MSC/M/43/2015
(Adopted at MSC-44)

Minutes

of the 43rd Meeting of the Member State Committee (MSC-43)

15-17 September 2015

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 43rd meeting of the Member State Committee (MSC) (for the full list of attendees and further details see Part II of the minutes). The Chairman also informed the Committee about the observers from a Member State Competent Authority wishing to attend parts of the meeting and upon his request the Committee agreed to their admission to the MSC-43 in line with the Member State Committee Rules of Procedure Art 6(10).

Item 2 - Adoption of the Agenda

The Agenda was adopted as modified at the meeting based on the draft agenda as provided for the meeting. One item under Item 11 - Any other business (AOB) was proposed by the Chairman and the second item was included based on a request from a stakeholder observer (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-43.

Item 4 - Administrative issues

The Chairman informed the Committee about a project that has been initiated by the MSC Secretariat (MSC-S) to review MSC's written procedure approaches across different MSC agreement seeking processes. Members were invited to contribute to the review and provide their feedback on MSC written procedures to the Secretariat.

Item 5 – Adoption of the minutes of the MSC-42 meeting

The minutes of MSC-42 were adopted as modified at the meeting.

Item 6 – Substance evaluation

6.1 Community Rolling Action Plan (CoRAP) & MSC opinion development

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

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 2016-2018. The Committee also appointed two of its members as a rapporteur and a 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 2016-2018. Further, MSC appointed four volunteering MSC members and three member's expert as the working group members to support the rapporteurs in the opinion development.

6.2 Decision making process

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

No written procedure on substance evaluation took place in advance of the MSC-43 meeting.

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)*)*

SEV-FR-011/2013 3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate (EC No. 202-112-7)

Session 1 (open)

Two 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 France (FR-CA) presented the outcome of substance evaluation (SEv) of the above-mentioned substance (referred to as TODI in short) which was performed by the FR-CA on the basis of the initial grounds for concern relating to human health/suspected CMR, suspected sensitiser, environment / suspected PBT, and for a high consumer use. MSC was guided through the information on the substance (including PfAs, Registrant(s) comments, and the eMSCAs responses to them).

Ten PfAs were submitted covering exposure, carcinogenicity and mutagenicity. One PfA proposed to limit the focus of the decision to the requests to clarify the exposure before further requests for data related to human health and to the environment are made, consequently shortening the deadline from 15 to 3 months. Furthermore better specification in the DD was proposed on the details on exposure scenarios for industrial uses, including what further information is needed from the Registrant to conclude on the claim that polymerisation step is in closed systems under "strictly controlled conditions" and what other information is needed regarding the second industrial use (compounding).

In another PfA on exposure scenarios regarding the life cycle it was suggested to clarify the information that is still needed. Better specification in the DD was proposed on the details of information needed regarding the identification and quantification of residues in the polymer, the articles made from the polymer and their uses.

In addition it was proposed to add in DD a note encouraging the intention of the Registrant to include in the dossier update newly available studies on algae and cyanobacteria, daphnia and fish conducted with TODA (the degradation product of TODI that is of concern for the environment).

In relation to carcinogenicity, PfAs were received suggesting 1) that due to the rapid hydrolysis of TODI to TODA and the carcinogenicity potential of TODA the inclusion of carcinogenicity data for TODA in the TODI database should be requested; 2) to request for a carcinogenicity study on the registered substance (Annex X, section 8.9.1) with a note to the Registrant reminding that he can use a read-across approach to fulfill this data gap.

In relation to the options for concluding the residual concern for mutagenicity, one PfA suggested to explore the options to 1) conduct an *in vivo* Comet assay via the inhalation route and investigate the lung and liver or 2) provide evidence to demonstrate that the *in vivo* UDS (Unscheduled DNA Synthesis) test is a reliable negative.

Also regarding mutagenicity (and ultimately, carcinogenicity) one PfA suggested a step-wise assessment strategy starting with reassessment of the available genotoxicity database for TODI. If the tests reported in the dossier were valid and representative, no further assessment of mutagenicity/carcinogenicity would be necessary. If after the reassessment either or both gene mutations and clastogenicity cannot be ruled out following dermal and inhalation exposure they suggest a request for an *in vivo* comet assay with administration by inhalation route (replacing the current request) or alternatively, at the discretion of the Registrant, i.e. if investigation of germ cells was identified as necessary, a TransGenic Rodent (TGR) assay. In both cases examination of local tissues at the port of entry (respiratory tract) and of tissues that could only be reached after systemic distribution of potential mutagens should be requested. The PfA suggested for a thorough evaluation whether the results of the tests should be attributed to TODI or to its hydrolysis product TODA.

Another PfA considered that a read-across approach using data on TODA appeared plausible, but expressed uncertainty on the legally best way forward. This PfA described the reasoning by which pathways TODI could cause mutations *in vivo* and proposed to request an *in vivo* Comet assay, with oral exposure and analysis of glandular stomach, duodenum/jejunum and liver to verify several those pathways for which information is lacking. The *in vivo* Comet assay could be waived if the Registrant could show that the

metabolic enzymes present in the gut and gut microflora do not convert TODI or TODA into metabolites that are mutagenic *in vitro* and TODA is not absorbed orally.

Other PfAs proposed 1) adequate identification of the composition of the material to be tested 2) to improve accuracy of DD in relation to the metabolism of TODI into TODA in organisms and 3) to use the classification and hazard statements according to CLP Regulation, with a clarification that the Registrant has classified the substance as a respiratory sensitizer category 1 and a skin sensitizer category 1A.

One PfA also mentioned, that with regard aquatic toxicity TODA's official classification is less stringent (chronic cat 2) than the proposed self classification for TODI with chronic cat 1.

The Registrants provided written comments on the PfAs which were reiterated during the discussion. With regards to the exposure to the substance, the Registrant claimed its use is in a closed system under strictly controlled conditions and submitted as proof a (confidential) document in the written comments and a compliance statement of the only DU in Europe that article 18. 4 are in place. The Registrant's representative explained that the polymer is used in a niche market of technical polymers exclusively at one site in Europe. The polymer is currently used in sealed metal equipment for industrial products from which there is no exposure from the monomer. It is not used for any consumer use or other products even if the website of the Registrant's company lists other uses of TODI.

With regards to the hydrolytic stability of TODI, the Registrant's representative claimed a half-life of 16 hours as presented in the registration dossier. They also explained that data on TODA is not available in the dossier because of the tight deadlines in preparing the dossier. However they are willing to discuss the available data on TODA carcinogenicity as far as accessible.

During the discussion, MSC members expressed their concern on the carcinogenicity of TODI and asked the Registrant representatives if it would be appropriate to classify TODI as Carc 1b based on the quick hydrolysis to TODA which is classified as such. The Registrant's representatives replied that TODI is not only converted to TODA but to other degradation products. Additionally, other examples exist like MDI and MDA where based on the available data MDI did not induce cytogenetic damage *in vivo* whereas MDA did. For TODI according to the Registrant a lack of gene mutation was already shown by the negative *in vivo* UDS test.

With regards to exposure one MSC member explained that standard operating procedures need to be in place to show strictly controlled condition (SCC). ECHA Secretariat (SECR) further explained that ECHA's practical guide 16 has several sections that deal with SCC, however, the best proof of use under SCC is to actually visit the site and see the level of commitment in putting the standard operating procedures into practice.

Whilst the representatives of the Registrant at this time reiterated their openness for a site audit, yet they kept on stressing confidentiality. The Registrant's representatives explained that they are representing the importer and have been in an intensive exchange with the downstream user producing the polymer granulates. However, further downstream uses in the polymer's life-cycle were not represented. Until now the DU provided only limited information to the Registrant for inclusion in the registration dossier (besides the written confirmation of compliance with article 18.4), however, the DU is willing to share more information with the Registrant and authorities as long as it is kept confidential (as they are site specific) and can be generated with reasonable efforts.

Clarification was requested on the use of TODI as a laboratory reagent declared in the CSR of the registration dossier. The representatives of the Registrant explained that this refers to sampling to control the polymer reaction.

With regards to fish testing, the representatives of the Registrant were reminded of their obligation under REACH to update the registration dossier once new information becomes

available, since it appeared that the Registrant had some new data on aquatic toxicity which was not included in the dossier.

Session 2 (closed)

During the closed session, MSC discussed whether there is a potential for exposure and whether the SCC presented by the Registrant should be considered. MSC recognised that even though the eMSCA did a comprehensive work in an attempt to clarify several aspects of the substance yet based on the information provided in the registration dossier, many uncertainties exist with regards to worker exposure to TODI and relevant degradation/transformation products, particularly in the steps following the preparation of the polymer, i.e. compounding, production of articles and use of the articles, where there could be a concern related to the release of the residual monomer/degradation /transformation products from the polymer. For human health there is a remaining concern for mutagenicity and carcinogenicity whilst for the environment there is a concern associated with the observed aquatic toxicity as reflected by the Registrant's self-classification Aquatic Acute 1 and Aquatic Chronic 1.

Because of the potential that the substance is a non-threshold carcinogen, the MSC members came up with two options, either to request the information on exposure and hazard (carcinogenicity , mutagenicity, acute toxicity to algae and cyanobacteria, daphnia and fish) in one DD or, alternatively, to first request for the exposure data and with a shorter deadline for submission of information. Considering that in case of non-threshold carcinogenicity/mutagenicity even very low exposure would be relevant it is difficult to determine in advance what exposure information may trigger the need for hazard data. MSC unanimously agreed to request first information on exposure in order to better address the concerns for carcinogenicity, mutagenicity and environmental risk assessment. Then in a step-wise approach depending on the resulting information from the requests in this DD, additional studies or information may be requested in the follow-up decision.

MSC unanimously agreed to request additional information on uses and exposure on TODI, the degradation product TODA and/or potential other degradation/reaction substances of concern originating from TODI and likely to migrate out of the polymer. These include detailed description of the systems and the SCC for industrial uses (polymerisation, research and development and compounding steps), quantitative data reflecting exposure in industrial settings and surrounding areas for workers and the environment , exposure scenarios for the industrial steps, as well as details on the life cycle for each use and/or each type of manufactured articles (particularly for the compounding step and the use in articles) and an extraction study to identify and quantify potential residual TODI, TODA and/or potential other degradation/reaction substances of concern originating from TODI and likely to migrate out of the polymer.

MSC unanimously agreed that there is a residual concern on the safe use of the substance. To ensure proportionality and for animal welfare reasons, MSC unanimously agreed not to request at this stage for hazard data with the consequence of reducing the timeframe by which the Registrant would need to provide the requested information on exposure within 9 months.

However, the eMSCA and MSC noted in the DD that based on the above scientific considerations there may already be sufficient evidence for the Registrant to self-classify the registered substance as Carc. 1b. This would imply that additional risk management measures would have to be put in place. MSC unanimously agreed to invite the Registrant to consider the option of self-classification as Carc. 1b in addition to the existing self-classifications. Furthermore, MSC included a note to encourage the Registrant to include in the dossier update newly available studies on algae and cyanobacteria, daphnia and fish conducted with TODA.

Depending on the assessment of the data on exposure and/or in the absence of the self-classification proposed above and the information on the related risk management measures submitted in the updated registration dossier within the deadline, the eMSCA will consider the need to request further information on mutagenicity and on other

endpoints necessary to clarify the initial grounds of concern during the follow-up to the substance evaluation.

SEV-DE-011/2014 di-tert-butyl 3,3,5-tri-methylcyclohexylidene diperoxide (EC No. 229-782-3)

Session 1 (open)

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

The evaluating Member State Competent Authority (eMSCA) from the German CA (DE-CA) presented the outcome of substance evaluation of the above-mentioned substance performed by DE-CA on the basis of the initial grounds for concern relating to suspected PBT/vPvB properties. The members were informed that additional concerns regarding the relevant exposure to the environment were identified during the course of the evaluation. MSC was guided through the information on the substance (including PfAs, Registrant(s) comments, and the eMSCAs responses to them).

Fourteen PfAs were received in total on the persistence (P), bioaccumulation (B) and toxicity (T) assessment as well as on the environmental exposure assessment. Because PfA submitters where satisfied with the way the eMSCA had considered their PfAs on the T assessment and the environmental exposure, MSC focused on the PfAs on the P and B assessment.

With regards to the P assessment, the DD requested biodegradation simulation testing in sediment (EU C.24/ OECD 308) and surface water (EU C.25/OECD 309). PfAs suggested that the OECD 309 test should be conducted first followed by the OECD 308 test or OECD 307 (soil simulation biodegradation test) in order to allow the second study to be waived if the first study result would confirm that the substance meets the vP criterion. It was further proposed to request the tests at a temperature of 20^{o}C to enhance formation of metabolites, whilst the kinetic part of the test to be conducted at 12^{o}C.

Another PfA proposed that the Registrant run one test, either OECD 307, 308, or 309 with preference either for the OECD 307 or 308 because sediment and soil appear to be the compartments of concern. The PfA questioned whether the OECD 309 study is feasible for a liquid with very low water solubility and very high Koc value.

Since the Registrant had already performed a sewage treatment plant simulation test (OECD 303A), one PfA proposed to add a justification explaining why the OECD 303A test alone is not considered sufficient to clarify the P concern and make the Registrant aware that in follow-up further soil testing may be requested.

Another PfA proposed to conduct the three simulation test OECD 307, OECD 308, and OECD 309 in parallel.

With regards to the B assessment, a PfA proposed to add the request for a water solubility test as QSAR predicts higher water solubility values and the available BCF test do not indicate an exceedance of the water solubility. Dependent on the result of the water solubility test a reassessment of the current BCF test and a new BCF test (e.g. OECD 305 I, aqueous test) may need to be performed.

Another PfA proposed to extend the current deadline for provision of the requested information to 30 months.

The Registrant provided written comments on the biodegradation strategy which were reiterated during the meeting discussion. They argued that based on the sewage treatment simulation test (OECD 303A) the soil would be the main exposure route. During the meeting, the representative of the Registrant explained that this test demonstrated very quick removal, and that the mechanism of removal is a defence mechanism where the peroxide bond is cleaved by an enzyme in the microbes (peroxidase) and not by hydrolysis. The formed alcohols and acids are then degraded in the normal way by microbiological activity. The Registrant indicated that they are conducting a Zahn-Wellens test on the substance and requested to finalise this test prior to proceeding with other tests. This test shows rapid removal and formation of degradation products.

The eMSCA explained that during the substance evaluation, the Registrant had provided only a draft report on the OECD 303A results. They were unable to find if the report relies on primary biodegradation or elimination. The representative of the Registrant explained that the study was concluded in April and the report was not finalised at that stage. He agreed that the substance adsorbs very strongly to the sludge however an extraction efficiency of above 90% was reached during the test, which he considers removes the concern for non-extractable residue formation (NER).

The eMSCA commented that the new Zahn-Wellens test performed by the Registrant is unlikely to change the outcome of the current assessment on persistency since it is a screening test and is used for substances which do not adsorb significantly.

When asked by an MSC member whether the Zahn-Wellens test would show that the substance undergoes fast primary degradation according to the P criteria in Annex XIII of REACH, the representative of the Registrant explained that the degradation due to the defence mechanism was very fast. It removed 100 mg/L in a very short period of time however they cannot yet say if this meets the seven day cut off window, even though it appears that way.

It was further pointed out by an MSC member that according to QSAR predictions this substance is not degrading fast. The representative of the Registrant attributed this difference between the test data and QSAR model predictions to the cleavage of the peroxide bond due to the defence mechanism that he explained earlier, since QSAR models usually rely on hydrolysis data.

Furthermore the representative of the Registrant was asked whether the registration dossier contained the information that NER formation is not a substantiated suspicion. He explained that this data was available quite recently and it is not in the dossier. The registration dossier would be updated accordingly.

Session 2 (closed)

During the discussion MSC recognised the need of requesting a new water solubility test especially since the QSAR-predicted values reported ranged from 4 µg/L to 30 µg/L. The lower the water solubility the more difficult it would be to conduct OECD 309 and obtain a reliable half-life. Furthermore, the water solubility needs to be clarified so as to verify the need for a reassessment of the BCF test provided in the registration dossier and the need for a new BCF test.

With regards to degradation testing, the eMSCA explained that they agree that the soil and sediment are the compartments of concern however, it would be difficult for them to interpret the results of the sediment and soil simulation tests without having the information from the degradation in surface water due to potential formation of non-extractable residues. In relation to the statements made by the representative of the Registrant on NER formation and the degradation mechanism during the meeting the eMSCA considered that no new information was presented in the registration dossier supporting the Registrants statements and which was not yet taken into account in the DD. During the MSC discussion the following considerations were made which also appear in one of the PfAs. The knowledge on the use and environmental emission profile for the registered substance is currently not detailed, but based on available information it is likely that it may reach surface water, soil and sediment. Direct emission and emission to STPs will result in exposure of surface water. This will also take place as a result of environmental transport and partitioning processes from sediment and soil. Consequently, besides soil and sediment, surface water is also an environmental compartment of concern, even though the relative share of the mass distribution of the substance to surface water at steady state according to multi-media environmental fate modelling seems to be considerably smaller than that to especially sediment.

MSC unanimously agreed to request a water solubility test using the shake flask method (OECD 105) and simulation testing on ultimate degradation in surface water (OECD 309). However, because of the points raised by the representative of the Registrant and lack of clarity on the actual water solubility value, in case the OECD 309 test is technically not feasible due to analytical limitations and this is scientifically justified or the results of OECD

309 do not allow to conclude that the registered substance is very persistent according to Annex XIII of REACH, a sediment simulation test (OECD 308) needs to be performed. In case only one simulation degradation test is performed by the Registrant a deadline of 27 months for submission of the information applies, whereas in case both simulation degradations tests are performed the deadline is set at 33 months.

d) General topics

Appeals update

SECR gave an update on the decisions from the Board of Appeal on three evaluation decisions one of which was a substance evaluation case.

Item 7 – Dossier evaluation

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

MSC-S introduced the report on the outcome of the written procedure (WP) for agreement seeking on seventeen dossier evaluation cases (see Part V for more detailed identification of the cases). WP was launched on 20 August 2015 and closed on 31 August 2015. By the closing date, unanimous agreement was reached on 15 DDs. For two DDs, WP was terminated by the MSC Chair on the basis of Article 20.6 of the MSC Rules of Procedure as at least one MSC member requested a discussion of the case at the MSC-43 meeting.

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

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

CCH-069/2015 – 2,2'-dimethyl-4,4'-methylenebis(cyclohexylamine) - EC No. 229-962-1

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 introduced the two PfAs that were received in total to ECHA's DD. The first PfA proposed adding a soil simulation test (OECD TG 307), noting that the Registrant had waived the simulation degradation tests. It provided justifications why the REACH criteria for waiving the studies were not met and why the potential of persistency of the substance and its degradation products needed to be assessed. In the PfA, the simulation test was proposed to be performed at 12°C, with several soils at different pH-level, and with a recommendation to use ^{14}C-radiolabelling.

The second PfA proposed to add a requirement for simulation testing on ultimate degradation in surface water (OECD TG 309), provided justifications why further degradation testing was required, and specified that the test should be performed at 12°C.

SECR had modified the DD for the meeting based on the PfAs.

The Registrant provided comments on the PfAs disagreeing with both. On the PfA on soil simulation testing, he argued that the substance is neither PBT nor vPvB and considered it to be potentially P/vP from a precautionary viewpoint. He further argued that adsorption at high pH-levels is not relevant for soils in Europe or in sewage treatment plants (STPs). He proposed to perform other tests or modified degradation tests, also relating to the PfA on surface water testing.

During the discussion on both PfAs one MSC member considered that the Registrant had clearly justified the PBT status of the substance and further questioned whether environmental degradation rates would have an impact on other than regional PEC values. SECR clarified how ECHA had viewed the need for biodegradation testing requested in the legal text in columns 1 and 2.

Session 2 (closed)

Following the PfAs, SECR considered whether this compliance check could include the standard information requirements of Section 9.2.1.2. and Section 9.2.1.3. of Annex IX of the REACH Regulation. In its discussions MSC considered these requests. One member argued that the indications for the need of these tests in accordance with the chemicals safety assessment (CSA) have not been provided in the PfAs. It was noted by MSC that the substance is evaluated under substance evaluation, and the evaluating Member State might be able to pursue these endpoints. MSC agreed not to pursue – at this moment under dossier evaluation compliance check process – the proposals for amendment regarding the information requests.

MSC agreed unanimously to the DD as amended at the meeting without requesting under this compliance check further simulation degradation tests.

CCH-046/2015 N-isopropyl-N'-phenyl-p-phenylenediamine (EEC. No 202-969-7)

Session 2 (closed)

MSC-S 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 a MSC discussion.

SECR introduced the two PfAs that were received in total to ECHA's DD on the request for an *in vivo* mammalian erythrocyte micronucleus test (EMN-test; EU B.12/OECD TG 474) or *in vivo* mammalian bone marrow chromosomal aberration test (BMCA-test: EU B.11/OECD TG 475).

The first PfA suggested improving clarity by the "Notes for consideration by the Registrant" defining the use of the tests and interpreting the outcome, related uncertainty and additional investigations depending on the substance reaching and exposing the target tissue.

The second PfA agreed that the substance is an *in vitro* clastogen/aneugen and that *in-vivo* follow-up was necessary; however, given the potential reactivity of the substance, which might limit the exposure to bone marrow, it suggested combining an *in vivo* comet assay (OECD TG 489) with either an EMN-test or a BMCA-test. It also suggested noting that it is necessary to perform an *in vivo* assay addressing chromosomal aberrations. The tissues to be investigated in the comet assay should include liver (identified as a target organ in the 90-d repeated dose toxicity study), glandular stomach and gonads.

SECR had modified the DD based on the PfAs.

The Registrant had provided written comments on the PfAs and on the DD. He proposed to conduct an oral EMN-test and noted the possibility of additional investigations based on the study results. However, the Registrant considered that combining this with the comet assay would require an additional dose-finding study, and would lead to a more complex study design and use of more animals.

In the discussion, one MSC member supported the PfA noting that gonadal tissue had not been included in the validation of the comet assay, and suggested at the meeting that the DD should include a description indicating the potential need for further testing in case of negative findings in this tissue. This was not pursued during the meeting. Another member clarified that the test guideline for the EMN-test defined how to proceed in case of a combined EMN-test and comet, while the test guideline for the BMCA-test does not. Other members also supported to have a combination on EMN-test and comet only to cover all possible concerns.

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

TPE-086/2015 3-methoxy-3-methylbutan-1-ol (EEC No. 260-252-4)

Session 2 (closed)

MSC-S 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 a MSC discussion.

SECR introduced the PfA that was received to ECHA's DD. The PfA on sub-chronic toxicity study (90-day) considered inhalation as the most appropriate route of administration as opposed to the requested oral route, because the exposure of humans via inhalation is likely as consumer and professional workers uses with spray application may generate aerosols of inhalable size. The physico-chemical and structural properties also indicated that the substance might become systemically available by the inhalation route. The test should be performed with the preferred species, *i.e.* rat, according to the test method EU B.29/OECD TG 413.

SECR had not modified the DD based on the PfA.

The Registrant provided written comments on the PfA expressing his preference to keep the oral route in agreement with the initial DD.

In the discussion some MSC members supported the inhalation route as the substance in consumer uses was of inhalable size. One member noted that the originally requested oral route could be agreed on, unless there were substantive arguments for the inhalation route. SECR referred to the ECHA guidance document, which defines oral route as default, while other routes could also be relevant such as dermal in this case, and argued that other than oral route should be soundly justified. One MSC member noted that the demonstrated route-to-route extrapolation was sufficient to conclude on risks and agreed with requesting for oral route. Another MSC member suggested updating the guidance.

MSC agreed unanimously to the DD as circulated for the written procedure.

d) General topics

1) Reporting on the status update on appeal cases *(open session)*

SECR provided MSC with feedback from the appeal cases on decisions on dossier and substance evaluation cases.

2) Status report on on-going evaluation work

This information was provided in advance of the meeting, and no further discussion took place.

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

● Prioritisation of substances for the 7th recommendation: Updated prioritisation results of all Candidate List substances not yet recommended

● Learnings from the process for the 6th draft recommendation as compared to the previous recommendations

SECR presented how the assessment of priority of the Candidate List substances had been carried out for this round, including a detailed assessment of 59 registered substances regarding their priority scoring. Results, using the agreed prioritisation approach and any updated information until 1 June 2015, were presented in a table format. Summary of changes compared to the assessment done for the 6th recommendation were also provided to facilitate the reader's review, and the table included verbal explanation and scores, and where relevant, further considerations. Realistic worst case assumptions had been used where lacking, contradicting or poor quality information was provided by the registrants. In order to prepare the draft recommendation for discussion in the next MSC meeting SECR invited for any comments, in particular on the assessment of any specific substances or any further considerations such as grouping. To start the discussion SECR provided observations about the highest scoring substances and potential grouping. Regarding the grouping of lead substances, SECR clarified that information received in last year's public consultation will be taken into account in any grouping for the 7th recommendation. This applies in particular to those comments and consideration which lead to leaving out from grouping some specific lead compounds during the last round. The potential number of

substances in the lead grouping remained similar to last year's, however, the substances included are different. The status of restriction proposals for both NMP and decaBDE were brought up by some members indicating that it should be considered how those might impact on the priority scoring.

One observer from an industry association questioned the overall value of selection of substances at this stage, considering the speed at which new substances are added to the Candidate List and the time required by the Commission to proceed with existing and therefore proposed that less substances than normal should now be prioritised. In his commenting he also mentioned the adverse situation for large consortia if inconsistency of the registration information leads to worst case assumptions for all registrants of the same substance, specifically when repeated efforts to have all registrants update their dossier proved to be fruitless. It was also mentioned that for industry/enterprises public consultations over Christmas period are not at all ideal. While referring to the authorisation process as being slow, an observer from an NGO acknowledged the continuous flow of priority assessments, and encouraged for more groupings as a way to increase efficiency and to avoid unwished substitution.

In the discussion several speakers brought up the need to reach out to Downstream Users to increase their awareness of the public consultation. SECR welcomed any further suggestions and ideas in that regard and encouraged communication at national level and by stakeholders. SECR also noted that again for this round registrants and notifiers of substances subject of the upcoming public consultation will receive a REACH-IT message as an attempt to increase the awareness of the possible progression of their substance(s) towards authorisation.

Another part of the discussion concentrated on any learnings from the process for the 6th draft recommendation as compared to the previous recommendations. On a general level subjecting more substances to the public consultation was considered to make the process more open and transparent. There was a perception that the impact of submitted comments and also the need to consider those comments fully would become more important when the initial list is long. SECR stressed that even with a draft recommendation without 'extra' substances comments will be fully considered and substances left out in case information from the comments justify considerable change in priority of a substance. There was also the view that the impacts of the public consultation on the final recommendation did not justify the additional workload caused by having more substances in the draft recommendation. In this feedback discussion the organisation of work of MSC, and in particular that of the Working Group of MSC, was reflected and some suggestions were made. SECR concluded that this feedback will be considered in preparing the 7th draft recommendation and related actions.

Item 9 – Opinion on the draft recommendation of priority substances to be included in Annex XIV: Tasks and appointment of Rapporteur and possible working group

Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the 7th draft recommendation and for Working Group membership

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

b) Establishment of a MSC Working Group to support the Rapporteur

These items were postponed to the next MSC meeting in October due to lack of time.

Item 10 – Update of stakeholder observers' participation at MSC (closed session)

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

In line with the MSC General approach[1] for admission of observers from accredited stakeholder organisations (ASO), MSC thoroughly considered the ASO participation during the past year, the renewed Animal Welfare NGOs' proposal regarding the ASO quota allocations, the expressions of interest in MSC work of new ASOs and the expressed

[1] http://echa.europa.eu/documents/10162/13578/general_approach_aso_in_msc_work_en.pdf

preferences of some of the ASOs for change of their observer status – from occasional to regular observers or vice versa.

Recognising the importance of ensuring the proper balance of ASO interests at the MSC meetings, the ASO areas of interests in different aspects of the MSC work and the envisaged workload under the MSC processes in the next one year, members discussed the proposal for re-allocation of seats within the 'Industry' and 'NGOs and Trade Unions' quotas and decided to keep unchanged the total number of ASO observers' seats as divided in these two quotas of 7 each. Further, while keeping unchanged the allocated one seat to the trade unions within the 'NGOs & trade union' quota, MSC decided to reduce one of the five seats assigned to the 'Environmental and Human health (ENV&HH) NGOs' to four seats, considering also the good collaboration within this rotational group which appeared to have led to a reduced need for participation, and to re-allocate this seat to the 'Animal Welfare NGOs' quota, in light of expected focus of MSC work on dossier evaluation process in the following year. Further, the Committee decided to reallocate within the 'Industry' quota the seat for Academic Organisations to the General Interest/Sectorial (Industry) Organisations due to clearly expressed interest of the MSC-interested academic organisations to follow the work of the committee on occasional basis.

As regards the ASO admission as MSC permanent observers in different quotas, MSC decided to reconfirm, within 'NGOs and Trade union' quota[2], the MSC regular observer status of: ETUC, the eight ENV&HH NGOs (ChemSec, Client Earth, EEB, Greenpeace, HEAL, Health Care without harm Europe, Women in Europe for Common Future and CHEM Trust) within their rotation group to share four seats[3] when participating in MSC plenary meetings; the four "Animal Welfare NGOs" (ECEAE, Eurogroup for Animals, HSI and PISC) within their group to share two seats[4] when participating in MSC plenary meetings (to be physically present per meeting).

Further, within the 'Industry' quota[5] MSC decided to re-confirm the regular observer status of Cefic, Concawe, Eurometaux, ORO and of CEPE and FECC (the latter two within their rotation group to share one seat[6]) when participating in MSC plenary meetings. Members agreed to keep the regular observer status also of UEAPME, the ASO representing SMEs, who will be mostly represented on a regular basis by the MSC observer from Cefic and will participate in the MSC meetings in person on an occasional basis. Finally, MSC decided to invite one newly registered ASO (European DIY Retail Association) as a MSC regular observer and to change the status of ECETOC from a regular to an occasional MSC observer.

As regards the admission of ASOs as MSC occasional observers, MSC decided to re-confirm the occasional observer status of the remaining ASOs interested in MSC work (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. The Committee also agreed on admission of five new ASOs (Aqua Europa, ECOPA, EECA, EFEO and FORATOM) as MSC occasional observers.

In addition, members gave a mandate to MSC-S to monitor the Animal Welfare NGO participation in the coming year and to ensure that the balance of interests is kept. If imbalanced contributions to MSC's work emerge, MSC-S is requested to consider within the 2016 MSC ASO review and propose a potential reduction of the total number of observer seats to 6:6 in the 'Industry' and in the 'NGOs & trade union' quotas.

The MSC Chairman thanked MSC for the decisions taken and pointed out that MSC-S will inform concerned ASOs of these MSC decisions and will update the list of the MSC ASO observers[7] on ECHA's website after the meeting.

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

Item 11– Any other business

As an AOB item SECR drew MSC's attention to one of the SVHC dossiers currently under public consultation i.e. 1,3-propanesultone. The dossier prepared by ECHA uses a slightly different format for Part II to provide a more structured way to present information such that it can be more readily used in the prioritisation. MSC was invited to provide direct feedback to the SECR on this trial format in order to assess potential re-application for future SVHC identification rounds and potentially the modification of the Annex XV template.

Under another AOB item one of the stakeholder organisations indicated that for transparency reasons they were very interested to have seen an MSC discussion for one of the dossier evaluation cases (CCH-047/2015 - Slimes and sludges, blast furnace and steelmaking) due to a potential difference in the approach used as compared to industry-developed guidance. The Chairman invited all regular observers to flag any future cases of high interest once the provisional draft agenda for a meeting is published and to submit a clear argument why they consider it is important for MSC meeting discussion.

Item 13– Adoption of conclusions and action points

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

Watze de Wolf

Chairman of the Member State Committee

II. List of attendees

Members/Alternate members
ALMEIDA, Inês (PT)
ANDRIJEWSKI, Michal (PL)
COCKSHOTT, Amanda (UK)
COSGRAVE, Majella (IE)
DEIM, Szilvia (HU)
DIMCHEVA, Tsvetanka (BG)
DUNAUSKIENE, Lina (LT)
FINDENEGG, Helene (DE)
GAIDUKOVS, Sergejs (LV)
GIMNAOU, Panayiotis (CY)
HUMAR-JURIC, Tatjana (SI)
KULHANKOVA, Pavlina(CZ)
LONDESBOROUGH, Susan (FI)
LOVRIC, Zdravko (HR)
LUNDBERGH, Ivar (SE)
MARTÍN, Esther (ES)
MIHALCEA UDREA, Mariana (RO)
PISTOLESE, Pietro (IT)
REIERSON, Linda (NO)
RUSNAK, Peter (SK)
STESSEL, Helmut (AT)
TYLE, Henrik (DK)
VANDERSTEEN, Kelly (BE)
VESKIMÄE, Enda (EE)
WAGENER, Alex (LU)
WIJMENGA, Jan (NL)
Representatives of the Commission
GARCÍA-JOHN, Enrique (DG GROW)
KOBE, Andrej (DG ENV)
Observers
ANNYS, Erwin (Cefic)
DROHMANN, Dieter (ORO)
GARMENDIA AGUIRRE, Irantzu (FECC)
HÖK, Frida (ChemSec)
KERÄNEN, Hannu (Concawe)
LEROY, Didier (CEPE)
TAYLOR, Katy (ECEAE)
WAETERSCHOOT, Hugo (Eurometaux)

ECHA staff
AJAO, Charmaine
BERCARU, Ofelia
BORNATOWICZ, Norbert
BROERE, William
CALEY, Jane
CARLON, Claudio
DELOFF-BIALEK, Anna
DE WOLF, Watze
DREVE, Simina
FEEHAN, Margaret
FALCK, Ghita
HALLING, Katrin
JOHANSSON, Matti
KARHU, Elina
KASARUHO, Anisa
KOVARI, Agnes
MÜLLER, Birgit
NAUR, Liina
PELLIZZATO, Francesca
RODRIGUEZ IGLESIAS, Pilar
PREVEDOUROS, Konstantinos
REUTER, Ulrike
RÖNTY, Kaisu
SCHULTHEISS, Christian
VAHTERISTO, Liisa
VALENTINI, Marco
VASILEVA, Katya

Proxies

- MARTÍN, Esther (ES) also acting as proxy of DRUGEON, Sylvie (FR)
- MARTÍN, Esther (ES) also acting as proxy of KOUTSODIMOU, Aglaia (EL)
- PISTOLESE, Pietro (IT) also acting as proxy of BUSUTTIL, Ingrid (MT)
- COSGRAVE, Majella (IE) also acting as proxy of DUNAUSKIENE, Lina during the afternoon of 15 September and morning of 16 September

Experts and advisers to MSC members

AAVIK, Jaanika (EE) (expert to VESKIMÄE, Enda)
ATTIAS, Leonello (IT) (expert to PISTOLESE, Pietro)
AVERBECK, Frauke (DE) (expert to FINDENEGG, Helene)
BALCIUNIENE, Jurgita (LT) (expert to DUNAUSKIENE, Lina)
BOUWMANN, Tialda (NL) (expert to WIJMENGA, Jan)
DE LENTDECKER, Cloé (FR) (adviser to DRUGEON, Sylvie)
SE SAINT JORES, Jérémy (FR) (adviser to DRUGEON, Sylvie)

DRLICKOVA, Martina (SK) (expert to RUSNAK, Peter)
GRACZYK, Anna (PL) (expert to ANDRIJEWSKI, Michal)
INDANS, Ian (UK) (expert to COCKSHOTT, Amanda)
KOZMIKOVA, Jana (CZ) (expert to KULHANKOVA, Pavlina)
LORI, Julia (FR) (adviser to DRUGEON, Sylvie)
MALKIEWICZ, Katarzyna (SE) (expert to LUNDBRGH, Ivar)
MICHEL, Cécile (FR) (expert to DRUGEON, Sylvie)
NYITRAI, Viktor (HU) (expert to DEIM, Szilvia)
RISSANEN, Eeva (FI) (adviser to LONDESBOROUGH, Susan)
ZELJEZIC, Davor (HR) (expert to LOVRIC, Zravko)

MSCA Experts for SEV cases
AUST, Nannett (DE)
THIERRY-MIEG, Morgane (FR)

By WEBEX-phone connection:
During the agenda item 6 for SEV-DE-011/2014: Lena VIERKE (DE), Beryl NYGREN (NO), Cécile BLOM (NO) and Marius GUDBRANDSEN (NO)
During the agenda item 6 for SEV-FR-011/2013: Victor DIAS (FR)
During the agenda item 7 for CCH-069/2015: Ian DOYLE (UK)
During the agenda item 8 from DG GROW: Valentina BERTATO, Giuseppina LUVARA, Wim RIEPMA and Jacek RODZWADOWSKI

Case owners:
Representatives of the Registrants were attending under the agenda item 6.2b for SEV-FR-011/2013 and SEV-DE-011/2014 and under the agenda item 7b for CCH-069/2015.

Apologies:
BUSUTTIL, Ingrid (MT)
DRUGEON, Sylvie (FR)
KOUTSODIMOU, Aglaia (EL)

II. Final Agenda

ECHA/MSC-43/2015/A/43

Final Agenda
43rd meeting of the Member State Committee

15-17 September 2015
ECHA Conference Centre
Annankatu 18, in Helsinki, Finland
15 September: starts at 4 pm
17 September: ends at 12:30 pm

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/043/2015
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-42

- Adoption of minutes of MSC-42

MSC/M/42/2014
For adoption

Item 6 – Substance evaluation

Closed session for 6.2c
Possibly partly closed session for 6d
Indicative time plan for 6.2b is Day 1&2

6.1 Community Rolling Action Plan (CoRAP) & MSC opinion development

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-43/2015/010
For discussion & decision

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

ECHA/MSC-43/2015/011
For discussion and possible decision

6.2 Decision making process

a) Written procedure report on seeking agreement on draft decisions on substance evaluation[8]

b) Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA's/ECHA reactions *(Session 1, tentatively open session)*:
For discussion followed by agreement seeking under 6.2c:

ECHA/MSC-43/2015/005

MSC code	Substance name	EC number	Documents
SEV-FR-011/2013	3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate	202-112-7	ECHA/MSC-43/ 2015/001-002
SEV-DE-011/2014	di-tert-butyl 3,3,5-tri-methylcyclohexylidene diperoxide	229-782-3	ECHA/MSC-43/ 2015/003-004

For discussion

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

Cases as listed above under **6.2 b**

For agreement

d) General topics

- Appeals update[9]

For information

Item 7 – Dossier evaluation

Closed session for 7c
Possibly partly closed session for 7d
Indicative time plan for 7b is Day 1

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

ECHA/MSC-43/2015/006
For information

[8] A written procedure has not been initiated for Substance Evaluation cases.
[9] A combination of Appeal updates for Substance and Dossier Evaluation may be introduced, if appropriate.

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

ECHA/MSC-43/2015/007

For discussion followed by agreement seeking under 7c:

Compliance checks

MSC code	Substance name	EC Number	Documents
CCH-069/2015	2,2'-dimethyl-4,4'-methylene-bis(cyclohexylamine)	229-962-1	ECHA/MSC-43/2015/008-009

For discussion

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

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

MSC code	Substance name	EC Number	Documents
Compliance checks			
CCH-046/2015	N-isopropyl-N'-phenyl-p-phenylenediamine	202-969-7	ECHA/MSC/D/2015/112-113[10]
Testing proposal examinations			
TPE-086/2015	3-methoxy-3-methylbutan-1-ol	260-252-4	ECHA/MSC/D/2015/138-139[3]

For agreement

d) General topics

- Appeals update[2]

For information

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

- Prioritisation of substances for the 7th recommendation: Updated prioritisation results of all Candidate List substances not yet recommended

ECHA/MSC-43/2015/012

For discussion

- Learnings from the revised process for the 6th draft recommendation as compared to the previous recommendations

For discussion

Item 9 – Opinion on the draft recommendation of priority substances to be included in Annex XIV: Tasks and appointment of Rapporteur and possible working group

Invitation for volunteers for the Rapporteurship in drafting the opinion of the MSC on the 7th draft recommendation and for Working Group membership

a. Draft terms of Reference and possible appointment of the Rapporteur

[10] Documents are available for members in MSC CIRCABC Substance specific folders.

ECHA/MSC-43/2015/014
For discussion & decision

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

ECHA/MSC-43/2015/015
For discussion & decision

Item 10 – Update of stakeholder observers' participation at MSC
Closed session

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

ECHA/MSC-43/2015/016
For discussion & decision

Item 11 – Any other business

- Call for feedback on the proposed new format of the SVHC dossier for Part II
- Suggestions from members

For information

Item 12– Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-43

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

- *Update by ECHA on the work on the next annual CoRAP update (presentation slides)*
- *Substance evaluation status report (presentation slides)*
- *Dossier evaluation status report (presentation slides)*
- *Update from other ECHA bodies and activities (ECHA/MSC/I/2015/024)*

Outside plenary activities (tentatively during lunch hour of Day 2)**:**
- *Presentation by ECHA entitled: Opportunities for 'Omics' under REACH*

IV. Main Conclusions and Action Points

Main conclusions and action points
MSC-43, 15-17 September 2015
(adopted at MSC-43)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues	
MSC was informed that the MSC Secretariat has initiated a project to review MSC's written procedure approaches across different MSC agreement seeking processes.	**Members** willing to contribute to the review are invited to provide their feedback on MSC written procedures to MSC-S as soon as possible.
Item 5 – Minutes of the MSC-42	
MSC adopted the draft minutes as provided for the meeting and further modified during the meeting.	**MSC-S** to upload final version of the minutes on MSC CIRCABC by 21 September 2015 and on ECHA website without undue delay.
Item 6 - Substance evaluation **6.1 Community Rolling Action Plan (CoRAP) & MSC opinion development** 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.	**SECR** to send the appointment letters to the Rapporteur and the Co-Rapportuer.
Item 6 - Substance evaluation **6.2 Decision making process** **b) Introduction to and preliminary discussion on draft decisions on substance evaluation after MS-CA's/ECHA reactions *(Session 1, tentatively 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-FR-011/2013 3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate (EC No 202-112-7) SEV-DE-011/2014 di-tert-butyl 3,3,5-tri- methylcyclohexylidene diperoxide (EC No 229-782-3)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases. **ECHA's Legal Affair Unit** in collaboration with the **eMSCA** to include appropriate text in the draft decision for SEV-DE-011/2014 on a shortened deadline in case only one simulation test is performed.
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 CIRCABC the final ECHA decisions agreed in written procedure, as indicated in document ECHA/MSC-43/2015/006.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
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)*** **c. Seeking agreement on draft decisions on testing proposal examinations 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): CCH-069/2015 2,2'-dimethyl-4,4'-methylene-bis(cyclohexylamine) (EC No 229-962-1) CCH-046/2015 N-isopropyl-N'-phenyl- p-phenylenediamine (EC No 202-969-7) TPE-086/2015 3-methoxy-3- methylbutan-1-ol (EC No 260-252-4)	**MSC-S** to upload on MSC CIRCABC the final ECHA decisions of the agreed cases.
Item 8 – ECHA's draft recommendation of priority substances to be included in Annex XIV • Prioritisation of substances for the 7th recommendation: Updated prioritisation results of all Candidate List substances not yet recommended • Learnings from the revised process for the 6th draft recommendation as compared to the previous recommendations	
MSC took note on the SECR's report on the work carried out as the priority assessment for preparing for the 7th draft recommendation.	**MSC** to provide any further input or views in writing to ECHA by 28th September 2015.
Item 10 – Update of stakeholder observers' participation at MSC • Discussion and update of the MSC decision about the invited organisations	
MSC took note of the presented update of the ASO observers' participation in the MSC work and took the following decisions: 1. With regard to the balance of interests and allocation of seats in different quotas, MSC decided to: • keep unchanged the total number of ASO observers' seats as divided in two quotas of 7 each[11], • re-allocate within the 'Industry' quota the seat for Academic Organisations to the General Interest/Sectorial Industry Organisations, • keep unchanged the allocated one seat to the trade unions within the 'NGOs & trade union' quota, • reduce one of the five seats assigned to the 'Environmental and Human health NGOs' to four seats, • re-allocate the seat from the ENV&HH NGOs to the 'Animal Welfare NGOs', in light of expected focus of MSC work on dossier evaluation process, • mandate the MSC Secretariat to monitor the Animal Welfare NGO participation in the coming year and to ensure that the balance of interests is kept, 2.With regard to the admission of ASOs as MSC permanent observers in different quotas, MSC decided to: • reconfirm the MSC regular observer status of: ➢ eight Environmental and Health Care NGOs (ChemSec, Client Earth, EEB, Greenpeace, HEAL, Health Care without harm Europe, Women in Europe for	**MSC** to review ASO participation in its work in one year's time **MSC-S** to inform ASOs concerned of outcome of MSC decisions taken and update the list of the MSC ASO observers on ECHA's website ater the meeting **MSC-S** to monitor the Animal Welfare NGO participation in the coming year and endeavour to ensure that the balance of interests is kept If imbalanced contributions to MSC's work emerge, **MSC-S** to consider and propose a potential reduction of the total number of observer seats to 6:6 in the 'Industry' and in the 'NGOs & trade union' quotas (within the 2016 MSC ASO review)

[11] Seven seats are assigned to the 'Industry' quota and seven seats are assigned to the 'NGOs & trade union' quota.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Common Future and CHEM Trust) 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, • change the status of ECETOC and EUROTOX from regular to occasional MSC observers, • invite EDRA as a MSC regular observer. 3. 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 Aqua Europa, ECOPA, EECA, EFEO and FORATOM as MSC occasional observers. Further, MSC decided to request the MSC Secretariat to consider within the MSC ASO review next year (2016/2017) a potential reduction of the total number of observer seats to 6:6 in the 'Industry' and in the 'NGOs & trade union' quotas, if experience would show that imbalanced contributions to MSC's work emerge.	
Item 11 – Any other business	
MSC noted the SECR's remark that a new format of the SVHC dossier for Part II (Uses and exposure) has been used by the SECR for one substance (1,3-propanesultone) in the current consultation round.	**MSC** to provide feedback on the new format for Part II (Uses and exposure) of a SVHC dossier by 15 October 2015.
Item 12– Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-43 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC CIRCABC by 18 September 2015.

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

Draft decisions unanimously agreed by MSC in WP:

Testing proposal examinations

MSC ID number	Substance name used in draft decision	EC number
TPE-074/2015	4,4'-(9H-fluoren-9-ylidene)bis(2-chloroaniline)	407-560-9
TPE-078/2015	3,5-diamino-4-[[4-[[2-(sulfooxy)ethyl]sulfonyl]-phenyl]azo]-2-[[2-sulfo-4-[[2-(sulfooxy)ethyl]-sulfonyl]phenyl]azo]benzoic acid sodium salt (Everzol Orange ED-G Crude)	480-890-9
TPE-081/2015	Octene, hydroformylation products, low-boiling	273-110-1
TPE-082/2015	N,N'-hexane-1,6-diylbis(hexahydro-2-oxo-1H-azepine-1-carboxamide)	227-563-7
TPE-083/2015	Reaction mass of N-[2-(2-oxoimidazolidin-1-yl)ethyl]methacrylamide and methacrylic acid	934-058-1
TPE-099/2015	Copolymer of neodecanoic acid oxiranylmethyl ester and 4-methylbenzenesulfonic acid	500-281-4
TPE-100/2015	2-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol	221-573-5
TPE-101/2015	2-(2H-benzotriazol-2-yl)-4,6-bis(1-methyl-1-phenylethyl)phenol	274-570-6
TPE-102/2015	6-tert-butyl-2,4-xylenol	217-533-1

Compliance checks (CCH)

MSC ID number	Substance name used in draft decision	EC number
CCH-047/2015	Slimes and Sludges, blast furnace and steelmaking	266-006-2
CCH-050/2015	Condensation products of tall-oil fatty acids with diethanolamine and triethanolamine	267-053-1
CCH-055/2015	Dioctadecyl 3,3'-thiodipropionate	211-750-5
CCH-056/2015	Oxirane, mono[(C12-14-alkyloxy)methyl] derivs.	271-846-8
CCH-066/2015	Ammonium carbamate	214-185-2
CCH-068/2015	Benzyl alcohol	202-859-9