There may also be other risk management options that could be used.

In particular, the use of authorisation as a driver for substitution does seem to be undermined for DMAc as suitable alternatives (with a lower hazard profile) are unlikely to exist. DMAc is one of a handful of 'aprotic polar solvents' and substitution of these could be very difficult. The aprotic polar solvents all have the advantage of being able to dissolve a wide range of substances, but do not have the acidic proton that most highly polar solvents have. For many reactions, the acidic proton can lead to complications in the reactions. Thus, as industrial solvents they are ideal for certain reaction types. For example, in second order nucleophilic substitution reactions (a very commonly used reaction in chemical synthesis) aprotic polar solvents allow for faster reaction times and help to minimise side reactions such as E2 eliminations reactions. The problem for substitution is that the other aprotic polar solvents with similar physico-chemical properties tend to have the same reproductive hazards. Thus, true substitution for a less hazardous substance cannot be achieved.

In addition, should DMAc be added to Annex XIV, then there is a high likelihood for multiple applications. As a threshold for the reproductive hazard may exist, these applications could proceed along the adequate control route and would require only those controls that are already in place. Thus, authorisation could be burdensome for both authorities and industry, without any significant added benefits.