MSC/M/48/2016
(Adopted at MSC-49)

Minutes
of the 48th Meeting of the Member State Committee (MSC-48)
6-9 June and 14-15 June

I. Summary Record of the Proceedings

Item 1 - Welcome and Apologies

The Chairman of the Committee, Mr Watze de Wolf, opened the meeting and welcomed the participants to the 48th 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 without further changes (final Agenda is attached to these minutes).

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

No potential conflicts of interests were declared by any members, experts or advisers with any item on the agenda of MSC-48.

Item 4 - Administrative issues

SECR informed MSC of a possibility to use a mobile application for authentication when connecting to S-CIRCABC and provided instructions on downloading and using the application.

Item 5 – Adoption of the minutes of the MSC-47 meeting

The minutes of MSC-47 were adopted as modified at the meeting.

Item 6 – Substance Evaluation

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

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on seven substance evaluation cases with nine draft decisions (DD) (see Part V for more case-identifier information). WP was launched on 13 May 2016 and closed on 23 May 2016. By the closing date, unanimous agreement was reached on eight DDs with one abstention for two cases. For one DD WP was terminated by the MSC Chairman on the basis of Article 20.6 of the MSC Rules of Procedure.

b. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA's/ECHA reactions (Session 1, open session):

c. Seeking agreement on draft decisions when amendments were proposed by MS-CA's/ECHA (Session 2, closed)

<u>SEV-UK-038/2014</u> Phenol, styrenated (1) (EC No. 262-975-0); Reaction mass of 2,4,6-tris(1-phenyl-ethyl)phenol and Bis(1-phenylethyl) phenol (2) (EC No. 915-333-5)

Session 1 (open)

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

The evaluating Member State Competent Authority (eMSCA) from United Kingdom (UK-CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance which was performed by the UK-CA on the basis of the initial grounds for concern relating to PBT properties, endocrine disruption and cumulative exposure. In the course of the evaluation, the eMSCA noted additional concerns regarding cumulative exposure to sediment, terrestrial and marine compartments, and for terrestrial secondary poisoning. MSC was guided through the information on the substance (including PfAs, Registrant(s) comments, and the eMSCAs responses to them).

Twelve proposals for amendments (PfAs) were received in total on a) initial information requests for: information for environmental risk assessment, Fish Sexual Development Test (FSDT) and on the addressees of the decision; and b) additional information requests on assessing the endocrine potential of the registered substance for human health.

Before the MSC meeting, the eMSCA, after considering the PfAs and the comments of the Registrants on the PfAs, accepted the PfAs on the information for the environmental risk assessment and the FSDT, hence these were not discussed during the meeting.

Regarding the addressees of the decision, it was proposed in one of the PfAs to not address the decision to registrants with only transported isolated intermediate uses under strictly controlled conditions, leading to the removal of the reference to the substance with EC number 915-333-5 from the DD. Otherwise, a specific justification for inclusion of these operators would need to be provided.

Another PfA proposed to include developmental/reproductive toxicity and endocrine disruption relevant for human health (not only to environment) as an additional concern in the DD. It was also proposed to include or request a read across between 'oligomerisation and alkylation products of 2-phenylpropane and phenol, previously registered as methyl-styrenated phenol' and this substance–styrenated phenol, for developmental/reproductive toxicity and endocrine disruption. The results from the EOGRTS currently being performed on the methyl-styrenated phenol could then be applied to the styrenated phenol. If no such read-across justification could be included in the DD, it was proposed to request an EOGRTS without F2 but with DNT/DIT cohorts on the registered substance.

Four separate Registrants provided written comments on the PfAs and the draft decision. These contained some diverging views on some elements of the PfAs. However, during the meeting, the representative speaking on behalf of all the Registrants presented a common view. They all agreed to include the registrants with only transported isolated intermediate uses under strictly controlled conditions as addressees of the decision in line with the eMSCA position since those registrants want to continue to generate information on the substance. With regards to the additional concern on the endocrine potential to human health and mammalian wildlife, they disagree with the PfA asking for EOGRTS. They prefer waiting for the results from *in vivo* data on one of the isomers of the substance awaited from another substance evaluation, before carrying on *in vivo* studies on this substance or 'constituent groups'. Furthermore, they requested clarification on the term used in the decision of 'Constituent group'.

With regards to who should be an addressee to this decision, ECHA requested confirmation that all the Registrants including all those with only transported isolated intermediate uses are in agreement to be addressees of this decision and sought to understand why the information that is to be generated is relevant for those registrants also. The Registrants representatives confirmed that all registrants including those with only transported isolated intermediate uses agreed to be addressees to this decision. It is important for them to test the substance since it is also considered as a metabolite under the plant protection products (PPP) regulation and hence a PBT and ED assessment needs to be undergone in this regards.

The MSC member of the PfA submitting Member State which requested identification of the additional concern of endocrine disrupting properties to human health explained that their intention was not to go straight into testing, but to perform a read across to the substance on which a EOGRTS is being performed as part of another substance evaluation. Hence, in the view of the PfA submitter the text in the DD on this endpoint as now suggested by the eMSCA was fine pending some editorial changes.

With regards to the clarification of the terminology of 'constituent group' one MSC member explained that this has been developed in the context of the current draft PBT guidance document update. Some substances are either very similar or there is a trend within the group that is predictable. For these cases, toxicity should be assessed per group because the substances are so structurally similar that it is justifiable to assess them together. The eMSCA expert explained that for this case a 'constituent group' refers to the monostyrenated phenol grouped in one, the distyrenated phenol grouped in another and the tristyrenated phenol in a third group.

Session 2 (closed)

During the closed session MSC discussed the roles of ECHA and enforcement authorities in the confirmation of strictly controlled conditions, and whether it would be advisable to go

against the standard practice not to address registrants with only transported isolated intermediate uses in a SEv decision. For this particular case it was however unanimously agreed to address the decision to all since all the registrants, including the registrants with only transported isolated intermediate uses agreed to be addressees of this decision.

ECHA Secretariat welcomed the choice of the registrants to all be addressed in this case.

Furthermore, MSC agreed unanimously to keep all the seven requests for gathering information for PBT assessment, endocrine disruption and for environmental risk assessment and to request for information available on the endocrine disruption potential of the registered substance per individual addressee with respect to human health.

SEV-FR-022/2014 Methyl 4-hydroxybenzoate (EC No. 202-785-7)

Session 2 (closed)

The MSC Chair had terminated the written procedure for MSC agreement seeking on this SEv draft decision prepared by the FR CA (eMSCA) and the case was brought to the meeting to discuss and conclude on the test species to be specified in the DD for the requested Fish Sexual Development Test (FSDT, test method OECD 234). The eMSCA's expert pointed out that the original DD requested the test to be performed with Japanese medaka (*O. latipes*) only, whereas the eMSCA agreed with a MSCA's PfA suggesting the inclusion of zebrafish (*Danio rerio*) as another appropriate test species in the DD.

Short discussion took place with regard to the other test species three-spined stickleback (*Gasterosteus acuelatus*) mentioned in the OECD 234 test guidelines. A MSC member proposed the issue of the suitability of the different test species to be brought for general discussion to the Endocrine Disruptor Expert group. Inclusion of this species in the DD was not supported in the PfA, and hence from procedural point of view inclusion in the current SEv decision would require an additional justification when giving such a choice to the Registrant.

In conclusion, MSC unanimously agreed with the request for FSDT (OECD TG 234) and that the test should be perform with either Japanese medaka (*Oryzias latipes*) or zebrafish (*Danio rerio*) leaving it to the testing laboratory to make the selection of either of these two test species. If possible for the selected test species, the determination of the genetic sex and secondary sex characteristics shall be included in the test design.

MSC unanimously agreed to the DD as presented at the meeting.

d. General topics

Appeals update

This item was postponed to the next meeting since there was nothing new to report on.

Item 7 – Dossier evaluation

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

SECR introduced the report on the outcome of the written procedure (WP) for agreement seeking on eighteen dossier evaluation cases (see Section VI for more detailed identification of the cases). WP was launched on 13 May 2016 and closed on 23 May 2016. By the closing date, unanimous agreement was reached on twelve DDs. By the closing date, one member abstained from voting on eight cases; another MSC member abstained from voting on ten cases. For six DDs, WP was terminated by the MSC Chairman on the basis of Article 20.6 of the MSC Rules of Procedure as at least one MSC member requested meeting discussion of the case at the MSC-48 meeting.

b. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals when amendments were proposed by MS-CA's (Session 1, open)

c. Seeking agreement on draft decisions on compliance checks and testing proposal examinations when amendments were proposed by MS-CA's (Session 2, closed)

Introduction to targeted evaluation of 90-day data for EOGRTS

SECR introduced the item on the targeted evaluation of the sub-chronic toxicity study (hereinafter 90-day study) data for further informing on the design of the extended one-generation reproductive toxicity study (EOGRTS) in decisions containing requests for both studies and the study design is not yet fully expanded. The approach as presented by ECHA is based on four different PfAs on this topic as submitted in the context of several compliance check cases e.g. CCH-042/2016, CCH-043/2016, CCH-053/2016, CCH-055/2016 and CCH-056/2016. The PfAs are not presented under those cases, but described in this introductory section together with the detailed MSC discussion. In addition, there were several PfAs suggesting further modifications to the EOGRTS design using already available information. These are described under the cases, separately from this discussion on targeted evaluation.

The first PfA on the targeted evaluation, denoted as PfA-1, suggested conducting first the 90-day study and submitting the study results to ECHA in a dossier update by 12 months. The requested 90-day study might provide information that would meet the condition or trigger one or all of the EOGRTS- cohorts, which might lead to a subsequent decision making process.

The second PfA, denoted as PfA-2, suggested two options for linking: (1) A two-decision approach: when a 90-day study is requested, remove the request for an EOGRTS and inform the registrant that an EOGRTS will be requested in a subsequent decision with a design taking into account the 90-day study results; (2) an enhanced one-decision approach: keep both requests, while first conducting the 90-day study and submitting the study results to ECHA in a dossier update by 12 months. ECHA with assistance from the Member States subsequently to decide if the results from the 90-day study, and/or other new information becoming available since the initial decision, would need to be taken into account in the EOGRTS design. (a) If no additional triggers are identified, ECHA should confirm that the original request and deadlines will be maintained. (b) If conditions or triggers for additional investigations are identified, ECHA should initiate a subsequent decision making process by modifying request for the study design and set a new deadline.

The third PfA, denoted as PfA-3, suggested splitting the decision into two. In the first decision, request the 90-day and all other studies, but not the EOGRTS. Based on the results of the 90-day study, and in case no acceptable waiver applies at the time, (re)draft a decision requesting the EOGRTS.

The fourth PfA, denoted as PfA-4, suggested (a) requesting the 90-d study in the current decision, followed by preparation of a separate decision to ensure that the findings in the 90-d study could be carefully weighed by Member State experts to decide on the design of EOGRTS. (b) Alternatively, the 90-d toxicity study and EOGRTS could be requested in the same decision, provided that the DIT (developmental immunotoxicity) and DNT (developmental neurotoxicity) cohorts are included.

SECR informed that in most cases the study design was not expected to change, as the initial decision would already be based on a comprehensive assessment of all relevant endpoints and information for the study design. They considered a one-decision approach to help in avoiding any further unnecessary delays in information generation on the reproductive toxicity endpoint, and in line with ECHA's compliance check policy as discussed with MSCAs and Commission at some recent CARACAL meetings.

Some MSC members and experts suggested that the laboratory capacity on performing the EOGRTS and the number of EOGRTS cases compliant for the 90-day study could be considered first. They further argued that if those cases were expected to fully occupy the laboratory capacity in the first years, the tests in cases with a non-compliance for the 90-day study and EOGRTS could be decided sequentially in two separate decisions. SECR reminded that most studies have only a basic study design, therefore laboratory capacity limits are not expected to be reached.

MSC discussed that the type of information that could be included in the targeted assessment could be the results from the 90-day study and other relevant available

information, i.e. information with a publication date after the date of adoption of the decision.

Bases on the MSC discussion, SECR suggested that the EOGRTS information requirement in the one-decision approach should incorporate a study design from the beginning; depending on whether the criteria described in column 2 at Annex IX/X section 8.7.3 are met, the study might need to already include extension of Cohort 1B (mating of F1 animals to produce F2 generation), Cohorts 2A and 2B to investigate developmental neurotoxicity (DNT) and/or Cohort 3 to address the concern for immunotoxicity (DIT).

MSC was of the view that to make an informed decision on the EOGRTS design, relevant information must be available to evaluate if the concern-based criteria were met. If all relevant information is not available at the time of decision making and the study design is not already including all the cohorts available in the modular design, sequential testing might be necessary to produce the missing information before finalizing the study design. The importance of the 90-day study to conclude on the study design of the EOGRTS was acknowledged, and a one-decision approach was agreed for DEv-decisions that contain both a request for a 90-day study and EOGRTS following the four related PfAs.

MSC agreed to follow a one-decision approach that covers the following aspects: (1) The decision contains a 12-month deadline for submitting the results of the sub-chronic toxicity study. (2) Once the results of the sub-chronic toxicity study have been submitted in a dossier update, the Member State competent authorities (MSCAs) are informed by ECHA. ECHA evaluates whether the originally requested EOGRTS design needs to be changed, based on the results of the newly submitted results of the 90-day study and any other relevant available information including information which was not considered initially before the date when Repeated Dose toxicity Study was requested. (3) Within 2 to 4 weeks after the submission of the dossier update, ECHA informs the MSCAs of the outcome of its evaluation and invites the MSCAs to react to it within a certain deadline. (4) If ECHA finds – and no MSCAs objects – that the EOGRTS design is not to be changed, the registrant can initiate the EOGRTS after 3 months from the relevant submission date of the dossier update. (5) If ECHA finds that the EOGRTS design needs to be changed, or if there is disagreement on this question between one or more MSCAs and ECHA, a new decision making process is initiated to amend the EOGRTS request. The new decision-making process then follows the standard procedure as outlined in Articles 50 and 51 REACH, and the corresponding draft decision to amend the EOGRTS design is sent to the registrant within 3 months from the deadline set for his dossier update to submit the 90-day study results. This approach also ensures that the Registrant has an opportunity to comment on any suggestions for a revised EOGRTS-design.

CCH-034/2016 2-dimethylaminoethanol (E.C. 203-542-8)

Session 1 (open)

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

SECR explained that three PfAs to ECHA's DD were submitted. The first PfA on *Extended one-generation reproductive toxicity study* (EOGRTS) suggested to modify the request by including an extension of Cohort 1B to produce the F2-generation arguing the uses of the registered substance are leading to significant consumer exposure, the substance may have an endocrine disrupting mode of action (MoA) because it is an inhibitor of choline uptake and metabolism, may play a role in hypo/hypermethylation, and there is uncertainty on its genotoxicity potential.

The second PfA on *Human health exposure assessment and risk characterisation for the workers* suggested the Registrant to provide revised information using the assessment factors (AF) recommended by ECHA Guidance, or a detailed scientific justification should be provided for the selection of preferred value for risk assessment (i.e., the national OEL and/or a DNEL and how the chosen approach meets the requirements. The evaluation of the scientific background for setting the national OEL needs to be assessed and compared with calculated DNELs).

Another PfA on *In vitro gene mutation study in mammalian cells* to accurately reflect in the DD the fact that in 2015 the OECD TG 476 was updated and split into two separate OECD TGs, namely TG 476 and TG 490, ensuring the alignment with previous decisions.

SECR modified the DD for the meeting based on the PfAs regarding *Human health exposure assessment and risk characterisation for the workers* and *In vitro gene mutation study in mammalian cells.*

The Registrant provided written comments prior to the meeting and disagreed with the PfA on *EOGRTS*. During the discussion the representative of the Registrant re-iterated his comment that the substance does not have consumer uses, but only professional and industrial uses. The representative of the Registrant further justified their view that the substance cannot be considered as endocrine disruptor (ED) because the function and MoA for choline levels was not clearly established and the substance is differing in structure to EDs that produce choline deficiency.

Specifically, based on existing experimental literature data, the likely MoA of DMAE is a perturbation of choline metabolism similar to other ethanolamines. However, there is not sufficient evidence for a direct link between 1) choline levels and non-neuronal acetylcholine levels, and between 2) acetylcholine (especially non-neuronal) and adverse effects on endocrine system. Thus, the representative of the Registrant concluded that the reasoning is only a very general assumption – and the same applies for the hypo and hyper methylation. Alternative methylation pathways exist i.e. via methionine, folate and Vitamine B12. No data exist on potency of DMAE to modulate DNA methylation although a structurally similar DEA (diethanolamine) is known to alter DNA methylation. However, the structural difference could play an important role according to the representative of the Registrant: in opposite to DEA, DMAE is already methylated and might donate methyl groups similarly to choline. Therefore, no conclusion on DNA methylation can be made for the registered substance.

One MSC member raised the question of the impact of the tonnage levels for the design of the EOGRTS. A stakeholder representative considered that the dosing should be carefully determined due to the fact that the substance is corrosive. During the discussion it was pointed out that the Registrant(s) have to give consideration to set correct dose levels for the EOGRTS.

The representative of the Registrant explained that for testing the substance used will be the chloride derivative which reduces substantially its corrosivity. Furthermore the substance is degraded in the human body within 15 minutes with incorporation of degradation products in phospholipids of liver only, which avoids the substance's interaction with the endocrine system or the accumulation of the substance or its metabolites in the body.

Session 2 (closed)

One MSC member commented that possible endocrine effects might be seen, not only due to the substance but also due to acetyl-choline (ACh) production induced by the substance, which then might be circulated further in the whole human body through blood and lymphocytes. The MSC member detailed that tests on rats showed that ACh is a neurotransmitter, accumulates in the lung, acts as a vasodilator, attacks the pancreas, produces diabetes in rats and stimulates adrenaline release which may be considered justified reasons and possibilities for identification of the substance as SVHC.

During the discussion arguments were raised for broad and strict categorisation of "endocrine effects", whether or not e.g. paracrine and autocrine effects should be included in the context of "indication of modes of action related to endocrine disruption" for extension of Cohort 1B. The importance of development of ECHA Endocrine Disruption Expert Group conclusions in this area and on ECHA guidelines was discussed highlighting that at present the topics related to endocrine modes of action are of continuous scientific debate and scientific links cannot be concluded in this specific case.

SECR brought forward justifications for using the definitions of endocrine and specific terms strictly in relation to the REACH Annex text and ECHA guidance, consequently not

regarding the substance as meeting the criteria of indication of mode of action related to endocrine disruption. In contrast some MSC members and experts supported a broader definition including MoA related to paracrine and autocrine effects and suggested that this general issue should be further discussed by the ECHA ED Expert Group. Based on the above considerations, MSC agreed unanimously to the DD as provided for the meeting.

CCH-035/2016 2-ethylhexyl acrylate (E.C. 203-080-7)

Session 1 (open)

One representative of the Registrant(s) was present during the initial discussion. In absence of specific confidentiality concerns in DD, an open session was held.

SECR explained that two PfAs to ECHA's DD were submitted. One PfA suggested to perform the EOGRTS including the Cohorts 2A and 2B and to determine the developmental neurotoxicity (DNT) as the information from the HSDB database indicates that exposure to the registered substance may result in neurotoxicity and there were indications from an *in vitro* study of effects on developing embryo or foetus.

The other PfA suggested the editorial correction in the DD of the deadline to submit the information requested from 30 months to 36 months.

The Registrant provided written comments prior to the meeting and disagreed with the PfA on EOGRTS. During the discussion the representative of the Registrant justified that there is not a trigger for a DNT request and that the substance was included in a group of similar compounds for which new data and updated category will be available mid 2017 which, in their view, should allow ECHA to decide on the acceptability of the category approach and the need for any additional studies.

The MSC member from the PfA submitting country appreciated that the new data for a potential RA would be important for a robust and justified decision, as the PfA was submitted on the basis of the data from the substance database only.

Session 2 (closed)

The MSC member from the PfA submitting country indicated that he saw no more need to further include the DNT request and withdrew the PfA.

MSC supported the change of the deadline from 30 months to 36 months as incorporated in the DD prior to the meeting, which would allow the registrants to assess the new category data before initiating the requested studies, and found unanimous agreement on ECHA's DD as provided for the meeting.

CCH-042/2016 Alcohols, C6-24 and C6-24-unsatd., distn (EC No. 310-079-6)

Session 1 (open)

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

SECR explained that seven PfAs were submitted to ECHA's DD. Five of the PfAs related to the EOGRTS. Four PfAs on the EOGRTS, with a link to the targeted assessment on the results of the sub-chronic toxicity (hereinafter 90-day) study, comprised suggestions as detailed in PfA-1, PfA-2, PfA-3 and PfA-4 (see introduction under item 7.bc).

The fifth PfA suggested including an F2 (extension of cohort 1B), as the use of the registered substance could be considered to lead to significant exposure of consumers. Furthermore, the substance is self-classified as Muta 2.

The sixth PfA on *in vivo* mammalian erythrocyte micronucleus test suggested an editorial change replacing the text of request on EU B.12/OECD TG 474 and EU B.11/OECD TG 475 with a more accurate text on OECD TG 474 and 475.

The seventh PfA on ready biodegradability suggested excluding test methods OECD TG 301 A and 301 E. They were not deemed appropriate, since the substance was highly adsorptive with low water solubility. The PfA further suggested requesting the Registrant

to provide sufficient rationale why the chosen test method was expected to deliver reliable test results.

SECR had modified the DD based on the sixth and seventh PfA in advance of the meeting.

The Registrant had not provided comments on the PfAs.

MSC was satisfied with ECHA's response on the sixth and seventh PfA, whilst MSC discussed all other PfAs at the meeting.

One MSC member asked for more details on the mutagenicity classification, and SECR clarified that the Registrant had self-classified the substance based on an *in vitro* mutagenicity study. A stakeholder observer queried whether the Registrant had in his chemical safety report (CSR) provided information on possible exposure via consumer uses or the environment, and SECR replied that the CSR did not contain any such data.

Session 2 (closed)

One MSC member noted that – according to the dossier – there was exposure under strictly controlled conditions (SCC). SECR proposed to have further clarifications on SCCs with the Registrant through other means, as there were no PfAs on this particular issue. MSC agreed that the consumer exposure could not be followed up at the moment and asked ECHA to alert it at the targeted review period after receipt of the 90-day study results.

SECR then summarised the discussion that (1) the DD would be amended according to the targeted assessment, as agreed (see item 7.d.1); (2) that F2 could not be requested at this stage; and (3) at the targeted assessment, using the results of the 90-day study and any new information, the EOGRTS design could be revised.

MSC agreed unanimously to the DD as amended at the meeting.

CCH-043/2016 Alcohols, C9-11-branched (EC No. 271-360-6)

Session 1 (open)

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

SECR explained that four PfAs were submitted to ECHA's DD. They all related to the EOGRTS, with a link to the targeted assessment on the results of the 90-day study, and comprised suggestions as detailed in PfA-1, PfA-2, PfA-3 and PfA-4 (see introduction under item 7.bc).

SECR had not modified the DD based on these PfAs in advance of the meeting.

The Registrant had provided comments on the DD (not reflected here) and on the PfAs. In his written comments the Registrant disagreed to extend EOGRTS to include developmental neurotoxicity and immunotoxicity (DNT and DIT) cohorts as unjustified. He agreed with the other PfAs, however, requesting at least 20 months to submit the results of the 90-day study. The representatives of the Registrant provided further comments on their integrated testing strategy (ITS) of five closely related alcohols. They had submitted two testing proposal examinations (TPEs) on 90-day studies earlier this year, pending approval from ECHA (at the time of the meeting). They argued that an extension of the standard 12-month deadline would be needed, in anticipation of the results from the two TPEs potentially providing data for a read-across to the registered substance.

One MSC member asked for more information on the group of related substances. Another MSC member inquired when information on TPEs and rationale for the proposed read-across were communicated to ECHA. The representatives of the Registrants clarified that they would test the lower (C8 alcohols) and upper (C13 alcohols) members of category and then apply read-across with interpolation, and that they had provided information on this in their comments to the original DD.

Session 2 (closed)

Some MSC members expressed hesitance to allow an additional 8 months between the 90-day study and the EOGRTS in this compliance check, with a seemingly conditional link to two TPEs still at a third party consultation period (at the time of the meeting). One MSC member queried on a way forward if MSC would not agree on the TPEs. Another member asked whether any results of the TPEs could negatively impact on the fulfilment of CCH requirements.

SECR informed that, in its view, the extra time would allow carrying out all 90-day studies; that the current DD still required to carry out the EOGRTS with the registered substance; that the DNT/DIT cohorts were not yet requested; that the results – whether from data on the registered substance or from read-across – would be subject to the targeted assessment before confirming the EOGRTS design. Furthermore, they considered that in the past TPEs on 90-day studies had not attracted PfAs and that therefore decisions on these testing proposals might be issued shortly after the end of the public consultation.

MSC welcomed the clarifications. Thereafter, SECR summarised that the DD would be amended according to the targeted assessment, as agreed (see item 7.d.1). SECR also considered beneficial to grant the Registrant an 8-month extension of the timeline to submit the results of the 90-day studies, thus due by 20 months instead of 12 months. The understanding on the extension was based on the Registrant's commitment to use an ITS to avoid unnecessary animal testing following Annex XI section 1.5 on grouping and read-across approach. ECHA noted that with this timeline extension it would not be endorsing the whole ITS and proposed read-across. The overall deadline of the decision would then extend from a total of 42 to 50 months.

MSC agreed unanimously to the DD as amended at the meeting.

CCH-048/2016 Dioctyltin oxide (EC No. 212-791-1)

Session 1 (open)

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

SECR explained that eleven PfAs were submitted to ECHA's DD, three of which on the design of EOGRTS and six on aquatic toxicity.

The first PfA on the EOGRTS design suggested removing the extension of Cohort 1B (mating of F1 animals to produce F2 generation). It reasoned, *inter alia*, that there were no concerns for germ cell mutagenicity; that very low water solubility indicated that uptake from the gastrointestinal tract would be very low; that no reliable evidence was presented on the potential to bioaccumulate; increased gestation length was already observed in parental animals – no need to have F2, and no information was available to indicate the mode of action (ED or other) for this effect.

The second PfA on the EOGRTS design suggested including the DNT cohort. It reasoned, *inter alia*, that several organotin compounds such as tributyltin (TBT), trimethyltin (DMT) and dibutyltin (DBT) were known neurotoxicants; that evidence showed organotin compounds (e.g. TBT, DBT) being placentally transferred to the offspring, distributed and persisting in brains of pups; and that DNT evidence existed for e.g. DMT. Furthermore, dioctyltin oxide (DOTO) affects GABA and dopamine concentrations in brain; and TBT mediates RXR-PPAR transcriptional regulation which should be measured within the EOGRTS.

The third PfA on the EOGRTS design suggested including the DNT cohort due to observations of increased gestation length and incidence of cysts in the ovaries raising a concern for effects on endocrine and/or sex hormone system.

The fourth and fifth PfA on aquatic toxicity (long-term toxicity on fish and invertebrates) suggested performing the fish sexual development study (OECD TG 234). It provided justification on potential PBT and ED properties, with chronic toxicity; on possible long-term effects even at low concentrations, due to known invertebrate toxicity by organotin compounds; evidence on sewage sludge and effluents of wastewater treatment plants

containing organotin compounds, with exposure on receiving water and sediment, and indirectly soil.

The sixth and seventh PfA on aquatic toxicity (long-term toxicity on fish and invertebrates) suggested testing on chronic toxicity with the fish sexual development test (FSDT) instead of the fish early-life stage test (FELS) due to ED properties of organotins. The justification included, *inter alia*, different available water solubility values; measurable concentrations achievable in acute *Daphnia* and fish tests; publications on organotin indicating effects appearing at very low concentrations regarding ED and PBT properties; dioctyltin oxide (DOTO) being probable PBT; and T-criterion assessment needing a NOEC from the study. The eighth and ninth PfA on long-term toxicity on fish and invertebrates, and long-term terrestrial toxicity suggested requesting the aquatic long-term study for *Daphnia* and fish; depending on the outcome also requesting long-term terrestrial toxicity studies. The PfAs agreed that available QSAR estimations were for neutral organics and might not be fully validated for DOTO. However, chronic toxicity might be below water solubility, thus not an argument to waive aquatic chronic toxicity studies. If no chronic aquatic toxicity was to be expected, then long-term toxicity to terrestrial organism would also be unlikely and no such studies needed.

The tenth PfA on bioaccumulation in aquatic species suggested – on a basis of the transition evaluation on three dioctyltin substances with a conclusion of not meeting the PBT/vPvB criteria and the common degradant DOTO not meeting the B criteria –different ways forward, possibly as combinations: deleting the bioaccumulation study request, but might be required in regulatory follow up; requiring a dossier update to strengthen read-across, including hydrolysis, to justify the analysis in the available bioaccumulation study; requesting a PBT assessment of all constituents and potential degradation products; requiring tiered approach to above-mentioned updates and assessments, and bioaccumulation testing for any constituents assessed to meet the vP criteria, but where insufficient information was available to conclude B/vB.

The eleventh general PfA suggested some editorial modifications.

The Registrant had provided comments on the DD (not reflected here) and on several PfAs. In his written comments on the first PfA on EOGRTS design the Registrant agreed that F2 was not triggered. Also, he disagreed to include DIT because chronic immunotoxic effects had been not described for dioctyltin chloride (DOTC), a structurally similar compound, the nature of the observed effects are always acute. In the comments on the second and third PfA on EOGRTS design he disagreed to include DNT cohort, arguing that several organotins known as neuro-toxicants are not structural analogues to DOTO.

In the comments on the fourth and fifth PfA on aquatic toxicity (long-term toxicity on fish and invertebrates) the Registrant disagreed, arguing that the substance was considered insoluble in water; that available studies show no adverse aquatic effects; that an assessment on three octyltin substances showed no evidence on PBT/vPvB; that no sound evidence of an ED mode of action has been determined; and that the highest environmental exposure was expected during manufacturing, with no exposure from municipal sewage treatment plants as production wastewaters were extensively treated and sludge incinerated.

In the comments on the sixth and seventh PfA on aquatic toxicity (long-term toxicity on fish and invertebrates) he disagreed, partly building on arguments on previous PfAs, due to difficulties with low solubility and presence of impurities which are more soluble (highest with monooctyltinoxide, MOTO), and higher concentrations used in tests than calculated value of monomeric DOTO.

In the comments on the eighth and ninth PfA – on long-term toxicity on fish and invertebrates and long-term terrestrial toxicity – the Registrant disagreed as DOTO has very low water solubility, and preferred to first perform a study on terrestrial organisms with better soluble impurity MOTO.

In the comments on the tenth PfA on bioaccumulation he disagreed foreseeing no need to re-evaluate PBT/vPvB; considering hydrolysis not possible due to very low water solubility; and preferring testing with the impurity MOTO.

The representatives of the Registrant further reconfirmed their arguments on the PfAs. They emphasized that in their view all organotins did not behave similarly and that octyltins were not found neurotoxic, but methyltin is neurotoxic, equivocal and marginally sufficient for classification based on development neurotoxicity. They also informed that the PNDT study design included a module for acute immunotoxicity to check possible links to osteoporosis since most immunosuppressive substances (drugs) showed evidence to this property that is similar to ED properties; also, the related marker could be checked from blood. Therefore, based on the results, the need for a DIT cohort could be revisited. They considered that increased gestation length was insufficient evidence to conclude on potential ED mode of action and could have been caused by other mechanisms such as maternal toxicity, and in their view there were no corroboration findings or *in vivo* evidence on ED modes of action. Regarding the lack of evidence for bioaccumulation, they referred to monitoring studies which had not detected octyltins in rivers, wastewaters and related biosamples, but only in sediment.

SECR had modified the DD based on the tenth and eleventh PfAs in advance of the meeting.

One MSC member considered prolonged gestation in isolation as not sufficiently clear evidence on indication of endocrine mode of action, while the expert of another MSC member viewed it as a concern.

A MSC member drew attention to the recent remark on the substance being polymerised, as that information was not found in the CSR. The representatives of the Registrant confirmed this information became available only recently after a new study on polymeric units performed only after the compliance check was initiated. Another MSC member noted that the substance appeared rather to be a macromolecule, and considered it not meeting the REACH definition of a polymer. SECR inquired on the fate of the substance in acidic environment such as stomach, where the representatives of the Registrant informed that in the testing in a mimicked gastric environment no changes were detected in four hours.

Session 2 (closed)

The MSC member, representing the eMSCA responsible for the future substance evaluation of the registered substance, confirmed the support to request EOGRTS already in this compliance check.

One MSC member considered it premature to request F2, while several other MSC members saw enough indications to trigger its inclusion. Prolonged gestation can be a toxicity-trigger for F2, and it inclusion is also supported by the high log Kow. Discussion on the triggers for DNT cohorts focused on the strength of the evidence. Some MSC members and their experts considered the existing evidence as sufficient for triggering a DNT cohort in EOGRTS. One expert of an MSC member suggested that if the ED concern was confirmed in the EOGRTS, this would add strength to justify examination of DNT during the substance evaluation by e.g. requesting OECD 426.

Regarding the bioaccumulation, MSC agreed that the Registrant had sufficiently addressed the concerns in his comments, and asked ECHA to add a note for the consideration by the Registrant to consult the *ECHA Guidance on the information requirements and chemical safety assessment* in relation to the PvP/PBT assessment before conducting testing.

Following the PfAs on aquatic toxicity, SECR provided further information on the adaptation of the Registrant and there was discussion as to whether this compliance check could include the standard information requirements for long-term aquatic toxicity. A MSC member emphasized the wish to have OECD TG 234 carried out, preferably in this compliance check than later under substance evaluation. MSC agreed not to pursue – at this moment under this compliance check – the PfA for long-term toxicity to fish. MSC also noted that the substance is proposed to be evaluated under substance evaluation, which may allow to pursue this endpoint also more in depth and address a potential ED concern with an OECD 234 test (if appropriate).

MSC agreed to address the current information gap for long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5; test method: Daphnia magna reproduction test, EU C.20/OECD TG 211) with the registered substance.

MSC agreed unanimously to the DD as amended at the meeting. Three MSC members with voting rights abstained from voting, including members from Austria, Denmark and the Netherlands.

CCH-053/2016 Methyl 2-naphthyl ether (EC No. 202-213-6)

Session 1 (open)

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

SECR explained that five PfAs were submitted to ECHA's DD in total. Altogether five PfAs related to EOGRTS, of which three PfAs, with a link to the targeted assessment on the results of the 90-day study, comprised suggestions as detailed in PfA-1, PfA-2 and PfA-4 (see introduction under item 7.bc).

The fourth PfA on the EOGRTS design suggested including DNT and DIT cohorts, considering a concern due to existing information on the substance. Results from the 28-day repeated dose toxicity study in rat showed effects on one or more endocrine mechanisms or modes of action ((anti)oestrogenicity and possibly (anti)androgenicity) as possible triggers for the DNT and DIT. Also, *in vitro* and *in silico* information showed estrogenic activity and thyroid toxicity for the likely metabolite of 2-naphthol.

The fifth PfA on *in vitro* gene mutation study in mammalian cells suggested aligning with previous decisions, to accurately reflect the fact that in 2015 the OECD TG 476 was updated and split into two separate OECD TGs 476 and 490.

The Registrant had provided written comments on the PfAs. In his written comments on the three PfAs on EOGRTS the Registrant was in disagreement, as he had performed an OECD TG 407 study, where the protocol was specifically adapted to incorporate certain reproductive toxicity related effects and accordingly the NOAEL was derived. Further, he argued that the findings were supported by a read-across substance (which was not specified further in his comments).

SECR had modified the DD based on the fifth PfA in advance of the meeting.

The MSC member and the expert from the PfA submitting Member State reiterated their reasons for the fourth PfA, highlighting study results providing information on specific mode (or mechanism) of action on the sex hormone balance and the potential of metabolites and thyroid hormones; also defending these observations that would not be overruled in spite of another assays not showing such effects.

Session 2 (closed)

One MSC member suggested to wait for the results of the 90-day study before deciding on the DNT cohort, emphasising that the effects quoted in the PfA would not be meeting their threshold of concern. Another MSC member argued that the 90-day study had another scope than detecting ED properties and that the concern would not be removed even if no triggers were found in the 90-day study. Several MSC members supported the views of the fourth PfA, and that the 28-day study results already had given indications for a concern triggering a request for the DNT and DIT cohort.

SECR reiterated that in the targeted evaluation the need to include DNT and DIT cohorts would be reassessed, using results from the 90-day study and any other relevant available information that could trigger these changes in the study design.

MSC considered that the changes proposed by SECR based on all five PfAs were appropriate and agreed to further amend the DD according to the targeted assessment (see introduction under item 7.bc).

MSC agreed unanimously to the DD as amended at the meeting.

CCH-055/2016 Propyl acetate (EC No. 203-686-1)

Session 1 (open)

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

SECR explained that five PfAs were submitted to ECHA's DD in total. Four PfAs on the EOGRTS, with a link to the targeted assessment on the results of the 90-day study, comprised suggestions as detailed in PfA-1, PfA-2, PfA-3 and PfA-4 (see introduction under item 7.bc).

The fifth PfA on *in vitro* gene mutation study in mammalian cells suggested aligning with previous decisions, to accurately reflect the fact that in 2015 the OECD TG 476 was updated and split into two separate OECD TGs 476 and 490.

The Registrant had provided comments on the DD (not reflected here) and on four PfAs. In his written comments on the first four PfAs the Registrant agreed to split the decision into two with extended deadlines and acknowledging that the changes might be necessary if new information becomes available later which would trigger the extension of cohorts, which in their view should not be included by default if the decision is not split into two.

SECR had modified the DD based on the fifth PfA in advance of the meeting.

Session 2 (closed)

MSC considered that the changes proposed by SECR based on all five PfAs were appropriate and agreed to further amend the DD according to the targeted assessment (see introduction under item 7.bc).

MSC agreed unanimously to the DD as amended at the meeting.

CCH-056/2016 Reaction Mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and [...] (List No. 915-730-3)

Session 1 (open)

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

SECR explained that five PfAs were submitted to ECHA's DD related to the extended one-generation reproductive toxicity study (EOGRTS).

Further SECR informed the representative of the Registrant that in other cases with PfAs on sequential testing a generic agreement was reached to have all requests in the same decision but allowing for new information becoming available later which might trigger the extension of cohorts; therefore, the discussion would concentrate on case-specific information that already at this point in time might lead to inclusion of DNT or DIT cohorts in the EOGRTS.

Four PfAs on the EOGRTS, with a link to the targeted assessment on the results of the 90-day study, comprised suggestions as detailed in PfA-1, PfA-2, PfA-3 and PfA-4 (see introduction under item 7.bc).

The fifth PfA on the EOGRTS design suggested, if the request was kept, to include F2 (extension of cohort 1B). The view expressed in the PfA was that the use of the registered substance is leading to exposure of humans, as the substance has been detected in human milk. If the 90-day study showed any indication of ED effects, it would be appropriate to request the F2.

SECR had not modified the DD based on these PfAs in advance of the meeting.

The Registrant had provided written comments on the PfAs and agreed with overall conclusions, in particular as suggested in PfA-1. He also agreed to conduct the studies within the suggested timelines. He specifically confirmed the update of the dossier to have all necessary information to make further decisions on EOGRTS and the need to include additional cohorts. In his further comments the representative of the Registrant re-confirmed his agreement with the suggested testing. He also provided the view that no

identifiers for DNT and DIT cohorts were seen, but this would be checked with the 90-day study results.

One MSC member raised the concern that consumer exposure could occur, leading to the need to include F2. SECR responded that even when the exposure condition was met, F2 would still not be triggered as the currently available information on hazard did not indicate concern (thus there is no toxicity-trigger). Another MSC member noted that it was unclear if sufficient hazard information was available in the dossier, and whether the exposure trigger was fulfilled.

Session 2 (closed)

MSC considered it plausible not to request F2 at this stage, as suggested in the fifth PfA, and reassess the study design during the targeted assessment. MSC considered that the changes proposed by SECR based on first four PfAs on EOGRTS were appropriate and agreed to amend the DD according to the targeted assessment (see introduction under item 7.bc).

MSC agreed unanimously to the DD as amended at the meeting.

CCH-059/2016 Tert-butyl 2-ethylperoxyhexanoate-TBPEH (EC No. 221-110-7)

Session 1 (open)

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

SECR introduced the two PfAs on EOGRTS submitted. One PfA suggests that inclusion of an F2 (extension of cohort 1B) should be requested because based on available data it is not possible to evaluate if exposure to consumers occurs and because of controversial mutagenicity data. An in-depth rationale could be proposed by the Registrant to avoid carrying out the F2.

In another PfA it was suggested to include DIT and DNT cohorts, as the substance rapidly degrades hydrolytically to tert-butanol and 2-ethylhexanoic acid, and the effects seen on the thyroid gland could induce changes in thyroidal hormone levels, which may trigger DIT and DNT cohorts.

SECR had not modified the DD for the meeting based on the PfAs.

The Registrant(s) representatives explained that the product is an initiator in a polymerisation process and is used in closed systems. Also he stated that the substance does not represent a hazard for consumers because of its instability i.e. TBPEH degrades rapidly without residues which possibly cause harm for consumers. Furthermore, he indicated that the dossier has now been updated with mutagenicity data.

During the discussion an MSC member highlighted the contradictions in the data from investigations of thyroidal hormone levels in mice or in rats, and the difficulties in their interpretation. The changes of the hormone levels is already a trigger the additional cohorts but also interim measurements in the EOGRTS could be relevant for triggering further cohorts.

Another MSC member noted that the disseminated dossier for the substance does not yet include the updated data on mutagenicity. SECR noted that the request for an extension of cohort 1B to produce the F2-generation requires a proper level of justification as stated in REACH regulation and in ECHA guidance documents.

During the discussion an MSC member highlighted the contradictions in the data from investigations of thyroid in mice or in rats, and the difficulties in their interpretation. The effects on thyroid gland could induce changes in thyroid hormone levels which may trigger the additional cohorts but also interim measurements in the EOGRTS could be relevant for triggering.

MSC members discussed further on the test design and reflected on several scientific aspects: a) the applicable top doses which would be needed to observe effects in mice, b) any interspecies differences in sensitivity, c) the relationship between histopathologic

changes with hormonal changes, d) gender specificity, e) the substance specific mechanisms and related symptoms and f) whether data on mode of action or mechanism of action is required.

Session 2 (closed)

It was noted that the scientific aspects discussed had not always been captured in the PfA, and hence MSC decide not to strive to come to a resolution on them but considered that these aspects should be addressed by the Registrant. MSC considered that as an additional investigation in the EOGRTS, the registrant could take into account measuring thyroid hormone levels (T4 and TSH) in females of the parental generation before mating. The results of this additional investigation could be used by the registrant, in his further consideration whether triggers to include the DNT- cohorts in the study design are met.

MSC agreed unanimously to the DD as provided for the meeting.

CCH-060/2016 Tetrahydrofurfuryl alcohol (EC No. 202-625-6)

Session 1 (open)

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

SECR introduced the PfAs on EOGRTS which suggested to remove DNT and DIT cohorts, as substance has a harmonised classification as Repr 1B H360Df which the PfA-submitter considered to be an Annex column 2 adaptation, and because DD does not demonstrate that the available data are inadequate to support a robust risk assessment.

MSC discussion focused on the relevance of including DIT/DNT cohorts for human health and on technical versus legal arguments for removing DIT/DNT cohorts from the request. One stakeholder supported the inclusion of DIT and DNT cohorts as requested in the DD submitted for the meeting.

Session 2 (closed)

During the discussion MSC considered that the classification to Repr 1B for developmental toxicity may not be always enough and takes into account necessary RMMs, and supported the request for EOGRTS with the inclusion of DIT and DNT cohorts.

SECR clarified the legal grounds why removing DIT and DNT cohorts is outside of the scope of the column 2 waiver.

MSC agreed unanimously to the DD as provided for the meeting.

TPE-039/2016 Trometamol (EC No. 201-064-4)

TPE-040/2016 2-amino-2-ethylpropanediol (EC No. 204-101-2)

Session 1 (open)

Two representatives of the Registrant participated in the initial discussion. Given that the two cases were closely linked, and in agreement with the Registrants' representatives, they were introduced and discussed intertwined. In absence of specific confidentiality concerns in DD, an open session was held.

SECR explained that two PfAs to ECHA's DD were submitted for TPE-039/2016, and one PfA for TPE-040/2016. Both PfAs suggested rejecting the proposed read-across, for the 90-day repeat dose toxicity study as well as for the PNDT study, to use 2-amino-1,3-propanediol (APD) as the source-substance for testing, and proposed instead to use the registered substance in each of the two cases.

The Registrant disagreed with the PfAs and in his comments elaborated on the structural similarities of the four substances in the category and the limited changes in hydrogen bonding, steric restrictions and chemical transformations that these may cause. He also referred to inertness of the alkyl moieties and that no metabolism of these substances is expected. In the view of the Registrants the chemical similarities permit reasonable predictability for the toxicological endpoints, which justify the read-across approach. At the meeting the registrant's representative repeated those arguments, further building on the

pKa values within this group being close together. He also briefly repeated the lack of findings in existing studies (for two of the four substances) and QSAR predictions supporting the assumption of low toxicity for the two endpoints in question as well as the general low toxicity of these molecules for the endpoints for which tests studies have been reported.

In the discussion the MSC member representing the CA submitting PfA explained that it is necessary to ensure that a high level of justification and documentation is maintained when waiving information requirements using read across from one substance to another or in a category. In his view for higher tier endpoints it is difficult to predict properties solely from the structures, and therefore, it should be much to better substantiated that it is unlikely the substance has (or has not) certain properties. It was noted that the Registrant did not sufficiently explain how different substituents in the group may impact toxicity, and attention was drawn to the fact that trometamol does not share the structural similarity with the three other substances in this group (triol vs. diol). It was felt that the proposed category is still "work in progress" and one needs to see first the test results with the source substance in order to more definitively conclude on the plausibility of the read-across. Further discussion took place as regards the ionisation ratio at different pHs, specifically at pH 8, impacting bioavailability of the different substances in different parts of the gastro-intestinal tract, and in addition the possibility of active transport of the substance or its metabolites over the membrane. Registrant's representative in his response made reference to low bioavailability confirmed by high excretion via the kidney.

SECR responded to the observation that ECHA's RAAF (Read-across Assessment Framework) had not been applied for the preparation of these testing proposals indicating that the framework had not been available at the time of submission, but that assessment of a read across is possible also without it.

For TPE-040/2016, some specifics were also noted in the discussion. The read-across was further questioned due to different physical state of the source substance in comparison with the registered substance. Furthermore, attention was drawn to the inconsistency in the category-approach namely that trometamol is not part of the category for this testing proposal whereas it was for TPE-039. Also a marked differences in the acute toxicity to fish between the different substances were noted by some MSC participants even though they also noted that the toxicity itself was still low. It could be hypothesized that the difference is caused by differences in mechanisms or a difference of pH during the test.

Session 2 (closed)

The significance of the findings as presented in the read-across justification document from the Registrant was not argued according to one member. In particular he drew attention to the missing argumentation for assumed low absorption. Other members agreed that differences in pKa-values within the proposed category could have a big impact to metabolism and absorption at intestinal pH's. Furthermore, some of screening studies available included somewhat ambiguous results in the view of one expert, and hence a further look at predicted metabolites would be needed. Others argued that the structural similarity for these particular cases was obvious, and its impact on toxicity was not very likely. They also argued that the pKa-values were also in the same range, even if not the same, and hence the overall justification for the read-across to the target substance could be considered plausible. Noting the inconsistencies for the two groups/categories, several Committee members were not satisfied on how the argumentation had been built for the two substances. Also some members expressed uncertainty over the exact hypothesis for the read-across strategy, and hence questioned how it therefore could be considered plausible.

Based on the above considerations, MSC agreed unanimously to amend the DD in order to make it clear that determination on the validity of the read-across, including the proposed grouping approach, is premature at this point. Based on the currently submitted information the read-across approach proposed by the Registrant might be plausible but eventual validity of the read-across hypothesis and grouping approach will be reassessed once the requested information is submitted.

MSC found unanimous agreement on both ECHA's DD as amended at the meeting.

Two members abstained from voting on TPE-039/2016 and one member abstained from voting on TPE-040/2016.

CCH-029/2016 1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt (EC No. 204-886-1)

Session 2 (closed)

SECR explained that agreement was initially sought in written procedure. The written procedure was terminated by the Chairman of MSC on request of one MSC member suggesting MSC discussion on this DD.

SECR introduced the two PfAs that were received to ECHA's DD. The first PfA on *in vitro* gene mutation study in mammalian cells suggested alignment with previous decisions, to accurately reflect the fact that the testing guideline (TG) 476 of OECD was updated in 2015 and split into two separate TGs 476 and 490. The second PfA suggested adding a new request of a pre-natal developmental toxicity study (EU B.31/OECD TG 414) in a first species (rats or rabbits), oral route, as existing information provided was not considered to fill the information gap.

The Registrant had provided comments on the DD (not reflected here) and on the PfAs. In his written comments the Registrant agreed with the first PfA. However, he disagreed with the second PfA as in his view existing data confirmed that there were no developmental effects of sodium saccharin at the given dose levels, and several long-term studies (multiple generation studies) available for this substance confirmed that the substance did not have developmental effects.

SECR had modified the DD in advance of the written procedure based on the first PfA.

The MSC member who requested for termination of the written procedure explained that the MSCA could not find information related to developmental toxicity in the public domain, according to which there would be no concern on pre-natal developmental toxicity (PNDT). The information in the dossier and in public literature could not substantiate the read-across. Therefore, it was not possible for them to conclude that the read-across was acceptable and therefore the test should be requested.

A MSC member commented on the case being a special one and would have welcomed a more clear description of the substance. Another MSC member suggested improving documentation and accompanied justifications. SECR explained that the substance, which is also accepted as a food ingredient, had not been considered to be of concern on developmental toxicity based on available information from international assessments and provided an internet link to that. MSC welcomed SECR's agreement to improve transparency on similar cases in future.

MSC agreed unanimously to the DD as circulated for the written procedure. One MSC member abstained from voting.

CCH-039/2016 6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol (EC No. 201-618-5)

Session 2 (closed)

The MSC Chairman had terminated the written procedure for MSC agreement seeking on request of a MSC member and the case was brought to the meeting to further discuss and conclude on the more appropriate route of exposure in the bioaccumulation study.

As requested also in the PfA the MSC member stopping the written procedure reiterated the suggestion to that the aqueous exposure route is more appropriate and a dietary bioaccumulation study should only be conducted in cases where it is sufficiently demonstrated that an aquatic exposure is technically not possible. Hence in this case the choice should not be left to the Registrant.

SECR explained that ECHAs general approach for OECD 305 had been to give both aqueous and dietary options, but could support that for this particular case in which the

substance properties suggests that aquatic testing should not pose a problem, a clear preference for aqueous exposure could be indicated in the DD.

It was agreed by MSC to introduce a note for consideration for the Registrants advising to consult the ECHA *Guidance on information requirements and chemical safety assessment*, on the PBT assessment for further information on the integrated testing strategy for the bioaccumulation assessment and to revise the PBT assessment when information on bioaccumulation is available.

MSC unanimously agreed the DD as modified at the meeting.

CCH-046/2016 Diammonium peroxodisulphate (EC No. 231-786-5)
CCH-049/2016 Dipotassium peroxodisulphate (EC No. 231-781-8)
CCH-050/2016 Disodium peroxodisulphate (EC No. 231-892-1)

Session 2 (closed)

The MSC Chairman had terminated the written procedure for MSC agreement seeking on these three draft decisions on request of a MSC member and the cases were brought to the meeting to further discuss and conclude on the deadline for submitting the requested information.

As requested also in the PfAs the Member stopping the written procedure reiterated the suggestion to split the deadline for submitting information on exposure with a shorter deadline (6 months) than that on hazards (48 months). Considering the skin and respiratory sensitising properties of the substances the Committee agreed that two deadlines would be useful in this specific case in order to ensure adequate protection of the health of workers and consumers, without undue delay, while still allowing sufficient time for conducting new tests as required in the DDs.

MSC unanimously agreed to all the three DDs as modified at the meeting.

TPE-045/2016 Quaternary ammonium compounds, bis (hydrogenated tallow alkyl)dimethyl, chlorides, reaction products with polyethylene-polyamines and tall-oil fatty acids, humates hydrochlorides (EC No. 272-745-1)

Session 2 (closed)

The MSC Chairman had terminated the written procedure for MSC agreement seeking on request of a MSC member and the case was brought to the meeting to further discuss and conclude whether oral or inhalation application is the most appropriate administration route for the pre-natal developmental toxicity (PNDT) study.

As requested also in the PfA the MSC member stopping the written procedure reiterated the suggestion to choose the inhalation route as the most appropriate route of exposure for consistency in exposure route for RDT and PND testing. Also it was recommended to use a step-wise testing approach considering the outcome of the RDT test to inform on dose selection for the PNDT test.

One MSC member pointed out that the bioavailability for the substance via either route of exposure may be limited, still the oral route would be preferred as default route for the PNDT test and saw no reason to deviate from it. Another MSC member highlighted the need to make some editorial changes in the DD to avoid perceived contradictory wordings.

SECR provided a justification that for PNDT testing the oral route is the most appropriate route of administration for substances except gases in order to focus on the detection of hazardous properties on reproduction as indicated in ECHA Guidance. For the registered substance administration by the oral route provides also a higher possibility of systemic availability because higher doses can be administered. For the RDT test the route of administration may also depend on the substance's properties and use pattern to investigate potential effects at the site of contact in addition to systemic effects. Hence MSC concluded that the PNDT test should be performed by the oral route and amended the DD.

Based on the above considerations MSC unanimously agreed the DD as modified at the meeting.

d. General topics

1) Presentation on targeted evaluation of 90-day data for EOGRTS

The contents of this agenda item are presented in the beginning of item 7.bc.

2) Appeals update

This item was postponed to the next meeting since there was nothing new to report on.

Item 8 – SVHC identification - Seeking agreement on Annex XV proposals for identification of SVHC

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

SECR gave a brief report on the outcome of the written procedure for SVHC agreement seeking on the identification of *benzo[def]chrysene (benzo(a)pyrene) (EC No. 200-028-5)* proposed to be identified as SVHC based on Article 57 (a)-(e) of REACH due to its carcinogenic, mutagenic toxic for reproduction, persistent, bioaccumulative and toxic, very persistent and very bioaccumulative properties. It was reported that MSC agreed unanimously on identification of *benzo[def]chrysene (benzo(a)pyrene)* as an SVHC in the written procedure launched on 17 May 2016 and closed on 27 May 2016. SECR noted that the final agreement documents will be made available on MSC S-CIRCABC and on the ECHA website and the substance will be included in the Candidate List of SVHCs.

b. Agreement seeking

1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor, 3-BC) (EC No 239-139-9)

The dossier submitter (DS) representative from the German CA presented to MSC the Annex XV proposal for identification of 1,7,7-trimethyl-3-(phenylmethylene)bicycle [2.2.1]heptan-2-one (3-benzylidene camphor, 3-BC) as an SVHC under Article 57 (f) due to its **endocrine disrupting properties** for which there is evidence of probable serious adverse effects to the **environment** giving rise to equivalent level of concern (ELoC) to CMR, PBT and vPvB substances under Article 57 (a)-(e). DS explained the rationale for preparing the dossier and pointed out that the proposal for the **environment** has been prepared on the basis of various *in vitro* data, in vivo fish data and supporting data from rodent studies. Both types of data point to estrogenic and anti-androgenic mode of action and probable adverse effects in wildlife species.

The DS outlined the main comments received in the public consultation on this proposal and the DS's responses to them. The public consultation yielded both supporting and diverging views. The views received during the public consultation were also raised at the MSC meeting.

There was a view expressed which, since the substance is not yet registered under REACH but only preregistered, questioned the regulatory relevance of the SVHC identification and inclusion in the Candidate List. However, DS expressed the view that this substance is an expected drop-in alternative for other UV filter substances already under regulatory action, hence leading to possible registrations in future which justifies the proposal for the substance to be identified as an SVHC. Furthermore, 3-BC is detected in environmental monitoring studies and has a potential for persistence and bioaccumulation based on screening level data. SECR noted that while these type of considerations may be relevant for deciding whether to initiate SVHC identification, they are not relevant for the identification process itself.

The key study used by the DS (Kunz et al. 2006b) was challenged by some members as insufficient for identifying the substance as SVHC. This *in vivo* fish test conducted following the OECD test guideline 229 is a level 3 test according to the OECD conceptual framework. A member raised concerns that the results on the adverse apical end point of fecundity may not be reliable since two treatment groups showed reduced spawning before exposure

started, and a high loss of test substance occurred during the 48h water renewal periods, although the study provides strong indications that 3-BC interacts with the fish endocrine system. Some members considered that for these reasons a repeat of the study seemed warranted. However, since 3-BC is not registered, generation of further information under Dossier or Substance Evaluation is currently not possible.

A view was expressed that more certainty on the ED properties is needed, thus an OECD level 4 or 5 test is preferred to take the decision. Another member argued that clear adverse effects at level 3 testing are sufficient when combined with a weight of evidence approach showing endocrine mode(s) of action, whereas a negative outcome at level 3 cannot be accepted to be indicative of a lack of endocrine mode(s) of action due to the low statistical power of the test. A view was also expressed that a thorough assessment by the DS of available mammalian data could have provided additional evidence for further strengthening the weight of evidence.

The DS responded to the concerns on the key *in vivo* fish study that because OECD TG 229 has a low statistical power for detecting ED effects it could easily miss adverse effects related to fecundity. In this case however, effects were detected. Hence combined with supporting information, including mode of action information and rodent species test results as reviewed by Hass et al. (2012), there is sufficient evidence that 3-BC meets the WHO/IPCS definition of an endocrine disrupter. This judgement was supported by the majority of MSC members.

Additionally there was a view expressed that identification as SVHC due to ED properties is not possible in the absence of agreed ED criteria other than on a case-by-case basis. Basing the ELoC assessment on a comparison of 3-BC with previously identified ED substances and on the potential of 3-BC to bioaccumulate was not considered sufficient. Whilst one member agreed with the view that fate parameters (together with potency) could form part of the identification, yet for this case, the bioaccumulation potential was indicated only through QSAR data and a more definitive assessment was lacking. These views were not supported by many MSC members, who considered that there was sufficient evidence for the probability of serious adverse effects of equivalent level of concern for the environment.

MSC went through the text of the Support Document with amendments introduced at the meeting for identification of **3-BC** as SVHC under Article 57(f) as giving rise to an equivalent level of concern due to endocrine disrupting properties in relation to the **environment**.

When the MSC agreement documents and support documents were brought to a vote, a majority of the members agreed that the available information for **3-BC** was sufficient to conclude that there is scientific evidence of probable serious effects giving rise to an equivalent level of concern in relation to **environment** (i.e. to substances listed in points (a) to (e) in Article 57 of the REACH Regulation). Three MSC members abstained and two members did not agree on the identification of 3-BC under Article 57(f) as giving rise to an equivalent level of concern in relation to environment. The editorial changes required to convert the MSC agreement document into a MSC opinion were introduced, and the minority view was orally presented. The latter is to be submitted in writing after the meeting so as to be annexed to the MSC opinion.

The Chairman thanked the dossier submitter for the proposal submitted and MSC for its deliberations on it.

(±)-1,7,7-trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1] heptane-2-one (4-methylbenzylidene camphor, 4-MBC) (EC No. 253-242-6)

The dossier submitter (DS) representative from the German CA presented to MSC the Annex XV proposal for identification of (±)-1,7,7-trimethyl-3-[(4-methylphenyl)methylene] bicyclo[2.2.1] heptane-2-one (4-methylbenzylidene camphor, 4-MBC) as an SVHC under Article 57 (f) due to its **endocrine disrupting properties** for which there is evidence of probable serious adverse effects to the **environment** giving rise to equivalent level of concern (ELoC) to CMR, PBT and vPvB substances under Article 57 (a)-(e). DS explained the rationale for preparing this SVHC dossier, in particular referring to the wide dispersive

uses of 4-MBC (incl. its ongoing use in cosmetics), the monitoring data indicating its emissions to the environment, the evidence regarding the endocrine disruptive properties of 4-MBC and its structural analogue 3-BC in wildlife species, as well as the identified difficulties to quantify a safe level for 4-MBC in the environment. Further, the DS pointed out that the proposal is based on weight of evidence built upon the available *in vitro* data for 4-MBC, supporting *in vivo* data from fish studies and read-across from the structural analogue 3-BC showing that 4-MBC is an endocrine disruptor in the environment with estrogenic and anti-androgenic modes of action. Furthermore, the DS noted that 4-MBC has a potential for persistence and bioaccumulation based on screening level data.

The DS outlined the main comments received in the public consultation on the proposal and the DS's responses to them. DS pointed out the structural, biological and metabolic similarities of 3-BC and 4-MBC that clearly indicate that both substances are strong oestrogen receptor binders.

In the following discussion, several members expressed their strong reservations with regard to this SVHC proposal and asked for further clarification on a number of issues, including: the strength of the *in vivo* evidence provided, the interpretation of the water solubility data, the lack of evidence to support adverse ED effects at population level, feasibility of the applied read-across from 3-BC, the uncertainty of the fish data, insufficiently demonstrated ELoC assessment in comparison with the CMR, PBT and vPvB substances, in particular considering the existing indications for the PBT potential of this substance. Several members noted that the substance-specific information considered in this SVHC proposal, although quite limited, gives indications for ED concerns for the environment. However, the available mammalian/rodent data, also relevant for the environmental hazard assessment, have not been considered yet in this proposal. MSC discussed the potential need for more *in vivo* data generation to investigate the effects in fish and outlined other possible improvements in the read across justifications and in the ELoC conclusions.

DS responded to the issues raised and, taking into consideration the MSC discussions, decided to withdraw this SVHC identification proposal for 4-MBC in order to further elaborate on the justification provided in the documentation.

The Chair thanked the dossier submitter for the proposal submitted to the SVHC identification process and MSC for its deliberation on it.

Dicyclohexyl phthalate (DCHP) (EC No. 201-545-9)

The dossier submitter (DS) representative from the Swedish CA presented to MSC the Annex XV proposal, prepared in cooperation with the DK CA, for identification of Dicyclohexyl phthalate (DCHP) as an SVHC under Article 57 (c) due to its **toxicity for reproduction** and under Article 57 (f) due to its **endocrine disrupting properties for** which there is evidence of probable serious adverse effects to both **human health** and the **environment** giving rise to equivalent level of concern (ELoC) to CMR, PBT and vPvB substances under Article 57 (a)-(e). DS explained the rationale for preparing the dossiers. Further, the DS pointed out that the part of the proposal concerning the reproductive toxicity of DCHP is based on the recent REACH Committee's decision regarding its harmonised classification as Repr. 1B. As regards the endocrine disrupting properties of DCHP to **human health**, it was clarified that this part of the SVHC proposal is based on experimental data on mode of action and adverse effects in mammalian species in particular rodent species that are considered relevant for humans. In relation to the part concerning the **environment**, the proposal has been prepared on the basis of experimental data on mode of action and adverse effects in rodents that were considered relevant for mammals in general. Furthermore, some additional data on potential ED effects in fish were presented.

The DS outlined the main comments received in the public consultation on the proposal and the DS's responses to them. DS concluded that only the inherent properties of DCHP should be evaluated in the ELoC assessment under Article 57 (f). The assessment was based on the WHO/IPCS definition of endocrine disrupters further elaborated by the European Commission's Endocrine Disruptors Expert Advisory Group, and also on the

factors specified in ECHA´s generic approach paper on SVHC identification according to Article 57 (f) with sensitisers mentioned as an example. The DS also emphasised that there is no legal requirement that information about environmental fate and exposure should be considered at this stage and that no reference is made to this in Article 57 (f), which only refers to probable serious effects due to e.g. endocrine properties. The DS was of the view that exposure-related considerations are instead relevant during later stages of the authorisation process.

In the subsequent discussion, MSC sought further clarification with regard to a number of issues including: data interpretation from two Hershberger assays mentioned in the dossier, the relevance of the *in vitro* data for concluding on the MoA, the metabolism of the parent compound, the (absence of a) need for agreed EU criteria for ED identification in relation to the current proposal, as well as the sufficiency of data provided in the dossier, in particular with regard to the potential effects on the environment.

An adviser to an MSC member pointed out that in his interpretation the results of the Hershberger assays were not consistent with the postulated anti-androgenic mode of action. This issue was further clarified by DS and it was concluded that there is no inconsistency. Furthermore it was hypothesized that the observed decrease in fetal testosterone could be obtained due to indirect toxicity. After an exchange of views it was concluded that in either case the function of the endocrine system is altered causing adverse impacts. Thus, the MSC members unanimously acknowledged that DCHP fulfils the WHO/IPCS definition of an endocrine disruptor (ED).

Industry advisers to an MSC ASO observer re-iterated their comments provided during the public consultation with regard to the dataset used for this SVHC proposal and the consistency of the information in the dossier, in particular regarding the weight of evidence and the justification provided on the read across to the phthalates already identified as SVHCs. As regards the environment, they argued that no adverse ED effects from DCHP have been seen in mammals or other species at the population level.

Referring to the responses provided to comments received in the public consultation (in the response to comments table (RCOM)), the DS disagreed with the industry's conclusion on the dataset and the WoE used to conclude on the MoA and the potential adverse effects caused by DCHP. Further, the DS shared the view that although in principle the environmental fate and behaviour are not relevant for the SVHC identification process, in this particular case, the fate of DCHP in the environment may be an important element to look at already at this stage, as DCHP may have a potential for bioaccumulation.

After consideration of the arguments and observations made, the DS requested the Annex XV proposal be split into two with one proposal covering the human health part of the original proposal under both Article 57 (c) and (f). The DS informed MSC of its decision to **withdraw** its proposal for identification of DCHP under Article 57 (f) as giving rise to an equivalent level of concern due to endocrine disrupting properties in relation to the **environment** in order to further elaborate on the justification provided in the documentation and consider requesting further ecotoxicological data during substance evaluation process, e.g. additional data in fish.

MSC went through the proposal for DCHP identification for **human health** and the text of the Support Document with amendments introduced at the meeting.

MSC unanimously supported the text and conclusion on identification of DCHP as SVHC due to its toxic for reproduction properties under Article 57 (c) and also unanimously acknowledged that there is scientific evidence on the endocrine disrupting activity of DCHP and on the link between this activity and the adverse effects to human health. However, some MSC members did not support the conclusion of Equivalent Level of Concern (ELoC) but argued that instead the same concern would be addressed if the substance were identified under Article 57(f) as well as Article 57(c). Hence, they did not agree with the text of section 6.2 of the Support Document. MSC could not resolve the divergence of views on this issue.

Some members asked the DS to consider separating the proposal for the SVHC identification of DCHP following Article 57 (c) from the part referring to Article 57 (f). A

separate identification would allow the inclusion of the substance into the Candidate list according Article 57 (c). However, other members supported the combined identification proposed by the DS.When the MSC agreement document and support document were brought to a vote, a majority of the members agreed to identification of DCHP as SVHC due to its toxic for reproduction properties under Article 57 (c) and 57 (f), i.e. the available information for DCHP was sufficient to conclude that there is scientific evidence of probable serious effects giving rise to an equivalent level of concern in relation to **human health** (i.e. to substances listed in points (a) to (e) in Article 57 of the REACH Regulation).

Five members abstained from the vote.

A minority of five members were of the view that the concern related to endocrine disruption would be addressed if the substance were identified as an SVHC under Article 57(c) as the same effects were considered in the recently established harmonised classification of DCHP due to toxicity for reproduction.

Consequently, these members did not agree on the identification of DCHP under Article 57(f) as giving rise to an equivalent level of concern in relation to **human health** (i.e. to substances listed in points (a) to (e) in Article 57 of the REACH Regulation). The minority view submitted after the meeting in writing will be published in a separate document together with the MSC opinion.

The Chair thanked the dossier submitter for the proposal submitted to the SVHC identification process, and MSC for its deliberations on it.

Item 9 – ECHA's draft 7th recommendation of priority substances to be included in Annex XIV

See Item 10.

Item 10 – Opinion of MSC on ECHA's draft 7th recommendation of priority substances to be included in Annex XIV

MSC discussed the draft MSC opinion on ECHA's 7th draft ECHA Recommendation for inclusion of candidate list substances into Annex XIV after hearing the Rapporteur's and her Working Group's review of the documentation and public comments received.

All 11 substances were addressed separately and also as groups, where appropriate, and the discussion was structured to topics related to prioritisation and general issues, transitional arrangements, and exemptions. For each topic SECR provided also its highlights for MSC's consideration, i.e. issues to raise MSC's special awareness and/or to get MSC's views on.

As regards prioritisation some discussion took place whether the small reduction in the priority (and the respective score) for one of the sensitizers (HHPA), should lead to a reconsideration of the priority of HHPA/MHHPA and their exclusion from this recommendation. After review of the updated registration data the score is in the range of other substances that were not included in this draft recommendation. Most of MSC did not have a strong view on this. Some were rather hesitant towards their exclusion as they considered the change in priority score rather small and they did not see added value from repeating the public consultation (with an additional workload). Few others indicated preference for possibly dropping those substances. For the other substances the information provided did not seem to impact prioritisation, and hence also did not lead to further discussion.

Some discussion took place on the transitional arrangements. One industry observer mentioned that use of some new tools to improve the quality of applications requires time, and industry also needed time to develop good quality dossiers for smooth processing in RAC and SEAC. Some members contributed to the discussion acknowledging improvements and the steep learning curve also from industry, however, noting that some additional time might be useful. The suggestion to MSC from the Rapporteur and WG was to consider longer application dates for orange lead and lead monoxide than initially proposed by ECHA. It was clarified that the reasons for that consideration were the

challenges to industry together with the claimed complexity of the supply chains for the main uses in the scope of authorisation. An observer from an NGO expressed hesitation for any prolongation of the latest application dates (LADs). An industry observer referred to a previous contribution on how LADs could be set in an objective way recognizing the complexity and workload to establish the AfAs. The observer also drew attention to the potential overlap of LADs with those of other substances already on the authorisation list where big volume of applications for authorisation are expected, resubmissions of expired early AfAs, and where different LADs may result to an unmanageable process. He also mentioned possibility to differentiate LADs by use in order to capture substances for a certain use in one go. In responding to the last intervention SECR explained that at the recommendation step of the authorisation process there is not enough information available for a consistent treatment of use-based requests for LADs.

As regards possible exemptions SECR provided MSC with an overview at a general level and also its analysis as regards the situation for the lead substances specifically. While it was generally recognised that for the lead substances a binding OEL was available which could cover workplace RMM under Art. 58 (2) an exchange of views, and on whether RoHS and ELV and Batteries Directives would provide sufficient basis to give exemptions according to Article 58(2) took place. The Rapporteur presented the consideration from the WG that ROHS and ELV may provide grounds for exemptions to Annex XIV. One MSC member indicated that his MSCA did not support the proposed wording in the draft opinion, and further explained about the differences, for example in the coverage of the life-cycle of the substances concerned in the legislations which makes the risk management provided by ROHS and ELV complementary to the authorisation requirement, not providing sufficient basis for exemption under Article 58(2). In his view this part should be reworded in the draft opinion whereas the annex to the opinion should cover discussion on the possibilities for exemption. This view was supported by some other members, however, for the time being the majority of MSC could support the statement in the current draft opinion. One member considered the soft wording acceptable, although she stated that her Member State remains against inclusion of the the lead compounds in Annex XIV. Another member questioned the usefulness of including lead substances used in battery manufacturing in the recommendation as recycling is very efficiently in place. Several interventions were made also by the stakeholders, among others there was a challenge that the lead substances are transformed into lead metal and lead dioxide, substances that are not currently on the candidate list, when used for the production of batteries, and that this lead is in a fully enclosed product - i.e. the battery - with releases to the environment, if any, in the form of lead ions. In response, SECR explained that assessment of exemptions from authorization should consider the whole life-cycle of the substance and the assessment should also cover the relevant degradation and transformation processes.

As regards use of leads in PVC stabilisers an industry stakeholder observer referred to the parallel process on development of a restriction proposal, and that for example the exposure of man via environment, quoted as low, will be well documented there. A member of MSC responded to this by clarifying that reference to any restriction proposal will be possible provided such is formally received before adoption of the opinion.

A remark was made by one industry observer on MSC's independence and the need to stay within its mandate. He suggested to carefully review MSC's consideration that it may not be appropriate to allow an exemption from the authorisation requirement on the basis of the Water Framework Directive (WFD) (and other legislation) in order not to limit the possibility of the Commission to take actions to achieve the objectives of that legislation.

In closing the rapporteur thanked for the feedback, and invited for further inputs in writing, and concluded that the draft opinion with minor edits will be provided for adoption in September.

Item 11 – Any other business

- Outcome of a Dutch study done into testing of (possible) ED substances

An expert from the Netherlands (NL) delivered a presentation describing a project performed by the University of Utrecht entitled 'health cost that may be associated with endocrine disrupting chemicals'. This is an inventory of health endpoints associated with endocrine disrupting chemicals (EDCs) and potential socio-economic costs. The project results suggest that the potential impact to society could be substantial. Several studies try to quantify the societal costs, but these were quantified for only 16 out of 80 health endpoints. Regulation of EDC in Europe is delayed and the potential costs could be high but the basic information requirements under REACH provide limited information on these health effects and limited or no triggers (ED MoA) for further testing. Based on that NL explained to MSC views on the EOGRTS test design which could be impacting future discussions at MSC.

- Suggestions from members

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

Item 12– Adoption of conclusions and action points

The conclusions and action points of the meeting were adopted at the meeting (see Annex IV).

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ANDRIJEWSKI, Michal (PL)
ATTIAS, Leonello (IT)
BORG, Ingrid (MT)
COCKSHOTT, Amanda (UK)
CONWAY, Louise (IE)
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
DIMCHEVA, Tsvetanka (BG)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FRANZ, Michel (FR)
GYMNAOU, Panagiotis (CY)
HERMES, Joe (LU)
HUMAR-JURIC, Tatjana (SI)
JANTONE, Anta (LV)
KOUTSODIMOU, Aglaia (EL)
KREKOVIĆ, Dubravka Marija (HR)
KULHANKOVA, Pavlína(CZ)
LONDESBOROUGH, Susan (FI)
LOVRIC, Zdravko (HR)
LUNDBERGH, Ivar (SE)
MARTÍN, Esther (ES)
MIHALCEA UDREA, Mariana (RO)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
WIJMENGA, Jan (NL)
Representatives of the Commission
SCHUTTE, Katrin (DG ENV)
Observers
ANNYS, Erwin (Cefic)
BINKS, Steve (Int. Lead Association)
FAβBENDER, Christopher (PISC)
HYNES, Jarlath (HIS)
HÖK, Frida (ChemSec)
JANOSI, Amaya (Cefic)
KERÄNEN, Hannu (CONCAWE)
PALERMO, Christine (Cefic)
POSSER, Christopher (Cefic)
TILLIEUX, Geoffroy (EuPC)
VAN VLIET, Lisette (HEAL)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
ANDROULAKIS, Ioannis
BERCARU, Ofelia
BICHLMAIER, Ingo
BROERE, William
CARLON, Claudio
CARTLIDGE, George
CLENAGHAN, Conor
CONSTANTINI, Camelia
DELOFF-BIALEK, Anna
DE WOLF, Watze
DEYDIER, Laurence
DILHAC, Benoit
DREVE, Simina
FALCK, Ghita
HAUTAMÄKI, Anne
HERBATSCHEK, Nicolas
HOFFSTADT, Laurence
HUUSKONEN, Hannele
JOHANSSON, Matti
JUTILA, Arimatti
KARHU, Elina
KOJO, Anneli
KORJUS, Pia
LEPPER, Peter
LOUEKARI, Kimmo
MÜLLER, Birgit
NAUR, Liina
NYMAN, Anna-Maija
PELLIZZATO, Francesca
PHILLIPS, Andrew
SIMON, Rupert
STILGENBAUER, Eric
REUTER, Ulrike
RODRÍGUEZ-IGLESIAS, Pilar
RODRÍGUEZ-RUÍZ, Amaya
RYAN, Paul
RÖNTY, Kaisu
SCHOENING, Gabriele
STILGENBAUER, Eric
SUMREIN, Abdel
VAHTERISTO, Liisa
VALENTINI, Marco
VALKOVICOVA, Eva
VASILEVA, Katya
VOM BROCKE, Jochen

Proxies

- ATTIAS, Leonello (IT) also acting as proxy of BORG, Ingrid (MT) during 6-9 June
- COCKSHOTT, Amanda (UK) also acting as proxy of DEIM Szilvia (HU) on 14-15 June
- COCKSHOTT, Amanda (UK) also acting as proxy of COSGRAVE, Majella (IE) on 15 June
- CONWAY, Louise (IE) also acting as proxy of DEIM, Szilvia (HU) on 6 June and afternoon of 9 June
- FINDENEGG, Helene (DE) also acting as proxy of MARTÍN, Esther (ES) on 14-15 June

- HUMAR-JURIC, Tatjana (SI) also acting as proxy of ALMEIDA, Inês (PT) on 15 June
- KOUTSODIMOU, Aglaia (EL) also acting as proxy of PALEOMILITOU, Maria (CY) on 14-15 June
- LUNDBERGH, Ivar (SE) also acting as proxy of VANDERSTEEN, Kelly (BE) on 14-15 June
- STESSEL, Helmut (AT) also acting as proxy of WAGENER, Alex (LU) on 14-15 June
- TYLE, Henrik (DK) also acting as proxy of DUNAUSKIENE, Lina (LT) in the afternoon of 7 June
- VANDERSTEEN, Kelly (BE) also acting as proxy of WIJMENGA, Jan (NL) on 9 June

Experts and advisers to MSC members
BARTHELEMY-BERNERON, Johanna (FR) (expert to FRANZ, Michel)
BOUWMAN, Tialda (NL) (adviser to WIJMENGA, Jan)
COPOIU, Oana (RO) (expert to MIHALCEA-UDREA, Mariana)
DE KNECHT, Joop (NL) (expert to WIJMENGA, Jan)
GARCÍA, Patricia (ES) (expert to MARTÍN, Esther)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
GRINCEVICIUTE, Otilija (LT) (expert to DUNAUSKIENE, Lina)
HERZBERG, Frank (DE) (adviser to FINDENEGG, Helene)
HOLMER, Marie Louise (DK) (adviser to TYLE, Henrik)
INDANS, Ian (UK) (expert to COCKSHOTT, Amanda)
JONGENEEL, Rob (NL) (adviser to WIJMENGA, Jan)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LØFSTEDT, Magnus (DK) (expert to TYLE, Henrik)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBERGH, Ivar)
MENDONÇA, Elsa (PT) (expert to ALMEIDA, Inês)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
PIBERGER, Ann Liza (DE) (expert to FINDENEGG, Helene)
REILER, Emilie Marie (DK) (expert to TYLE, Henrik)
RISSANEN, Eeva (FI) (adviser to LONDESBOROUGH, Susan)
ROSENTHAL, Esther (DE) (expert to FINDENEGG, Helene)
TERENDIJ, Carline (FR) (adviser to FRANZ, Michel)
UZOMECKAS, Zilvinas (LT) (expert to DUNAUSKIENE, Lina)
ZELJEZIC, Davor (HR) (expert to KREKOVIĆ, Dubravka Marija)

MSCA Experts for SEV cases
DOYLE, Ian (UK)

MSCA Experts for SVHC cases
ARNING, Jürgen (DE)
WARHOLM, Margareta (SE)

By WEBEX-phone connection:
During the whole meeting: Cécile MICHEL (FR) and Agnieszka DOBRAK-VAN BRELO (BE)
During 6-9 June: Katarzyna MALKIEWICZ (SE)
During 14-15 June: Kelly VANDERSTEEN (BE) and Esther MARTÍN (ES)
During agenda item 7 for CCH-048/2016: Romana HORNEK-GAUSTERER (AT) and Simone MÜHLEGGER (AT)
During agenda item 7 for TPE-045/2016: Ian DOYLE (UK)
During item 8: Els BOEL (BE) and Franziska KAßNER (DE)
During agenda item 11 on Outcome of a Dutch study done into testing of (possible) ED substances: Betty HAKKERT (NL) and Julia VERHOEVEN (NL)
From DG GROW: Enrique GARCÍA JOHN (during items 6,8,9,10), Valentina BERTATO (during items 8, 9), Jacek ROZWADOWSKI (during items 8,9, 10), Georg STRECK (during items 6, 8-9) and Maila PUOLAMAA (during items 6,9-11)

Case owners:

Representatives of the Registrants were attending under the agenda item 6b for SEV-UK-038/2014, under the agenda item 7b for CCH-034/2016, CCH-035/2016, CCH-043/2016, CCH-048/2016, CCH-056/2016, CCH-059/2016, TPE-039/2016 and TPE-040/2016.

Apologies:
PALEOMILITOU, Maria (CY)
PISTOLESE, Pietro (IT)
WAGENER, Alex (LU)

III. Final Agenda

ECHA/MSC-48/2016/A48

Agenda
48th meeting of the Member State Committee

6-9 June and 14-15 June 2016
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

6 June: starts at 9 am
9 June: breaks at 4 pm
and
14 June: resumes at 9 am
15 June: ends at 4 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/048/2016
For adoption

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

Item 4 – Administrative issues

For information

Item 5 – Minutes of the MSC-47

- Draft minutes of MSC-47

MSC/M/47/2016
For adoption

Item 6 – Substance evaluation

Tentative timing: 6-8 June
Closed session for 6c, partly closed for 6d

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

ECHA/MSC-48/2016/061
For information

b. Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA's/ECHA reactions *(Session 1, tentatively open session)*:

ECHA/MSC-48/2016/058

For discussion followed by agreement seeking under 6c:

MSC code	Substance name	EC number / Document
SEV-UK-038/2014	Phenol, styrenated (1); Reaction mass of 2,4,6-tris(1-phenyl-ethyl)phenol and Bis(1-phenylethyl) phenol (2)	262-975-0 (1); 915-333-5 (2)

ECHA/MSC-48/2016/056-057
For discussion

c. Seeking agreement on draft decisions when amendments were proposed by MS-CA's/ECHA *(Session 2, closed)*

Case as listed above under **6b** and a case returned from written procedure for agreement seeking in the meeting[1]:

SEV-FR-022/2014 Methyl 4-hydroxybenzoate (EC No. 202-785-7)

For agreement

d. General topics

Appeals update[2]

For information

Item 7 – Dossier evaluation

Tentative timing: 7-9 and 14-15 June
Closed session for 7c, partly closed for 7d

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

ECHA/MSC-48/2016/059
For information

b. Introduction to and preliminary discussion on draft decisions on compliance checks and testing proposals when amendments were proposed by MS-CA's *(Session 1, tentatively open session)*

ECHA/MSC-48/2016/060

For discussion followed by agreement seeking under 7c:
Compliance checks

MSC code	Substance name	EC No./ Document
CCH-034/2016	2-dimethylaminoethanol	203-542-8 ECHA/MSC-48/2016/032-033
CCH-035/2016	2-ethylhexyl acrylate	203-080-7 ECHA/MSC-48/2016/034-035
CCH-042/2016	Alcohols, C6-24 and C6-24-unsatd.,	310-079-6

[1] Documents are available in MSC S-CIRCABC in the substance specific folder under 06. Substance evaluation
[2] A combination of Appeal updates for Substance and Dossier Evaluation may be introduced, partly in closed session, if appropriate.

	distn.residues	ECHA/MSC-48/2016/036-037
CCH-043/2016	Alcohols, C9-11-branched	271-360-6 ECHA/MSC-48/2016/038-039
CCH-048/2016	Dioctyltin oxide	212-791-1 ECHA/MSC-48/2016/040-041
CCH-053/2016	Methyl 2-naphthyl ether	202-213-6 / ECHA/MSC-48/2016/042-043
CCH-055/2016	Propyl acetate	203-686-1 / ECHA/MSC-48/2016/044-045
CCH-056/2016	Reaction Mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and [...]	915-730-3 / ECHA/MSC-48/2016/046-047
CCH-059/2016	Tert-butyl 2-ethylperoxyhexanoate	221-110-7 ECHA/MSC-48/2016/048-049
CCH-060/2016	Tetrahydrofurfuryl alcohol	202-625-6 / ECHA/MSC-48/2016/050-051

Testing proposal examinations

MSC code	Substance name	EC No. / Document
TPE-039/2016	Trometamol	201-064-4 / ECHA/MSC-48/2016/052-053
TPE-040/2016	2-amino-2-ethylpropanediol	204-101-2 / ECHA/MSC-48/2016/054-055

For discussion

c. Seeking agreement on draft decisions on compliance checks and testing proposal examinations when amendments were proposed by MS-CA's *(Session 2, closed)*

Cases as listed above under **7b** and cases returned from written procedure for agreement seeking in the meeting[3]:

CCH-029/2016	1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	EC No. 204-886-1
CCH-039/2016	6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol	EC No. 201-618-5
TPE-045/2016	Quaternary ammonium compounds, bis (hydrogenated tallow alkyl)dimethyl, chlorides, reaction products with polyethylene-polyamines and tall-oil fatty acids, humates hydrochlorides	EC No. 272-745-1
CCH-046/2016	Diammonium peroxodisulphate	EC No. 231-786-5
CCH-049/2016	Dipotassium peroxodisulphate	EC No. 231-781-8
CCH-050/2016	Disodium peroxodisulphate	EC No. 231-892-1

For agreement

d. General topics

1) Presentation on targeted evaluation of 90-day data for EOGRTS
2) Appeals update

For information

[3] Documents are available in MSC S-CIRCABC in the substance specific folders under 05. Dossier evaluation

Item 8 – SVHC identification - Seeking agreement on Annex XV proposals for identification of SVHC

Tentative timing: 6-9 June

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

ECHA/MSC-48/2016/062
(room document)
For information

b. Agreement seeking[4]

Substance name	**EC number/ Documents**
1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor, 3-BC)	239-139-9 / ECHA/MSC-48/2016/063-065
(±)-1,7,7-trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1] heptane-2-one (4-methylbenzylidene camphor, 4-MBC)	253-242-6 / ECHA/MSC-48/2016/066-068
Dicyclohexyl phthalate (DCHP)	201-545-9 / ECHA/MSC-48/2016/069-071
Benzo[def]chrysene (Benzo[a]pyrene, BaP)[5]	200-028-5

For agreement

Item 9 – ECHA's draft 7th recommendation of priority substances to be included in Annex XIV

Tentative timing: 14-15 June

Responses of ECHA to the comments received in the public consultation on ECHA's 7th draft recommendation

ECHA/MSC-48/2016/016-031
For information and discussion

Item 10 – Opinion of MSC on ECHA's draft 7th recommendation of priority substances to be included in Annex XIV

Tentative timing: 14-15 June

MSC opinion on ECHA's Draft 7th recommendation of priority substances to be included in Annex XIV

- First draft opinion of MSC on ECHA's 7th draft recommendation

ECHA/MSC-48/2016/072
For discussion

Item 11 – Any other business

- Outcome of a Dutch study done into testing of (possible) ED substances

[4] Agreement seeking of 3-benzylidene camphor and 4-methylbenzylidene camphor is for 6-8 June and DCHP for 7-9 June.
[5] Case to be removed from the agenda if agreed in written procedure before the meeting.

For information

- Suggestions from members

For information

Item 12 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-48

For adoption

Information documents:

Information documents are not allocated a specific agenda time but the documents are available on MSC CIRCABC before the meeting. Based on the listed documents and the meeting agenda, if any MSC member considers that information documents may merit a discussion under any agenda point, they should inform MSC Secretariat

- *Substance evaluation status report (presentation slides)*
- *Dossier evaluation status report (presentation slides)*
- *Information note on activities of other ECHA bodies (ECHA/MSC/I/2016/014)*
- *SVHC report (Annex XV) template update (ECHA/MSC/I/2016/015)*

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-48, 6-9 June and 14-15 June 2016
(*adopted for items 5, 6 and 8 at MSC-48 on 9 June, adopted for the rest of the items on 15 June*)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 5 – Minutes of the MSC-47	
MSC adopted the draft minutes with few changes made in the meeting.	**MSC-S** to upload final version of the minutes on MSC S-CIRCABC by 15 June 2016 and on ECHA website without undue delay.
Item 6 - Substance evaluation **a) Written procedure report on seeking agreement on draft decisions on substance evaluation**	
MSC took note of the written procedure report.	**MSC-S** to upload on MSC S-CIRCABC the final ECHA decisions agreed in written procedure.
b) Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA's/ECHA reactions *(Session 1, open session)* **c) Seeking agreement on draft decisions when amendments were proposed by MS-CA's/ECHA *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions as modified in the meeting: **SEV-UK-038/2014** Phenol, styrenated (1); Reaction mass of 2,4,6-tris(1-phenyl-ethyl)phenol and Bis(1-phenylethyl) phenol (2) (EC No. 262-975-0 (1) and 915-333-5 (2)) **SEV-FR-022/2014** Methyl 4-hydroxybenzoate (EC No. 202-785-7)	**MSC-S** to upload on MSC S-CIRCABC the final ECHA decisions of the agreed cases.
Item 7 – Dossier evaluation **a. Written procedure report on seeking agreement on draft decisions on dossier evaluation**	
MSC took note of the report.	**MSC-S** to upload on MSC S-CIRCABC the final ECHA decisions agreed in written procedure.
Item 7 – Dossier evaluation **b. Introduction to and preliminary discussion on draft decisions on testing proposals and compliance checks after MS-CA reactions *(Session 1, open session)*** **c. Seeking agreement on draft decisions on a testing proposal examination and a compliance check when amendments were proposed by MS-CA's *(Session 2, closed)***	
MSC reached unanimous agreement on the following ECHA draft decisions (as modified in the meeting, where	**MSC-S** to upload on MSC S-CIRCABC the final ECHA decisions of the

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
appropriate): **Compliance checks:** CCH-029/2016 1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt (EC No. 204-886-1) CCH-034/2016 2-dimethylaminoethanol (EC No. 203-542-8) CCH-035/2016 2-ethylhexyl acrylate (EC No. 203-080-7) CCH-039/2016 6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol (EC No. 201-618-5) CCH-042/2016 Alcohols, C6-24 and C6-24-unsatd., distn.residues (EC No.310-079-6) CCH-043/2016 Alcohols, C9-11-branched (EC No. 271-360-6) CCH-046/2016 Diammonium peroxodisulphate (EC No. 231-786-5) CCH-048/2016 Dioctyltin oxide (EC No. 212-791-1) CCH-049/2016 Dipotassium peroxodisulphate (EC No. 231-781-8) CCH-050/2016 Disodium peroxodisulphate (EC No. 231-892-1) CCH-053/2016 Methyl 2-naphthyl ether (EC No. 202-213-6) CCH-055/2016 Propyl acetate (EC No. 203-686-1) CCH-056/2016 Reaction Mass of 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one and [...](EC No. 915-730-3) CCH-059/2016 Tert-butyl 2-ethylperoxyhexanoate (EC No.221-110-7) CCH-060/2016 Tetrahydrofurfuryl alcohol (EC No. 202-625-6) **Testing proposal examinations:** TPE-039/2016 Trometamol (EC No. 201-064-4) TPE-040/2016 2-amino-2-ethylpropanediol (EC No. 204-101-2) TPE-045/2016 Quaternary ammonium compounds, bis (hydrogenated tallow alkyl)dimethyl, chlorides, reaction products with polyethylene- polyamines and tall-oil fatty acids, humates hydrochlorides (EC No. 272-745-1)	agreed cases.
Item 7 – Dossier evaluation **d. General topics** 1) Presentation on targeted evaluation of 90-day data for EOGRTS	
MSC took note of the approach for a targeted evaluation, where the results from sub-chronic toxicity (90-day) study would be submitted in 12 months and evaluated with any new information during 3 months as they may result in changes in the design of the EOGRT study.	
Item 8 – SVHC identification - **Seeking agreement on Annex XV proposals for identification of SVHC** **a. Written procedure report on seeking agreement on identification of SVHCs**	
MSC took note of the report.	**MSC-S** to upload on MSC S-CIRCABC

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	the final MSC documents on Benzo[def]chrysene (Benzo[a]pyrene, BaP) (EC No.200-028-5) that was identified as an SVHC in written procedure. **SECR** to add the newly identified SVHC to the Candidate List within its next update.
Item 8 – SVHC identification - Seeking agreement on Annex XV proposals for identification of SVHC **b. Agreement seeking**	
• 1,7,7-trimethyl-3-phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor, 3-BC) (EC No. 239-139-9) MSC **did not reach** unanimous agreement on the Annex XV proposal to identify 3-BC as an endocrine disruptor for the **environment** giving rise to an equivalent level of concern as PBT/vPvB and CMR substances under Article 57(f). The majority of MSC supported the proposed SVHC identification for 3-BC, while two members held a different view. • Dicyclohexyl phthalate (DCHP) (EC No.201-545-9) MSC supported by concensus the part of the SVHC proposal concerning the DCHP identification as an SVHC under Article 57 (c). While members unanimously acknowledged that there is scientific evidence on the endocrine activity of DCHP and on the link between this activity and the adverse effects to human health, MSC did not reach unanimous agreement on whether this constitutes an equivalent level of concern to carcinogenic, mutagenic and toxic to reproduction substances under Article 57(f) as giving rise to an equivalent level of concern due to endocrine disrupting properties in relation to human health. A majority of the members supported this substance's SVHC identification under Article 57 (c) and (f). A minority of five members did not support this proposal for SVHC identification because they held a different view regarding the part for SVHC identification under 57(f). MSC took note on the dossier submitter's decision to withdraw the part of its SVHC proposal concerning the identification of DCHP under Article 57 (f) as giving rise to an equivalent level of concern due to endocrine disrupting properties in relation to the environment in order to further elaborate on the justification provided in the documentation. MSC took note on the dossier submitter's decision to withdraw the Annex XV dossier for SVHC identification of • (±)-1,7,7-trimethyl-3-[(4 methylphenyl)methylene]bicyclo[2.2.1] heptane-2-	**MSC members who voted against** the SVHC identification of DCHP and 3-BC to provide their minority views in writing to the MSC-S in draft by 9 June and its final version by 14 June 2016. **MSC-S** to finalise the MSC opinion documentation on DCHP and 3-BC without undue delay. **MSC-S** to refer the MSC opinions on DCHP and 3-BC, the minority positions and the other supporting documentation to the Commission for further decision making by 30 June 2016. **MSC-S** to upload MSC opinions on DCHP and 3-BC, the minority positions and the other supporting documentation on MSC S-CIRCABC and on the ECHA website by 30 June 2016.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
one (4-methylbenzylidene camphor, 4-MBC) (EC No. 253-242-6), that had been proposed under Article 57 (f) as giving rise to an equivalent level of concern due to endocrine disrupting properties in relation to the environment in order to further elaborate on the justification provided in the documentation.	
Item 9 – ECHA's draft 7th recommendation of priority substances to be included in Annex XIV Responses of ECHA to the comments received in the public consultation on ECHA's 7th draft recommendation	
MSC took note of the draft responses to the comments received during the public consultation.	**SECR** to consider the comments received at MSC-48.
Item 10 – Opinion of MSC on ECHA's draft 7th recommendation of priority substances to be included in Annex XIV MSC opinion on ECHA's Draft 7th recommendation of priority substances to be included in Annex XIV • First draft opinion of MSC on ECHA's 7th draft recommendation	
	MSC to provide any written comments and feedback on the draft opinion to the Rapporteur via MSC functional mailbox by 24 June 2016. **MSC-S** to compile the comments received to be provided to the Rapporteur and WG members by 27 June for further consideration when revising the draft opinion, together with the feedback received at MSC.
Item 12– Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-48 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC S-CIRCABC by 16 June 2016.

V. Substance evaluation cases addressed for MSC agreement seeking in written procedure (WP):

Draft decisions unanimously agreed by MSC in WP

MSC ID number	Substance name used in draft decision	EC number
SEV-FR-040/2014	Reaction product of ammonium molybdate and C12-C24-diethoxylated alkylamine (1:5-1:3)	412-780-3
SEV-IT-027/2014	Ethyl methacrylate	202-597-5
SEV-IT-028/2014	Trixylyl phosphate	246-677-8
SEV-NL-030/2014*	Tris(methylphenyl) phosphate	215-548-8
SEV-NL-032/2014	Ditolyl ether	248-948-6
SEV-NO-033/2014	Alkanes, C16–(branched), C20-(branched) and C24-(branched)	700-992-1 (previously 292-461-1)

* Three draft decisions

VI. Dossier evaluation cases addressed for MSC agreement seeking in the written procedure (WP)

MSC unanimously agreed on dossier evaluation draft decisions in the written procedure:

Compliance checks (CCH)

MSC ID number	Substance name used in draft decision	EC or List number
CCH-027/2016	1,1,1-trifluoroethane	206-996-5
CCH-028/2016	1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters	275-809-7
CCH-031/2016	2,6-di-tert-butyl-p-cresol	204-881-4
CCH-032/2016	2,6-di-tert-butyl-p-cresol	204-881-4
CCH-033/2016	2-Butyne-1,4-diol	203-788-6
CCH-037/2016	2-methylundecanal	203-765-0
CCH-038/2016	3-(5,5,6-trimethylbicyclo[2.2.1]hept-2-yl)cyclohexan-1-ol	222-294-1
CCH-045/2016	Cis-2-tert-butylcyclohexyl acetate	243-718-1
CCH-051/2016	Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl methacrylate	231-403-1
CCH-057/2016	Reaction product of propylidynetrimethanol, propylene oxide and ammonia	500-105-6

Testing proposal examinations

MSC ID number	Substance name used in draft decision	EC or List number
TPE-029/2016	bis(4-tert-butylcyclohexyl) peroxydicarbonate	239-557-1
TPE-037/2016	4,4'-Isopropylidenedicyclohexanol, oligomeric reaction products with 1-chloro-2,3-epoxypropane	500-070-7