MSC/M/55/2017
Adopted at MSC-56

Minutes

of the 55th Meeting of the Member State Committee (MSC-55)
12-14 September 2017

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 55th meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Section II of the minutes).

The Chairman informed MSC that they may expect to receive a questionnaire from ECHA which is intended to help in the development of ECHA's IT-tools that are also meant for use by MSCAs/members. The questionnaire which will contain general questions and also some questions related to four work packages, will be sent via email to MSC members, alternates and some advisers.

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 as Section III).

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-55.

Item 4 - Administrative issues

SECR informed MSC that from July onwards Committee plenary remote participation must be organised in Secure WebEx as confidential or restricted information needs to be shared. The decision does not change the way SECR is allowing participants to join remotely, however, in order to allow external participants to connect, SECR has to have their contact information 5 days in advance of the Committee meeting. SECR also reminded MSC of the technical requirements needed for the connection. MSC members were asked to consider early on if an expert from their side should follow any further plenary meeting remotely, and to ensure such registrations are done well in advance, and that SECR is informed accordingly.

SECR informed MSC on progress being made in streamlining administrative procedures in all Committees and expert groups of ECHA. One of the outcomes for MSC is a small change to the declaration templates that are attached to the Rules of Procedure and which is now for adoption at the next Management Board meeting. In practice this means that the current templates will be replaced by a web link with an aim to make the administrative procedures easier for all actors involved.

The Chairman informed MSC of a new ECHA study on registration dossier updates which among other recommendations highlights the importance for the registrants to update their dossiers without undue delay whenever there is a change or new information available. According to the report, one of the recommendations is to include action for trade associations to facilitate increased awareness of benefits of updating and risks of not updating dossiers. The Chairman also provided observations related to MSC-55 meeting underlining several dossier evaluation cases which clearly showcase the importance of registration dossier updates for registrants, and for an efficient processing of cases during the MSC decision making.

The following scenarios and associated risks for registrants were mentioned by the Chairman:

Failing the Technical Completeness Check (TCC) in the Proposal for Amendment (PfA) commenting phase	MSC does not have access to information which could allow them to drop the information request(s)
Passing the TCC 'last minute'	MSC does not have time left to check the information and decide on compliance

REACH-IT contact address outdated (or no back-up in case of absence)	The registrant will not receive the invitation for participation and informal interaction with MSC
Historical uses in the dossier suggestive of significant consumer or professional exposure	If the substance is also classified as a mutagen cat. 2 the EOGRTS design will include the request for extension of cohort 1B to produce the F2 generation
Not bringing forward relevant arguments based on information that is captured in the registration dossier	ECHA or MSC members do not have more in-depth expertise on dossier details than the registrant. Regulators cannot be expected to work as industry consultants and develop argumentations or substance specific adaptations for the registrant
Late inclusion of relevant literature	MSC members may not have time to (organise consultation with their experts and) take critical studies into account in test designs
Submitting (testing) strategies in order to generate data for possible adaptations of higher tier information requirements	MSC does not recognize this as available information. Information that is still to be generated in the (near) future cannot lead to MSC removing the information requirement

The Chairman presented an estimation on the potential length of the next meeting which is expected to require approximately 3 plenary days. The Chairman also presented and early stage estimation for the length of the MSC-57 meeting in December.

Item 5 – Minutes of the MSC-54 meeting

SECR informed the committee that the minutes of MSC-54 were adopted by MSC in written procedure and published in MSC S-CIRCABC and on ECHA's website.

Item 6.1 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2018-2020)

a) Draft terms of Reference and possible appointment of the Rapporteur and Co-Rapporteur

MSC agreed on the tasks of the rapporteur and the co-rapporteur in drafting the MSC opinion on the draft update of the CoRAP for 2018-2020. The Committee also appointed two of its members as rapporteur and co-rapporteur for this opinion preparation.

b) Discussion and possible establishment of a MSC Working Group to support the Rapporteur

MSC agreed on the mandate of a working group to support the MSC rapporteur in drafting the MSC opinion on the draft update of the CoRAP for 2018-2020. Further, MSC appointed three volunteering MSC members, two MSC alternates and two member's experts as the working group members to support the rapporteurs in the opinion development.

Item 6.2 – Substance evaluation - General topics

- Status report on on-going substance evaluation work

MSC took note of the status report.

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 sixteen dossier evaluation cases comprising fifteen draft decisions and one

draft agreement document (see Section V for more detailed identification of the cases). WP was launched on 17 August 2016. By the closing date 28 August 2016, MSC reached unanimous agreement on fourteen DDs and one agreement document. In line with his DoI one member declared a potential conflict of interests and did not vote on the respective case. The Chairman considered this as a sufficient mitigating measure. One member abstained from voting on three cases. For one DD, MSC Chairman terminated the WP on the basis of Article 20(6) of the MSC Rules of Procedure.

As for the agreement document on one compliance check case, SECR explained that the Registrant had submitted updates of the dossier. Based on its assessment SECR considered that consequently all information requests of the DD had been fulfilled. Therefore, after the MSC agreement in written procedure, SECR would not need to adopt a compliance check decision and it would inform the Registrant accordingly.

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 session)*

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

CCH-044/2017 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl) oxy]-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa- 3,5-dithia-4-stannatetradecanoate (EC No. 260-828-5)
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 two proposals for amendment (PfA) to ECHA's DD had been submitted. The first PfA on *Extended one-generation reproductive toxicity study in rats, oral route (Annex IX, Section 8.7.3.; test method: EU B.56./OECD TG 443)* requested the extension of cohort 1B to include the F2 generation since the dossier mentions the following use: "Article with intended or foreseeable mouth contact, e.g. toys; Articles with foreseeable impact on indoor exposure due to large indoor surface, e.g. flooring". It can be considered that significant exposure to consumer and/or professionals may occur. Additionally the substance is classified as Mutagen Category 2, thus the criteria for extension of cohort 1B are met.

The second PfA suggests to include a new request for a *Long-term toxicity testing on fish (FELS; OECD TG 210)* because two hydrolysis products of the substance are classified as toxic substances and one other further metabolised product is classified as Repr. 2, H316d (suspected of damaging the unborn child).

Based on the PfAs SECR had modified the DD in advance of the meeting concluding that cohort 1B must be extended to include mating of the animals and production of the F2 generation.

SECR explained that the DD was not modified prior to the meeting to include the *FELS (OECD TG 210)* test because there is evidence of rapid hydrolysis (full hydrolysis within 10 mins) from a preliminary water solubility study, supported further by the available toxicokinetics data at low pH. SECR explained also that the possible concern due to specific mode of action cannot be supported since the short term toxicity test on fish is valid, and that the hydrolysis products of concern are soluble so that they would be expected to be present in the test media. Additionally SECR explained that in the dossier there is also data available from a long term test on Daphnia.

The MSC member from the MSCA submitting the PfA accepted SECR justification for not including in the DD the new request for FELS (OECD TG 210).

The Registrant had provided written comments on the DD (not reflected here) and on the PfAs. The Registrant's representative reiterated that he considered that a stepwise

assessment before deciding on further reproductive toxicity testing more appropriate, given that the additional mutagenicity testing currently requested may remove the triggers for inclusion of the extension of cohort 1B to produce the F2 generation. Registrant's representative expressed the view that getting reliable results for classification of metabolites can be achieved through a sequential strategy containing first mutagenicity testing and secondly a follow-up testing, which will not delay the timelines requested in the DD.

Upon a request for clarification on the leaching rates in saliva from plastic articles containing the substance, due to its use in toys as reported by one of the Registrants, the case-owner representative clarified there is an ongoing discussion between registrants to discount this use in toys as a historical one.

Diverging views were expressed by MSC members for a sequential assessment, and MSC discussed extensively on the possibilities for an adaptation strategy, whether the trigger for F2 requires a harmonised classification and labelling, on the data needed for the classification of the metabolites, information for future testing design and deadline requested. It was pointed out that in the decision making process, in order to have an appropriate discussion in MSC meetings and to reach an agreement in an efficient way, firstly is the responsibility of the Registrant(s) to submit enough and reliable data and information on the uses in an up-to-date dossier.

SECR clarified that the deadline of 42 months cannot be reduced in absence of a PfA requesting this, and that the studies requested allows also sequential testing and possible testing proposal inside the specified deadline.

Session 2 (closed)

The MSC member submitting the PfA on EOGRTS design emphasized that since the information on consumer exposure is present in the dossier, in their view there is a need to amend the draft decision and to accept their PfA.

SECR summarised that there is a lack of information and inconsistency on the uses indicated by the three Registrants in the joint dossier and on the controversial information provided on the kind of uses in articles and the lifecycle of articles.

During the discussion several MSC members raised questions on the migration of the substance from the matrix, shared their views on removing the concern triggers, and agreed that a potential update of the dossier removing the historical uses could be appropriate in removing the significant exposure trigger for the F2 generation. Different views were expressed by other MSC members that even if uses are deleted from the dossier the source of exposure from some uses (like flooring) will remain for long time.

SECR provided detailed data that were included in the registration dossier on the maximum concentration of substance released from small plastic articles, information on results from modelling estimated exposures, levels of uncertainty from leaching in water versus saliva, and other parameters used for the assessment of leaching, and concluded that after comparing all data with DNELs there is no significant exposure. Furthermore, SECR informed the participants on the results from an internal ECHA project in which the substance migration from a plastic doll was evaluated, concluding that exposure modelling showed the risk characterisation ratio for oral exposure far below 1. SECR clarified that in absence of established migration limits they used the risk characterisation ratio as the measure for assessing whether or not significant exposure may occur. On the basis of the available data in the dossier and the assessment presented, SECR then proposed to reject the PfA to include the extension of cohort 1B to produce the F2 generation.

At one MSC member's expert question if in the dossier there are information on professional uses. SECR responded that in the lead dossier no professional uses are indicated and stressed that in the legal text the extension of cohort 1B to include the F2 generation is required only if the substance has significant exposure of consumers or professionals, taking into account consumer exposure from articles.

MSC agreed unanimously to the DD as submitted to MSCA consultation (for submitting PfAs) amended only in Appendix 1, regarding the reference to ECHA Guidance on

information requirements and chemical safety assessment, and not including the new information request for FELS (OECD TG 210) test, or extending cohort 1B to produce the F2 generation with change of the premating exposure duration in the information request for EOGRTS. One MSC member abstained from voting.

CCH-054/2017 Sodium hydroxymethanesulphinate (EC No. 205-739-4)

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 two proposals for amendment (PfA) to ECHA's DD have been submitted. The first PfA suggested to include a request for an assessment of potential germ cell mutagenicity. The second PfA proposed to make the testing for carcinogenicity, pre-natal development toxicity (PNDT) and extended one-generation reproductive toxicity (EOGRT) conditional on the germ cell mutagenicity assessment. If the registered substance is found to be a germ cell mutagen category 1B the requested studies could be waived.

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

The Registrant had provided written comments on the PfAs which were reiterated at the meeting. The Registrant agreed with the PfA to provide an assessment of the potential germ cell mutagenicity. This assessment was submitted in the written comments. The representatives of the Registrant explained that systemic exposure is likely after oral ingestion, however, they considered there is insufficient information to conclude if the germ cells are reached and thus no conclusion about the germ cell mutagenicity potential can be derived. To follow-up on the clastogenic mode of action, they proposed to preferably conduct the mammalian spermatogonial chromosome aberration test (OECD TG 483). They explained that this test is under validation with two big Contract Research Organisations (CROs) which would possibly be ready at the end of 2018. The Registrant further proposed to start with a dose range finding study coupled with a toxicokinetic analysis to see if the substance reaches the gonads.

Regarding the carcinogenicity request, the representatives of the Registrant strongly disagreed with the performance of a carcinogenicity study. The Registrant explained that they updated their registration dossier during the decision making process which in their view removed the exposure trigger for the carcinogenicity study. They mentioned that the revised life-cycle and the updated exposure and risk assessment now clearly demonstrate that the substance has no widespread dispersive use and that there is no evidence of frequent or long-term human exposure.

During the discussion, one MSC member expressed sympathy for the approach proposed by the representatives of the Registrant to perform a toxicokinetic analysis. However, other MSC members expressed the concern that the registration dossier for this substance has major data gaps in reproductive toxicity and addressing these should not be postponed further. The testing strategy from the Registrant came too late in the process also considering that there were many earlier opportunities, before and during the decision making process, when such a strategy could have been submitted and discussed with ECHA.

Session 2 (closed)

Regarding exposure to the registered substance, SECR explained that the updated dossier had no professional uses but PROC 4 was still listed in the dossier. In the view of ECHA this still constituted frequent human exposure, and hence, in combination with the established mutagenicity of the substance, the triggers for the carcinogenicity study are still met.

MSC discussed the possibility to waive the requested test for carcinogenicity, PNDT and EOGRTS on the basis of the substance's (potential for) germ cell mutagenicity. MSC agreed that excluding an information request from a decision is only possible based on

currently available data. The only available data regarding mutagenicity was an *in vitro* gene mutation study, an *in vivo* micronucleus study and a self-classification of Muta. 2, which was not enough to remove the information requirements for carcinogenicity, PNDT and EOGRTS.

Concerning the interpretation of REACH standard information requirement for germ cell mutagenicity in general, one MSC member expressed the view that their interpretation is that REACH allows requesting of the germ cell mutagenicity tests as part of the standard information requirements. SECR explained their view that for this particular case, if the testing strategy of the Registrant, proposed only now, was to be pursued, a number of uncertainties still remained: 1) the finding of a test laboratory to conduct such studies, 2) the timing by when the validation of OECD TG 483 could be achieved, 3) the timeline by when the data requested in the decision would be submitted, and 4) the test results could still turn out to be negative, and thus neither a harmonised classification nor a self-classification as germ cell mutagen would be proposed. Furthermore, for a substance to be classified by RAC (Risk Assessment Committee) as a germ cell mutagen it seems that the recently updated CLP guidance document suggests that it is not sufficient to show that the substance reaches the germ cells but that it interacts with them. Finally, MSC considered that this substance is listed in the public CoRAP for evaluation by the Netherlands in the coming years, so any remaining concern can be covered by this substance evaluation at a later stage.

Hence based on all these considerations, MSC concluded to keep the requests for the three tests. It agreed not to include the testing strategy as proposed by the Registrant as an information request.

MSC agreed unanimously to the DD as amended at the meeting. The UK MSC member abstained from voting on this case.

CCH-057/2017 Esterification products of 1,3-dioxo-2- benzofuran-5-carboxylic acid with nonan-1-ol (List No. 941-303-6)

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. The toxicologist representing the Registrant cancelled, for a justifiable reason, at the last-minute his participation for the meeting, so MSC was made aware of the intended interventions by the other representative of the Registrant without an opportunity to ask further clarifying questions.

The Registrant used a grouping and read across approach to waive most of the CCH endpoints for the registered UVCB substance (TM9). The analogue substances used and mentioned below are - substances TM8-10 (1,2,4-Benzenetricarboxylic acid, mixed decyl and octyl triesters / 1,2,4-Benzenetricarboxylic acid, decyl octyl ester; EC numbers 290-754-9 / 268-007-3), TM8 (Trioctyl benzene-1,2,4-tricarboxylate; EC number 201-877-4) and TOTM (Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate; EC number 222-020-0).

SECR explained that four PfAs to ECHA's DD had been submitted. The first PfA on the grouping and read across approach used by the Registrant considered this approach plausible, and suggested to request the Registrant to provide additional evidence with the registered substance, such as toxicokinetic information and/or modelling, to help strengthening the justification and to address the shortcomings of not having sub-chronic studies with analogues.

The other three PfAs proposed changes to the EOGRT study design. One PfA proposed to remove the request for extension of cohort 1B to produce the F2 generation, the second PfA proposed to include cohorts 2A/2B (DNT) and cohort 3 (DIT) whilst the third PfA proposed to include cohort 3 (DIT) only to the study design.

SECR had not modified the DD in advance of the meeting based on the PfAs. However, it had clarified the mode of administration for the 90-day study and EOGRTS by specifying gavage using corn oil, since that has an impact on the bioavailability of the registered substance.

The Registrant had provided written comments on the PfAs which were reiterated at the meeting. The representative of the Registrant expressed her disagreement with the conclusion of ECHA that the read across does not hold. She explained that they intend to use the result of a 90-day study and a PNDT study on a first species being conducted by gavage using corn oil for a different substance - TM8 (ongoing study following another CCH by ECHA). These two studies would be available in November 2017. According to the representative of the Registrant, TM8 is a substance very similar to the main constituent of the registered UVCB substance TM9. The representative of the Registrant requested for a 3-month extension of the deadline in the DD to assess both the TM8 results and their application in the data gap filling for TM9.

MSC members posed some clarifying questions to the representative of the Registrant on the proposed grouping and read across approach. She explained that they are suggesting this approach since TM8 constitutes 63% of the registered UVCB substance TM9. When asked whether the Registrant is planning to perform any toxicological studies on the registered substance to make the bridge towards the read across substance the representative of the Registrant gave the impression that this was not their intention since they planned to use *in silico* modelling like QSARs to obtain the missing information. However, no further information was provided on the applicability domain of the *in silico* models, or the constituents of the complex UVCB substance which the Registrant intends to model.

The discussion on the PfA to drop the request for extension of cohort 1B to mate and produce the F2 generation from the EOGRTS design did not focus on whether there are uses leading to significant exposure of consumer or professionals, but focused on the indications that the internal dose of the registered substance will reach a steady state only after an extended exposure, and the indications of one or more relevant modes of action (MoA) related to endocrine disruption (ED).

MSC discussed the registered substance's bioavailability in light of the reported high log Kow of 13. The representative of the Registrant indicated that they plan to investigate absorption using an *in vitro* model such as the Caco-2 permeability assay. SECR referred to ECHA IR&CSA Guidance[1], which states that a log Kow above 4.5 would trigger the F2 generation.

Regarding indications for an ED MoA, the representative of the Registrant argued that there was no evidence of ED effects. This was supported by an MSC member based on their interpretation of dietary 28-day studies available for the proposed read-across substances. However, it was noted that the 28-day study and 90-day study are not designed to investigate the ED effects, and a relevant OECD guidance indicates that weaker acting oestrogen and androgens might not show such ED effects in those studies. Hence, a consistent pattern on ED effects observed in those studies cannot be expected. Additionally, the representative of the Registrant stated that the substance TM8 does not have a similar MoA as the phthalates, whereas, SECR highlighted that the analogue substance TOTM, used by the Registrant in the read-across approach, has indications of ED MoA.

Regarding the putative immunological effects, the representative of the Registrant provided a summary of the data on neutrophils from the analogue substances TM8, TOTM and TM8-10 following 28-day and 90-day exposure.

Session 2 (closed)

MSC considered the request of the representative of the Registrant to extend the deadline of the DD by three months. For this purpose, SECR checked the composition of the registered substance once more and found that C8 (in relation to TM8) accounts for significantly less than the 63% of the TM9 registered substance stated by the Registrant. Secondly it was confirmed that, due to the lack of data on the 28-day repeat dose toxicity and the reproductive toxicity screening study for the registered substance, one cannot

[1] ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.6 - version 6.0, July 2017

bridge the registered substance with the read across substance TM8, unless new data is produced on the registered substance. Based on these considerations, MSC concluded that the proposed read-across will not lead to a supportable outcome, hence the deadline was not extended.

During the discussion whether to include the DNT and DIT cohorts in the study design for EOGRTS it was acknowledged that the absence of results from the 90-day study on the registered substance and of bridging studies from the analogue substances used by the Registrant, prevent from deciding in a definitive manner on the most appropriate design.. The observed effects on neutrophils alone might be too weak to trigger the DIT cohort. Hence MSC unanimously agreed not to request for the DNT and DIT cohorts at this point in time, and await further the 90-day study results on the registered substance to assess whether the cohorts would be triggered taking the results of the 90 study and other available and relevant information into account.

With regards to the discussion to delete the extension of cohort 1B to produce the F2 generation since the log Kow is above 4.5 and the results from TOTM show ED effects, MSC concluded to keep the original EOGRTS design. However they requested SECR to be clear in the decision about the importance of the results of the 90-day study on the registered substance and about the possible bioaccumulation of the substance, since such information can lead to a justified revision of the EOGRTS design.

The DD specified separate submission deadlines so that sequential testing and submissions are possible.

MSC agreed unanimously to the DD as amended at the meeting. Five MSC members (DK, FR, NL, SE, UK) abstained from voting.

CCH-058/2017 Pin-2(3)-ene (EC No. 201-291-9)
Session 1 (open)

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

SECR introduced the case and the two PfAs submitted to ECHA's DD. The first PfA on Pre-natal developmental toxicity (PNDT) study in a second species requested replacing –the generally preferred species rabbit with a second species that is appropriate and duly justified considering the human relevance, and to remove the proposal to perform a range finding study in rabbits. The PfA considered that rabbits may not be an appropriate species because of the antimicrobial activity of the substance.

Based on the PfAs SECR had modified the DD in advance of the meeting for the PNDT request by removing rabbit as the preferred species and revising the request accordingly.

The Registrant had provided written comments on the DD (not reflected here) and on the PfAs indicating that they prefer to perform PNDT on rabbits.

The MSC member from MSCA submitting the PfA on PNDT (requesting removing rabbits as preferred species) supported how SECR addressed their PfA and the amendment of the DD regarding this request.

The second PfA proposed to include the DIT cohort 3 in the design of the extended one-generation reproductive toxicity study (EOGRTS). Arguments for the inclusion were: 1) decreased numbers of sperm per mg cauda and cauda sperm in both mice and rats in the sub-chronic inhalation studies, 2) decreased absolute and relative thymus weight in male mice and female rats in the same studies, and on 3) decreased leukocyte and lymphocyte counts in male mice and male rats in the same studies. SECR explained that the DD was not modified prior to the meeting to include the DIT cohort 3 to the requested EOGRTS considering that the decreased number of sperm in cauda epididymis is an indication of mode(s) of action related to endocrine disruption, however it is not considered as evidence of (a) specific mechanism(s)/mode(s) of action with an association to (developmental) immunotoxicity. SECR stressed that the findings at the highest dose in female rats (reduced thymus weight) and in male mice (reduced thymus weight and decreased leukocyte and lymphocyte counts) are not relevant findings to be used for triggering as

they are considered secondary to the other systemic toxicity effects. Furthermore the reduction in relative thymus weight (mid dose in female rats) is not considered as a relevant trigger as the absolute thymus weight was not reduced. Additionally SECR explained that the reduced leukocyte count with reduced lymphocyte count occurred in male rats only is considered not sufficient to trigger the DIT cohort. SECR concluded that all these findings are secondary to the treatment-associated stress.

The Registrant had provided comments disagreeing with the inclusion of the DIT cohort 3 in the design of the EOGRTS.

MSC member's alternate representing the MSCA submitting the PfA expressed their strong reservations for not having indications of specific modes of actions (MoA), that the findings in the mid dose raise the problem of mortality in the rats, so that it is difficult to decide if the findings are related to effects on immune system or to overt toxicity at mid and higher doses. They disagree with SECR explanation that the effects are related to treatment associated stress.

One stakeholder representative highlighted the registrants' responsibility to include the relevant and up-to-date information in their registration dossiers, as this directly influences the efficiency and accuracy of the decision making process.

During the discussions some MSC members stressed that for this substance from the information provided in the dossier there are difficulties to discriminate if the findings for mid and low doses prove toxicity or are stress induced by the treatment, and agree that this represents a borderline case. They also pointed out that lack of blood effects does not give confirmation of side effects, that thymus effects were likely secondary and weight changes are not toxicologically relevant.

Session 2 (closed)

During the closed session MSC members agreed with inclusion of a note for consideration to the Registrant reminding him to use rats as the first species for the PNDT testing, and that he should provide a scientific justification if he decides to use another species.

As for the request for inclusion of the DIT cohort 3 to the requested EOGRTS, several MSC members elaborated on the type of effects that would trigger the DIT cohorts.

MSC member and his alternate representing the MSCA submitting PfA explained that several weak findings together should, in combination, be considered as strong enough to trigger DIT cohorts in the EOGRTS design. In their view, findings related to potential endocrine disrupting properties were observed. Although one specific MoA cannot be specified, based on the effects observed in vivo, and there is no clear evidence to link these substance specific findings to developmental immunotoxicity, they argued that the effects observed provide information about an effect on the sex hormonal system, and that effects on the sex hormonal system are associated with (developmental) immunotoxicity. Furthermore, it was argued that the findings related to immunotoxicity at the mid dose level are not confounded by the general toxicity or mortality in the rats and, although perhaps borderline findings, they are still sufficient to trigger the DIT cohort.

SECR explained that the findings referred to in PfA either are not sufficient to provide a link to DIT (decreased sperm number) or were observed at dose levels with severe other systemic toxicity and/or lethality, were transient, in one gender only, not consistent between different species, and, thus, they likely reflect the condition of the animals and not a specific toxicity (thymus and white blood cell findings). Although it may be challenging to discriminate whether changes in lymphocyte count and thymus weight are stress-related or not, they were interpreted as stress-related by the authors. Taking all the data into account, the SECR considers that the findings are not sufficient for a specific concern in relation to developmental immunotoxicity. Thus, they do not meet the criteria, alone or together, for triggering the DIT cohort. In general, SECR did agree that several weak lines of evidence taken together in principle could trigger the DIT cohort, when considered relevant and consistent, and not confounded with other systemic toxicity. It was pointed out that the individual lines of evidence should meet a sufficient level of

reliability, adequacy and relevance in order to be considered in a weight of evidence approach.

One MSC member's alternate questioned SECR view that the observed thymus effects are "likely secondary". She reffered to the statements by the authors of the NTP study that did not indicate that the thymus effects were considered secondary by them.

One MSC member expressed support for ECHA's view regarding the interpretation of the data. A majority of MSC supported the proposal not to include the DIT cohort as the triggers for inclusion of DIT were not met.

MSC agreed unanimously the DD as submitted to the meeting. Members from DK, NL, SE and one other member abstained from voting.

TPE-019/2017 2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (EC No. 260-829-0)

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 one PfA on pre-natal developmental toxicity (PNDT) study in a first species was received to the ECHA's DD. SECR clarified that the DD also included short-term toxicity (28-day) and sub-chronic toxicity (90-day) both combined with neurotoxicity studies. The PfA suggested delaying the PNDT study until the results of the sub-chronic toxicity (90-day) combined with neurotoxicity study were available. It also suggested that a new testing proposal should be submitted if a new study design was considered necessary, or the DD could be amended to standard sequential testing with changed deadline.

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

The Registrant confirmed in his comments that he agreed with the PfA to delay PNDT testing after the 90-day study. In addition, he informed that, based on offers received, reliable Contract Research Organisation (CROs) performing sequential testing were booked at the moment. Since the full design of necessary studies seemed not to be available at start, serious consideration should be given to extend the deadline to allow drawing conclusions on further testing.

SECR clarified that if either the PNDT or neurotoxicity study would lead to classification of Repr. 1B, then the other study could be waived; however, it did not seem likely for this particular substance. In addition, this testing proposal was on PNDT study and not on developmental neurotoxicity study (DNT).

A stakeholder representative mentioned that the 28-day study had not come up in the third party consultation. SECR clarified the procedure on the third party consultation (TPC) related to this case. TPC always refers to a specific hazard endpoint, apart from the substance identifiers, as required by the legal text. Further details, like the number of studies proposed, are only visible in the disseminated dossier, to which there is a link in the TPC table.

Session 2 (closed)

In its discussion MSC took note that in case neurotoxicity is confirmed based on the sub-chronic toxicity (90-day) combined with neurotoxicity study, then a modified PNDT study might not be the appropriate study to address this concern but rather a DNT (OECD TG 426). It further noted that PNDT and DNT investigate different hazardous properties and are not interchangeable, thus the PNDT study should remain as a request in the DD since it is a standard information requirement and currently there is a data gap. Also, MSC agreed that the deadline [of 30 months] already allowed for sequential testing for the requested studies in the DD.

Finally, SECR noted that the Registrant had submitted a testing proposal on a non-standard 28-day study based on REACH Annex IX, Section 8.6.2, column 2, to address his specific concerns on neurotoxicity.

MSC concluded to keep unchanged the request to conduct, without any delay in starting the testing, the PNDT study (EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route.

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

TPE-020/2017 Melamine (EC No. 203-615-4)
Session 1 (open)

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

SECR explained that two PfAs to ECHA's DD were submitted on the design of the extended one-generation reproductive toxicity study (EOGRTS). The first PfA proposed including the developmental immunotoxicity (DIT) cohort (cohort 3) based on the available scientific evidence, which gives rise to a particular concern for developmental immunotoxicity. The second PfA suggested to request an extension of cohort 1B to include mating of the animals and production of the F2 generation for the following reasons: uses of the registered substance are leading to significant exposure and there are indications of modes of action (MoA) related to endocrine disruption (ED) from available studies.

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

The representatives of the Registrant confirmed their written comments agreeing with the first PfA on inclusion of the DIT cohort and disagreeing with the second one on F2 inclusion. They noted that although initially when commenting on the DD, the Registrant had disagreed with the inclusion of the DIT cohort, later on the melamine consortium has changed its view and consequently, the Registrant agreed with the respective PfA based on thorough consideration of the latest literature findings (from May 2017) and the regulatory compliance obligations. They also provided oral clarification on the way they had scrutinised existing, relevant studies and referred to new scientific evidence, not yet included in the registration dossier, that support the inclusion of DIT cohort 3. Furthermore, the Registrant pointed out that they disagreed with the PfA proposing F2 inclusion, as in their view, the uses in the registration dossier do not lead to significant consumer or professional exposure, as melamine is used in a chemically reacted form (95 % of applications), or in a matrix (5 %) with no intended release from either. In their view, inclusion of F2 would require increased, unnecessary animal testing. The registrants also commented that melamine is not known as an endocrine disruptive substance, an endocrine mode of action for melamine has so far not been proven in a reliable study following e.g. OECD guidelines.
In the following discussion, MSC and the ECHA Secretariat sought clarification from the Registrant on a number of issues, such as: the Registrant's interpretation on several study findings and their relevance for triggering the DIT cohort and inclusion of F2. The Registrant's representatives were also asked to explain why they claimed non-consumer and non-professional uses of melamine with no exposure , when uses reported in the Substances in preparations in Nordic Countries (SPIN) database covering use of the substance on its own or in mixtures (http://spin2000.net/) and in the joint submission currently suggest the opposite.

The Registrant's representatives responded to the questions raised and noted that they made only high level observations and do not have a specific view yet on ED effects. The Registrant representatives noted that they were not aware of the claimed consumer uses in the joint submission. While acknowledging consumer and professional uses of articles containing (reacted) melamine and melamine "embedded in a matrix", which the Registrants considered ~~is~~ out of the scope of the melamine registration, they re-iterated one of their major arguments for rejecting the inclusion of F2 that there are no intended releases of the substance from any of these uses. They did not substantiate further that claim at the meeting. It was also noted that some of melamine uses have been already

regulated in the Food Contact Material Regulation, which set up a migration limit for melamine of 2.5 mg/kg of food material.

The members from the two PfA-submitting MSCAs pointed out that they are not convinced by the additional explanation provided by the Registrant on the safe use of melamine and maintained their positions for the reasons raised in the PfAs. Several members supported these views while two others expressed doubts, whether the existing evidence is sufficient to meet the criteria for triggering cohort 3 and an extension of cohort 1B.

Session 2 (closed)

SECR noted that this is a testing proposal, where the Registrant has always a possibility to expand the EOGRTS design with proper scientific justification, even if not explicitly required in DD. However, in the light of the latest scientific evidence to which the Registrant referred to and MSC discussed in the meeting, the ECHA's view in this particular case had also evolved as there seemed to be sufficient and relevant evidence to include cohort 3.

Regarding significant exposure criterion in relation to triggering extension of cohort 1B, a COM observer reminded that the inclusion of melamine in other legislation (Food Contact Material Regulation and the established migration limits there) does not exclude it from the scope of REACH, in particular when the substance is used in a mixture, e.g. its use in paints and finger paints that gives strong indications for significant exposure.

In the following discussion and based on the views exchanged, the majority of the MSC members concluded there is sufficient scientific evidence for requesting the DIT cohort in this case based on the specific immunotoxicity-related findings in the latest scientific studies on melamine.

It was noted that the Registrant's claim, that there is no significant exposure from any of the uses discussed in Session 1, had not been sufficiently substantiated. Moreover, as the substance is incorporated in paints in its free form, significant exposure can occur, e.g. to professionals from paints. MSC concluded that the described uses in the registration dossier alone are sufficient to meet the exposure criterion for the extension of cohort 1B to mate the animals to produce the F2 generation. Only if the Registrant provides additional proof in his registration dossier to exclude significant exposure during melamine uses, then extension of cohort 1B is not necessary.

Based on the above considerations, MSC concluded that the DD should be modified to include cohort 3 (DIT) and to extend cohort 1B to produce the F2 generation. MSC mandated the SECR to perform final editing of the DD reasoning (Annex 2) to reflect the discussion in the plenary.

MSC agreed unanimously to the DD as amended at the meeting. The MSC members from DE and UK abstained from voting.

TPE-027/2017 [3-(2,3-epoxypropoxy)propyl]diethoxy-methylsilane (EC No. 220-780-8)

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 one PfA on *in vivo* mammalian alkaline comet assay (OECD TG 489) suggested modifying the assay to take into account for potential DNA cross-linking properties of the substance (that is, having two sets of slides prepared and analysed, one set submitted to standard experimental conditions and another to modified experimental conditions enabling the detection of DNA crosslinks).

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

The Registrant confirmed the written comments he had provided prior to the meeting and disagreed with the PfA. He argued that comet assay was not suitable to detect crosslinking agents and that the test guideline does not state that a validated protocol exists for

detecting crosslinks and that further work was needed. He also noted that, as a pragmatic approach, prolonged electrophoresis could detect DNA cross-linking, but it was not included in the DD as a possible technique.

Session 2 (closed)

Some MSC members took note that it may be challenging to address crosslinks using comet assay. MSC also noted that the OECD TG does not include a specific protocol for treatment by MMS (methyl methanesulfonate) or by ionising irradiation and that more work on a modified protocol may be needed. Chromosome aberration or micronucleus studies might be more appropriate for crosslinks.

MSC concluded that while a modified comet assay to detect crosslinks is possible to perform, considering the substance's properties a modification of the standard comet assay is not requested in the DD.

Based on the discussion, the Chairman concluded that for case-specific reasons the DD should not include a request for a set of extra slides to detect DNA crosslinks to be prepared and analysed.

MSC agreed unanimously to the DD as amended at the meeting. One member abstained from voting.

CCH-074/2017 Castor oil, sulfated, sodium salt (EC No. 269-123-7)

Session 2 (closed)

SECR explained that agreement was initially sought in written procedure. The written procedure was terminated by the Chairman of MSC in accordance with Article 20(6) of the MSC Rules of Procedure.

A MSC member requested stopping the written procedure to allow a discussion on the PfA requesting to add several requests on human health and environment endpoints, which SECR had removed after receipt of the Registrant's comments on the DD. The PfA reasoned that the Registrant had not provided the detailed information mentioned in his comments in a dossier update, and that the substance identity of the registered UVCB substance and the testing material can only be compared if the whole study information is included in the dossier update.

SECR had not modified the DD in advance of the written procedure based on this PfA.

The Registrant had provided written comments on the PfA, indicating that he had submitted an update of the registration dossier in August 2017 to fulfil the information on all endpoints in the PfA.

The MSC member who requested discussion in the meeting reiterated the consideration that a respective dossier update should have been available at the time of referral and that the usual procedure should have been followed to keep the requests in the DD rather than removing them in absence of the dossier update.

The Chairman noted that the dossier update submitted by the Registrant in August 2017 had not passed the technical completeness check and that it was thus not available to the MSCAs and MSC members. The Chairman outlined that the MSC members did not have full information available for decision making and that SECR had concluded to withdraw the case from the current decision making process. The case will be included in a future MSCA consultation.

MSC agreed to the suggested approach and did not further discuss the DD of the case.

d. Decision making process - General topics

- Use of OECD TG 234 in the dossier evaluation processes

SECR gave a presentation on the activities related to the use of OECD testing guideline (TG) 234 in the dossier evaluation processes explaining that an evaluation working group (WG) of ECHA and MSCA experts had prepared a discussion paper with scientific assessment and suggestions. SECR noted that REACH standard information requirement

on long-term fish toxicity refers only to a type of test and not to a specific test method or guideline. The preferred option for long-term fish toxicity testing is the fish early-life stage test (FELS; OECD TG 210). In the draft document of the WG, the proposal is to identify the ED concern using (a) a human health assessment of the EOGRTS working group and (b) *in vitro* mechanistic data and *in vivo* effects of concern based on the environmental part of the Commission's ED list. Testing according to the fish sexual development test (FSDT; OECD TG 234) will be requested when ED concern is identified for a substance with a data gap for long-term fish toxicity testing. MSC took note of the presentation and the invitation for comments on the discussion paper by the end of September 2017. SECR would then consolidate views to prepare a joint path forward.

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

- Presentation by secretariat on summary of issues raised in public consultation
- Work plan of MSC Rapporteur and Working Group for opinion drafting
- Discussion on elements for the draft opinion on ECHA's 8th draft recommendation for Annex XIV

SECR gave a presentation on the summary of main issues raised in the public consultation on ECHA's 8th draft recommendation of priority substances for inclusion in Annex XIV. Only comments on NMP (1-Methyl-2-pyrrolidone) were received in the consultation which ended on 2 June 2017. Those comments were published after end of the public consultation on ECHA's website, and work by SECR is ongoing in analysing and providing responses to them. SECR also noted that no registration updates had been received until end of the public consultation. As regards NMP SECR provided a recap on the restriction proposal for this substance, with a further update by COM observer, and reminded MSC about the ongoing Risk Management Option Analysis on three aprotic solvents, one of which is NMP. The comments received on NMP were grouped according to 1) priority and general issues, 2) transitional arrangements and 3) exemptions in the summary presentation.

MSC's Rapporteur provided a status update on the seven substances included in the draft recommendation and subject of the public consultation, and the division of work within the Working Group (WG) supporting him and the Co-Rapporteur in drafting the MSC opinion. He invited MSC members to consider the draft recommendation and any comments received and based on those to provide feedback to him and the WG if any issues should be captured to the first draft opinion for discussion at the next plenary meeting. Members were requested to provide their considerations, if any, on substances that did not receive comments in the public consultation as soon as possible.

Item 9 – Update of stakeholder observers' participation at MSC

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

MSC thoroughly considered the ASO participation in the past year in line with the MSC General approach[2] for admission of observers from accredited stakeholder organisations (ASO). MSC took note as well on the feedback received from the regular ASO observers in this regard, the expressions of interest in MSC work of new ASOs and the expressed preferences of the new ASOs for their observer status (to become occasional MSC observers).

With regard to the ASO admission as MSC permanent observers in different quotas, MSC decided to re-confirm, within 'NGOs and Trade union' quota[3], the MSC regular observer status of: ETUC; the seven ENV & HH NGOs (ChemSec, Client Earth, EEB, Greenpeace, HEAL, Health Care without harm Europe and Women in Europe for Common Future) to share four seats[4] when participating in MSC plenary meetings within their rotation group;

[2] http://echa.europa.eu/documents/10162/13578/general_approach_aso_in_msc_work_en.pdf
[3] With seven seats allocated as follows: one seat for trade unions, four seats for ENV&HH NGOs, two seats for Animal Welfare NGOs
[4] i.e. four representatives from this rotation group to be physically present per meeting

the four “Animal Welfare NGOs” (ECEAE, Eurogroup for Animals, HSI and PISC) to share two seats[5] when participating in MSC plenary meetings within their group.

Within the ‘Industry’ quota[6] MSC decided to re-confirm the regular observer status of Cefic, CONCAWE, Eurometaux, ORO, and of CEPE and FECC (the latter two to share one seat[7] within their rotation group when participating in MSC plenary meetings). Members also re-confirmed the regular observer status of UEAPME (acknowledging the collaboration agreement of this ASO with the MSC observer from Cefic) with possible occasional participation in MSC meetings.

As regards the admission of ASOs as MSC occasional observers, MSC decided to re-confirm the occasional observer status of the remaining ASOs with maintained interest in MSC work (mainly sectorial ones). They are invited to follow the MSC work as sector-specific observers and participate in MSC plenary meetings on an occasional basis, in accordance with MSC General approach on the ASO admission to the MSC work at the discretion of the MSC Chairman’s decision. The Committee also agreed on admission of three new ASOs (Foreign Trade Association (FTA), Fertilizers Europe and European Federation of Allergy and Airways Diseases Patients' Association (EFA)) as MSC occasional observers.

In addition, members noted the feedback and the suggestions for improvement provided by the regular MSC ASO observers and supported the MSC-S proposal to consider them in its discussions on review of MSC decision making.

The MSC Chairman thanked MSC for the decisions taken and pointed out that MSC-S will inform ASOs concerned of these MSC decisions and will update the list of the MSC ASO observers[8] on ECHA’s website after the meeting.

Item 10 – Any other business

- Mutagenicity testing: Possible *in vivo* follow-up steps in case of exclusive *in vitro* aneugenic mechanism (follow-up from MSC-54)

SECR gave a presentation on the activities related to possible *in vivo* follow-up steps in case of exclusive *in vitro* aneugenic mechanism. MSC-54 had discussed the FISH/CREST staining requirements in an *in vitro* micronucleus test (MN; OECD TG 487). SECR described that following a positive result of an *in vitro* MN study, a follow-up *in vivo* test must be performed: it can be either a MN test (OECD TG 474), a chromosomal aberration test (OECD TG 475), or a comet assay (OECD TG 489). If the FISH/CREST staining technique was used in the *in vitro* MN test and demonstrated that a substance was exclusively aneugenic, then the most suitable *in vivo* follow-up test would be the MN test. It is the only one able to detect structural chromosomal aberrations and a change in the number of chromosomes (numerical chromosomal aberrations).

MSC welcomed the presentation. A MSC member noted that the OECD guideline for the MN test has the bone marrow as target tissue and does not include any site of contact tissue. The MSC Chairman suggested to have further discussion to clarify what follow up steps are possible when such more complicated circumstances may occur.

- Update on appeals and court cases (Partly closed session)

SECR gave an overview of the status of recent appeals on evaluation cases submitted to ECHA’s Board of Appeal, as well as on pending cases submitted to the European Court of Justice relating to the authorisation process. MSC took note of the information received.

- MSC decision making: review of the processes

MSC Chairman presented the learnings from phone calls with MSC members held during

[5] i.e. two representatives from this rotation group to be physically present per meeting
[6] With seven seats allocated to ASOs representing general industry interests
[7] i.e. one representative from this rotation group to be physically present per meeting
[8] http://echa.europa.eu/documents/10162/13578/list_aso_msc_observers_en.pdf

the summer. Common themes of members' preparations for meetings and suggestions for the MSC processes were listed. MSC Chairman also presented members' feedback on the changes already introduced.

Item 11 – Adoption of main conclusions and action points

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

II. List of attendees

Members/Alternate members
ANDRIJEWSKI, Michal (PL)
COCKSHOTT, Amanda (UK)
CONWAY, Louise (IE)
DEIM, Szilvia (HU)
DOBRAK-VAN BERLO, Agnieszka (BE)
DIMCHEVA, Tsvetanka (BG)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
FRANZ, Michel (FR)
GYMNAOU, Panagiotis (CY)
HERMES, Joe (LU)
HORSKA, Alexandra (SK)
HUMAR-JURIC, Tatjana (SI)
JANTONE, Anta (LV)
KOUTSODIMOU, Aglaia (EL)
KREKOVIĆ, Dubravka (HR)
KULHANKOVA, Pavlína(CZ)
LONDESBOROUGH, Susan (FI)
LUNDBERGH, Ivar (SE)
MARTÍN, Esther (ES)
MIHALCEA UDREA, Mariana (RO)
PISTOLESE, Pietro (IT))
REIERSON, Linda (NO)
STESSEL, Helmut (AT)
TYLE, Henrik (DK)
VESKIMÄE, Enda (EE)
WIJMENGA, Jan (NL)
Representatives of the Commission
GARCíA-JOHN, Enrique (DG GROW)
SCHUTTE, Katrin (DG ENV)
Observers
ANNYS, Erwin (Cefic)
BERNARD, Alice (ClientEarth)
DROHMANN, Dieter (ORO)
FAßBENDER, Christopher (PETA)
HÖK, Frida (ChemSec)
LOONEN, Helene (EEB)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AHRENS, Birgit
AJAO, Charmaine
ANASTASI, Audrey Anne
BERCARU, Ofelia
BICHLMAIER, Ingo
BROERE, William
CESNAITIS, Romanas
CARLON, Claudio
DE WOLF, Watze
DELOFF-BIAŁEK, Anna
DREVE, Simina
FALCK, Ghita
HALLING, Katrin
HOFFSTADT, Laurence
HUUSKONEN, Hannele
JAAGUS, Triin
JOHANSSON, Matti
KOVARI, Agnes
LE CURIEUX, Frank
LEPPÄRANTA, Outi
LOUEKARI, Kimmo
NAUR, Liina
NYGREN, Jonas
PHRAKONKHAM, Pascal
RODRIGUEZ-RUIZ, Amaia
RÖNTY, Kaisu
SOBANSKA, Marta
VAHTERISTO, Liisa
VALKOVICOVA, Eva
VASILEVA, Katya
VÄÄNÄNEN Virpi

Proxies
- MARTIN, Esther (ES) also acting as proxy of ALMEIDA, Inês (PT)
- PISTOLESE, Pietro (IT) also acting as proxy of BORG, Ingrid (MT)
- HUMAR JURIC, Tatjana (SI) also acting as proxy of MIHALCEA UDREA, Mariana (RO) during last hours on 14 September
- KULHANKOVA, Pavlina (CZ) also acting as proxy of KRECOVIC, Dubravka (HR) during last hours on 14 September
- TYLE, Henrik (DK) also acting as proxy of DUNAUSKIENE, Lina (LT) for short periods during the meeting.

Experts and advisers to MSC members
ATIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
BARTHELEMY-BERNERON, Johanna (FR) (expert to FRANZ, Michel)
CIESLA, Jacek (PL) (expert to ANDRIJEWSKI, Michal)

COPOIU, Oana (RO) (expert to MIHALCEA UDREA, Mariana)
DANIHELOVA, Martina (SK) (expert to HORSKA, Alexandra)
DE KNECHT, Joop (NL) (expert to WIJMENGA, Jan)
HOLMER, Marie Louise (DE) (adviser to TYLE, Henrik)
KAIRYTE, Monika (LT) (expert to DUNAUSKIENE, Lina)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LITTLE, Joanne (UK) (expert to COCKSHOTT, Amanda)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBERGH, Ivar)
ROSENTHAL, Esther (DE) (expert to FINDENEGG, Helene)
RISSANEN, Eeva (FI) (adviser to LONDESBOROUGH, Susan)
SAKSA, Jana (EE) (expert to VESKIMÄE, Enda)

By WEBEX/phone connection:
During the whole meeting: MENDONÇA, Elsa (PT)

Case owners:
Representatives of the Registrants were attending under the agenda item 7b for CCH-044/2017, CCH-054/2017, CCH-057/2017, TPE-019/2017, TPE-020/2017 and TPE-027/2017

Apologies:
ALMEIDA, Inês (PT)
BORG, Ingrid (MT)
PALEOMILITOU, Maria (CY)
VANDERSTEEN, Kelly (BE)
WAGENER, Alex (LU)

MSC/A/055/2017
FINAL

Agenda

55th meeting of the Member State Committee

12-14 September 2017
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland

12 September: starts at 9 am
14 September: ends at 12 am

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/055/2017
For adoption

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

Item 4 – Administrative issues

- Outlook for MSC-56 and MSC-57
- Use of secure webex

ECHA/MSC-55/2017/020
For information

Item 5 – Minutes of the MSC-54

- Final minutes of MSC-54

MSC/M/54/2017
For information

Item 6.1 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2018-2020)

Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update and for Working Group membership

a) Draft terms of Reference and possible appointment of the Rapporteur and Co-Rapporteur

ECHA/MSC-55/2017/001

For discussion & decision

b) Discussion and possible establishment of a MSC Working Group to support the Rapporteur

ECHA/MSC-55/2017/002
For discussion and possible decision

Item 6.2 – Substance evaluation - General topics

- Status report on on-going substance evaluation work

For information

Item 7 – Dossier evaluation

Tentative timing: Day 1 & 2 for item 7b
Closed session for 7c

a. Written procedure report on seeking agreement on draft decisions on dossier evaluation[9]

ECHA/MSC-55/2017/003
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, open session)*

For discussion followed by agreement seeking under 7c:

ECHA/MSC-55/2017/004

Compliance checks

MSC code	Substance name	EC/List No. / Document number
CCH-044/2017	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl) oxy]-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	260-828-5 / ECHA/MSC-55/2017/005-6
CCH-054/2017	Sodium hydroxymethanesulphinate	205-739-4 / ECHA/MSC-55/2017/007-8
CCH-057/2017	Esterification products of 1,3-dioxo-2-benzofuran-5-carboxylic acid with nonan-1-ol	941-303-6 / ECHA/MSC-55/2017/009-10
CCH-058/2017	Pin-2(3)-ene	201-291-9 / ECHA/MSC-55/2017/011-12

Testing proposal examinations

MSC code	Substance name	EC No. / Document number
TPE-019/2017	2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	260-829-0 / ECHA/MSC-55/2017/013-14
TPE-020/2017	Melamine	203-615-4 / ECHA/MSC-55/2017/015-16
TPE-027/2017	[3-(2,3-epoxypropoxy)propyl]diethoxy-methylsilane	220-780-8 / ECHA/MSC-55/2017/017-18

[9] Please see the Appendix at the end to see the list of cases agreed in MSC written procedure in advance of the meeting.

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 a case returned from written procedure for agreement seeking in the meeting:

CCH-074/2017[10] Castor oil, sulfated, sodium salt EC No. 269-123-7

For agreement

d. Decision making process - General topics

- Use of OECD TG 234 in the dossier evaluation processes

For information

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

Timing plan: Day 2

- Presentation by secretariat on summary of issues raised in public consultation
- Work plan of MSC Rapporteur and Working Group for opinion drafting
- Discussion on elements for the draft opinion on ECHA's 8th draft recommendation for Annex XIV

For information and discussion

Item 9 – Update of stakeholder observers' participation at MSC

Closed session

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

ECHA/MSC-55/2017/019
For discussion and decision

Item 10 – Any other business

- Mutagenicity testing: Possible *in vivo* follow-up steps in case of exclusive *in vitro* aneugenic mechanism (follow-up from MSC-54)
- Update on appeals and court cases *(Partly closed session)*
- MSC decision making: review of the processes
- Suggestions from members

For information

Item 11 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-55

For adoption

Information documents:

[10] Documents are available in CIRCABC in substance specific folders under Dossier evaluation folders.

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

- Status report on on-going dossier evaluation work (presentation slides)

Appendix to the MSC-55 agenda:

List of evaluation cases agreed in written procedure in advance of the MSC-55 meeting:

MSC code	Substance name	EC / List No.
CCH-042/2017	1-(4-methyl-2-nitrophenylazo)-2-naphthol	219-372-2
CCH-043/2017	2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	260-829-0
CCH-045/2017	Diisopropyl-1,1'-biphenyl and tris(1-methylethyl) -1,1'-biphenyl (mixture)	915-589-8
CCH-050/2017	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid	500-130-2
CCH-051/2017	Morpholine	203-815-1
CCH-052/2017	Zinc bis(dibutyldithiocarbamate)	205-232-8
CCH-056/2017	2-furaldehyde	202-627-7
CCH-061/2017	(Z)-N-octadecyldocos-13-enamide	233-226-5
CCH-062/2017	(Z)-N-octadec-9-enylhexadecan-1-amide	240-367-6
CCH-064/2017	Dibutyl maleate	203-328-4
CCH-065/2017	Bornan-2-one	200-945-0
CCH-068/2017	Quaternary ammonium compounds, C20-22-alkyltrimethyl, chlorides	271-756-9
CCH-077/2017	4,4'-methylene bis(dibutyldithiocarbamate)	233-593-1
CCH-079/2017	C14-18 alpha-olefin epoxide, reaction products with boric acid	939-580-3
CCH-082/2017	Isobutyl vinyl ether	203-678-8

Main conclusions and action points
MSC-55, 12-14 September 2017
(adopted in written procedure on 21st September 2017)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues • Use of secure webex	
	Members to consider early on if an expert from their side should follow any future plenary meeting via webex, and to ensure such registrations are done latest 5 days in advance of the meeting, and that SECR is informed accordingly.
• Outlook for MSC-56 and MSC-57	
MSC took note of the estimated number of days for the meetings.	MSC-S to upload the presentation on MSC S-CIRCABC
Item 6.1 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2018-2020) Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the CoRAP update and for Working Group membership a) Draft terms of Reference and possible appointment of the Rapporteur and Co-Rapporteur b) Discussion and possible establishment of a MSC Working Group to support the Rapporteur	
MSC adopted the mandate and the tasks of the rapporteur, and appointed one member as a Rapporteur and another member as a Co-Rapporteur for drafting the MSC opinion on the draft annual CoRAP update. MSC established a working group to support the Rapporteur and appointed volunteering members to it.	MSC-S to send the appointment letters to the Rapporteur and the Co-Rapporteur.
Item 6.2 – Substance evaluation - General topics • Status report on on-going substance evaluation work	
MSC took note of the report.	SECR to inform the SEV workshop invitees whether participation at the workshop is possible via webex.
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)	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
MSC reached unanimous agreement on the following ECHA draft decisions (as modified in the meeting): <u>Compliance checks</u> CCH-044/2017 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl) oxy]-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa- /3,5-dithia-4-stannatetradecanoate (EC No. 260-828-5) CCH-054/2017 Sodium hydroxymethanesulphinate (EC No. 205-739-4) CCH-057/2017 Esterification products of 1,3-dioxo-2-benzofuran-5-carboxylic acid with nonan-1-ol (EC No. 941-303-6) CCH-058/2017 Pin-2(3)-ene (EC No. 201-291-9) <u>Testing proposal examinations</u> TPE-019/2017 2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (EC No. 260-829-0) TPE-020/2017 Melamine (EC No. 203-615-4) TPE-027/2017 [3-(2,3-epoxypropoxy)propyl]diethoxy-methylsilane (EC No. 220-780-8)	MSC-S to upload on MSC S-CIRCABC the final ECHA decisions of the agreed cases.
MSC took note of ECHA's withdrawal of the following case from decision making. The case had been stopped in written procedure for agreement seeking in the plenary meeting: CCH-074/2017 Castor oil, sulfated, sodium salt (EC No. 269-123-7)	SECR to re-submit the case to an MSCA consultation after assessment of the updated dossier.
Item 7d. Dossier evaluation decision making process -General topics • Use of OECD TG 234 in the dossier evaluation processes	
MSC took note of the executive summary as presented, and the invitation for comments on the discussion paper.	MSC to review and submit written comments through the MSC FMB by 29th September 2017. SECR to organise an informal meeting in the sidelines of MSC-56 to try and resolve these in case major issues arise from those comments.
Item 8 – ECHA's 8th draft recommendation of priority substances to be included in Annex XIV • Presentation by secretariat on summary of issues raised in public consultation • Work plan of MSC Rapporteur and Working Group for opinion drafting • Discussion on elements for the draft opinion on ECHA's 8th draft recommendation for Annex XIV	
MSC took note of the summary of issues raised in the public consultation on NMP and took note of the status update by the Rapporteur.	MSC to provide any comments to the WG and Rapporteur by 21 September as an input to the 1st draft opinion. Rapporteur to present first draft opinion to MSC in October.
Item 9 – Update of stakeholder observers' participation at MSC • Discussion and update of the MSC decision about the invited organisations	
MSC took note of the update of the ASO observers' participation	MSC to review ASO participation in its

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
in the MSC work and took the following decisions: 1. With regard to the admission of ASOs as MSC permanent observers in different quotas, MSC decided to: • reconfirm the MSC regular observer status of: ➢ seven Environmental and Health Care NGOs (ChemSec, Client Earth, EEB, Greenpeace, HEAL, Health Care without harm Europe and Women in Europe for Common Future) within their rotation group to share four seats when participating in MSC plenary meetings (to be physically present per meeting), ➢ four "Animal Welfare NGOs" (ECEAE, Eurogroup for Animals, HSI and PISC) within their group to share two seats when participating in MSC plenary meetings (to be physically present per meeting), ➢ ETUC, Cefic, Concawe, Eurometaux and ORO, ➢ CEPE and FECC within a rotation group to share one seat when participating in MSC plenary meetings (as agreed between themselves who to be physically present per meeting). • keep the regular observer status of UEAPME who will be represented on a regular basis by the MSC observer from Cefic and will participate in the MSC meetings on occasional basis. 2. With regard to the admission of ASOs as MSC occasional observers, MSC desided to: • re-confirm the occasional observer status of the remaining stakeholder organisations (mainly sectorial ones) previously invited to follow the MSC work as sector-specific observers on an occasional basis, in accordance with MSC General approach on the ASO admission to the MSC work at the discretion of the MSC Chair's decision, • agree on admission of FTA, EFA and Fertilizers Europe as MSC occasional observers. Further, MSC noted the feedback and the suggestions for improvement provided by the regular MSC ASO observers and supported these are used as input to its discussions on review of MSC decision making.	work in one year's time. MSC-S to inform ASOs concerned of the MSC decisions and to update the list of the MSC ASO observers on ECHA's website after the meeting. MSC-S to consider potential improvements based on ASOs' suggestion and to inform MSC of the conclusions made and actions undetaken in the upcoming MSC plenaries.
Item 10 – Any other business • Mutagenicity testing: Possible *in vivo* follow-up steps in case of exclusive *in vitro* aneugenic mechanism (follow-up from MSC-54)	
MSC took note of the information presented	The Chairman to discuss with ECHA and MSC Mutagenicity experts possible next steps and timings, and to ensure reporting back to MSC. MSC-S to invite identified mutagenicity experts for more detailed discussions (e.g via Webex or in the sidelines of MSC-56).
• MSC decision making: review of the processes	

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
MSC took note of the report from the Chairman on the telephone interviews with members and the suggested next steps.	MSC-S to upload the presentation on MSC S-CIRCABC
Item 11 – Adoption of main conclusions and action points	
MSC agreed to provide comments in written procedure. In absence of comments the main conclusions and action points will be considered adopted.	MSC-S to upload the draft main conclusions and action points on MSC S-CIRCABC by 14 September 2017. MSC to review and submit written comments, if any, through the MSC FMB by 21th September 2017.

V. Dossier evaluation cases agreed by MSC in WP in advance of the meeting:

Compliance checks (CCH)

MSC ID number	Substance name used in draft decision	EC or List number
CCH-042/2017	1-(4-methyl-2-nitrophenylazo)-2-naphthol	219-372-2
CCH-043/2017	2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate	260-829-0
CCH-045/2017	Diisopropyl-1,1'-biphenyl and tris(1-methylethyl)-1,1'-biphenyl (mixture)	915-589-8
CCH-050/2017	4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid	500-130-2
CCH-051/2017	Morpholine	203-815-1
CCH-052/2017	Zinc bis(dibutyldithiocarbamate)	205-232-8
CCH-056/2017	2-furaldehyde	202-627-7
CCH-061/2017	(Z)-N-octadecyldocos-13-enamide	233-226-5
CCH-062/2017	(Z)-N-octadec-9-enylhexadecan-1-amide	240-367-6
CCH-065/2017	Bornan-2-one	200-945-0
CCH-068/2017	Quaternary ammonium compounds, C20-22-alkyltrimethyl, chlorides	271-756-9
CCH-077/2017	4,4'-methylene bis(dibutyldithiocarbamate)	233-593-1
CCH-079/2017	C14-18 alpha-olefin epoxide, reaction products with boric acid	939-580-3
CCH-082/2017	Isobutyl vinyl ether	203-678-8

Agreement document on a compliance check (CCH)

MSC ID number	Substance name used in draft decision	EC number
CCH-064/2017	Dibutyl maleate	203-328-4