MSC/M/70/2020

Minutes

of the 70th Meeting of the Member State Committee (MSC-70)
10-12 June 2020
web conference

Adopted on 7 September 2020

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 70th meeting of the Member State Committee (MSC) which was held as a web conference meeting (for the full list of attendees and further details see Part II of the minutes). The Chairman referred to the web conference instruction which the participants had received prior to the plenary meeting.

The Chairman informed MSC that part of plenary would be chaired for the first time by the newly appointed Deputy Chair, Ms Charmaine Ajao.

Item 2 - Adoption of the Agenda

The Agenda was adopted with an editorial change to the (timed) draft agenda that the session 6.4 and 7.4 on written procedure plans would not need to be held in closed session (final Agenda is attached to these minutes as Section III).

Item 3 - Declaration of specific interests to items on the Agenda

No potential specific interests were declared by any members, experts or advisers with any item on the agenda of MSC-70.

Item 4 - Administrative issues

- Outlook for MSC-70bis and MSC-71

The Chairman informed MSC that the MSC-70bis round dossier evaluation draft decisions did not receive PfAs, thus no involvement of MSC is required in finalising those.

The Chairman presented an outlook on the potential length of MSC-71 meeting which is expected to require up to 2.5 plenary days.

- Presentation on modules and use of Interact tool

SECR informed MSC about the latest updates on the Interact tool regarding the Meeting, Consultation and Collaboration modules. SECR presented plans on the onboarding of the users and informed MSC of the upcoming training in September 2020. SECR also reminded MSC that administration of access rights in Interact will be different from the current S-CIRCABC access management, requiring extra steps, and therefore members, experts and advisors with no physical token should request access as soon as possible. SECR informed MSC that the issue of retaining and archiving of documents from former meetings is under consideration and that SECR foresees it will stop this practice in the future.

Item 5 – Minutes of the MSC-69 meeting

The minutes of MSC-69 were adopted as provided for the meeting.

Item 6 – Substance evaluation

1. Written procedure plans on seeking agreement on draft decisions on substance evaluation

1.1. Introduction to the PfAs and Registrants comments on draft decisions on substance evaluation when amendments were proposed by MS-CA's/ECHA and preliminary discussion *(Closed session)*

The Deputy Chair reminded MSC of the changes in the Evaluation timelines for this MSC-70 round. The Member State Competent Authorities (MSCAs) and ECHA Secretariat were given 60 days to propose amendments (PfAs) to the draft decisions (DDs) compared to the usual 30 days, due to the COVID-19 situation, when everyone needed to adapt a new way of working from home.

Due to this, the deadline for Registrants to comment on the PfAs received became 1 June. For one Registrant, who submitted a request for a further extension with justification, the deadline to comment became 15 June. As the latest comments were received very close to the plenary, the MSC could not go for agreement seeking on the DD for these cases during MSC-70 plenary. Agreement would be sought in written procedure between 29 June and 8 July.

The discussions were held in closed session as it was not possible to seek the Registrants' agreement for a discussion in open session in the presence of MSC's stakeholders before the start of the meeting.

SEV-2-FR-013/2013 Tris(4-nonylphenyl, branched) phosphite (EC. No 701-028-2)

The expert from the evaluating Member State Competent Authority (eMSCA) from France (FR-CA) shortly introduced the case (SEV-2-FR-013/2013) to MSC referring to the Proposals for Amendment (PfAs) submitted, and their responses to them.

The Registrants did not submit comments by the deadline.

MSC supported that all PfAs can be considered resolved.

The eMSCA will finalise the draft decision (DD) for MSC's written procedure agreement seeking starting on 29 June.

SEV-BE-008/2018 Amphoteric Fluorinated Surfactant

The expert from the evaluating Member State Competent Authority (eMSCA) from Belgium (BE-CA) shortly introduced the case (SEV-BE-008/2018) to MSC referring to the Proposal for Amendment (PfA) submitted, their responses to it and the Registrant's comments.

The Registrant submitted comments that Amphoteric Fluorinated Surfactant (AFS) was a related substance to undecafluorohexanoic acid (PFHxA) for which a restriction had been proposed (end of 2019) after the Registrant commented on the first draft decision. The Registrant requested to conclude the substance evaluation of AFS immediately.

The eMSCA confirmed that AFS was indeed a related substance to PFHxA and was therefore part of the ongoing restriction proposal. The eMSCA proposed to terminate the substance evaluation of AFS, thereby leaving the ED concern unresolved and to reconsider the need for substance evaluation later when a decision on the restriction proposal for PFHxA, its salt and related substances has been reached.

MSC supported the approach to conclude the Substance evaluation.

The eMSCA will take into account the suggestions from MSC in amending the draft agreement document for MSC's written procedure agreement seeking starting on 29 June.

SEV-ES-010/2018 3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)hexane (EC No. 435-790-1)

The expert from the evaluating Member State Competent Authority (eMSCA) from Spain (ES-CA) shortly introduced the case (SEV-ES-010/2018) to MSC referring to the Proposals

for Amendment (PfAs) submitted, their responses to them and the Registrant's comments on the PfAs. The Registrant also requested for longer timelines to perform the tests.

MSC had a technical discussion on the use of sterile controls in the requested aquatic sediment simulation study (OECD TG 308), submitted through a PfA. MSC supported including a request for purified water and water-sediment sterile controls and advised the eMSCA to only provide general guidance to the Registrant in the draft decision (DD) on aspects to take into account when selecting the most appropriate sterilisation approach.

The eMSCA will take into consideration the MSC discussion in their finalisation of the DD for MSC's written procedure agreement seeking starting on 29 June.

SEV-2-AT-002/2012 Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate (EC No. 222-020-0)

The Deputy Chair informed that this was a 2nd evaluation decision focusing on a concern for environmental endocrine disruption. There was ongoing compliance check (CCH) on the same substance that was discussed under item 7 (CCH-038/2020) focusing on human health concerns. The Registrants had requested for more time to comment on the PfAs due to the COVID-19 situation. ECHA agreed to take into account comments on the PfAs submitted by 15 June 2020 close of business.

The evaluating Member State Competent Authority (eMSCA) from Austria (AT-CA) shortly introduced the case (SEV-2-AT-002/2012) to MSC referring to the Proposals for Amendment (PfAs) submitted, and their responses to them.

MSC supported that all PfAs could be considered resolved pending their assessment of the comments from the Registrants.

The eMSCA will take into consideration the Registrants' comments received by 15 June in their finalisation of the DD for MSC's written procedure agreement seeking starting on 29 June.

1.2 Written procedure timing plans

The Chairman reminded members of the planned timeline for launching of the written procedure of SEv after the meeting where the planned launch date is 29 June with closure of written procedure on 8 July.

The Chairman indicated that in the eventuality there was a draft decision which would not be agreeable during the written procedure, such a case could exceptionally be postponed for discussion and agreement seeking during the October meeting (MSC-71). In such instances, members can submit a request to stop the written procedure with a justification why further discussions make it more probable to find unanimous agreement on the draft decision.

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

No cases

3. General topics

None

Item 7 – Dossier evaluation

1. Written procedure plans on seeking agreement on draft decisions on dossier evaluation

1.1. Introduction to the PfAs and Registrants' comments on draft decisions on compliance checks and testing proposals when amendments were proposed by MS-CA's and preliminary discussion *(Closed session)*

Compliance checks

CCH-038/2020: Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate (EC No. 222-020-0)

ECHA Secretariat (SECR) introduced the case to MSC referring to the proposals for amendment (PfA) and SECR responses.

The Registrant had requested for more time to comment on the PfAs due to the COVID-19 situation. ECHA agreed to take into account comments on the PfAs submitted by 15 June 2020 close of business. By the time of the meeting, the Registrant had already submitted their comments disagreeing with the PfAs; a more detailed analysis was pending.

The MSC discussed the PfAs on the extended one-generation reproductive toxicity study (EOGRTS), which suggested including the cohorts 2A and 2B (developmental neurotoxicity, DNT) and cohort 3 (developmental immunotoxicity, DIT) based on available information on the registered substance, specific mechanism/mode of action with an association to DNT and DIT, namely (anti)estrogenic and (anti)androgenic effects observed *in vitro* and/or *in vivo*, and on a structurally similar substance bis(2-ethylhexyl) phthalate (DEHP) known to cause DNT and DIT.

The MSC discussed the data available to support including the DNT and DIT cohorts, taking note of the legal requirements for such a request. The MSC concluded that it considered all PfAs still unresolved. SECR will consider the MSC discussion and Registrant's comments in finalising the draft decision (DD) for the MSC agreement seeking via the written procedure.

CCH-051/2020 2,2'-azobis[2-methylbutyronitrile] (EC No. 236-740-8)

ECHA Secretariat (SECR) introduced the case to MSC referring to the proposals for amendment (PfA) and SECR responses. The Registrant had submitted their comments on the PfAs by the deadline on 1 June 2020. The MSC considered all PfAs resolved. SECR will consider the MSC discussion in finalising the draft decision (DD) for MSC agreement seeking via the written procedure.

1.2. Introduction of the written procedure timing plans

For the dossier evaluation (DEv) cases, the consultation period for MSCAs started on 28 February 2020 and closed on 27 April 2020. The length of the MSCA consultation was extended to 60 days instead of the standard 30 days due to the COVID-19 pandemic outbreak. Therefore, the processing of the DEv cases no longer coincided with the set MSC plenary meeting dates. The discussion at MSC-70, summarised above, was of an introductory nature, with a view to have both cases submitted to the written procedure, which will be launched on 29 June 2020 and closed on 8 July 2020. The written procedure report would be presented at the MSC-71 meeting in October 2020.

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

No cases

3. General topics

(1) Dossier evaluation *in vivo* comet assay requests in case of concerns for both chromosomal aberrations and gene mutation *(partly closed session)*

SECR presented an approach under dossier evaluation (DEv) for a request of a standard *in vivo* comet assay in case concerns for both chromosomal aberrations (CA) and gene mutation (GM) are identified *in vitro* for cases with no *in vivo* data. The presentation was a follow up on the discussion at MSC-68 and the material had been largely prepared in collaboration between SECR and experts from four Member States and the Cefic.

The presentation laid out various scenarios arising from a combination of bacterial cell and mammalian cell *in vitro* studies and identified the concern arising from each scenario. The *in vitro* studies considered are: (a) the Ames study (OECD TG 471), which detects point or gene mutations and leads to GM concern if positive; (b) the CA test (CAvit, OECD TG 473), which detects structural chromosomal aberrations and leads to CA concern if positive; (c) the micronucleus (MN) test (Mnvit, OECD TG 487), which detects aneugens and clastogens (i.e. numerical and structural chromosomal aberration, respectively) and leads to CA concern if positive; (d) the test using the Hprt gene (OECD TG 476), which detects gene mutations and leads to GM concern; (e) the tests using the xprt gene (OECD TG 476), which detects gene mutations and/or chromosomal events leading to GM and/or CA concerns; and (f) the tests using the TK gene (OECD TG 490), which detect gene mutations and/or chromosomal events, depending on colony size information, leading to GM and/or CA concerns, although sometimes with some scientific uncertainty.

Whilst the MSC agreed that requesting a standard *in vivo* comet assay was a good approach when both CA and GM concerns exist, MSC took note that a combined study of comet assay and the MN test would have several advantages: (a) it follows up two concerns (comet assay is a genotoxicity indicator test addressing GM and CA concerns and MN is a mutagenicity test investigating the CA concern); (b) it uses the same number of animals as one test; (c) it enhances the sensitivity to detect genotoxicity; (d) it investigates both site of contact tissues and distant organs; and (e) the comet assay alone is not adequate to study aneugenic substances. SECR estimated that the cost of a combined study would be about 25% more than for comet assay alone.

The MSC supported the proposal to request the combined comet assay and MN test for REACH Annex X substance. SECR shared also the view that the combined study can be considered as one study, hence it would be proportionate and adequate at REACH Annex VIII and IX as well.

The MSC also noted that although the discussion was mainly related to the compliance checks (CCH), the approach may as well apply to testing proposal examinations (TPE).

Based on the discussions, the MSC made several conclusions: (a) the combined comet assay and micronucleus (MN) test can be considered as one single study, which is in line with some other organisations; (b) such a combined study of the comet assay and the MN test would be, by default, most suitable when concerns for both CA and GM exist and no *in vivo* genotoxicity data were available in the dossier, and this would apply, by default, to DEv cases undergoing compliance checks and testing proposal examinations; (c) the approach would apply, in addition to REACH Annex X, also to Annexes VIII and IX, which fulfils the Annex requirements for "appropriate *in vivo* mutagenicity studies" and "appropriate *in vivo* somatic cell genotoxicity study", respectively. The MSC noted that in the situation where only the concern for CA exists, the choice can continue to be given between the comet assay, the MN test and the CA test. The MSC additionally concluded (in line with the agreement at MSC-56 for substances known to induce crosslink) to continue recommending to add the modified protocol for the comet assay for substances known to induce oxidative DNA damage.

The MSC agreed that its conclusions would comprise a suitable default approach for mutagenicity cases, when concerns for both CA and GM exist and no *in vivo* genotoxicity data were available in the dossier.

The MSC requested SECR to implement the agreed approach for the draft decisions (DD) standard text on DEv cases and apply it for new DDs to be sent to the Registrants. It

should also apply for ongoing cases which have been sent to the Registrants and are to be notified to MSCAs.

Finally, MSC invited SECR to communicate externally the new approach through appropriate channels.

(2) Invitation to discuss a decision tree for terrestrial endpoints under dossier evaluation

SECR presented the background on its internal approach to streamline the assessment of needs for terrestrial toxicity studies. It noted in particular that the criteria therein followed ECHA guidance documents and the REACH Regulation. The MSC took note of the information and SECR's invitation to nominate Member State environmental experts, if interested and resources allow, to discuss the topic on requesting terrestrial studies under dossier evaluation. The MSC invited SECR to present the outcome at its next meeting.

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

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

SECR gave a brief report on the outcome of the written procedure for SVHC agreement seeking on the identification of two substances, *Dibutylbis(pentane-2,4-dionato-O,O')tin* (EC No. 245-152-0) and *Butyl 4-hydroxybenzoate* (EC No. 202-318-7), proposed to be identified as SVHC based on Article 57 of Regulation (EC) 1907/2006. The former was proposed as SVHC due to toxicity for reproduction and the latter due to its endocrine disrupting properties for human health. MSC agreed unanimously on the identification of these two substances as SVHC in the written procedure launched on 19 May 2020 and closed on 28 May 2020. SECR explained that the final documents have been published in MSC S-CIRCABC and will be published on the ECHA website, and that these substances will be included in the Candidate List of SVHCs in its next update in June 2020.

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

Resorcinol (EC No. 203-585-2)

The dossier submitter (DS) representative from the French CA presented to MSC the Annex XV proposal for identification of resorcinol as an SVHC under Article 57 (f) due to its ED (endocrine disrupting) properties for which there is evidence of probable serious adverse effects to human health giving rise to equivalent level of concern (ELoC) to CMR, PBT and vPvB substances under Article 57 (a)-(e).

The DS gave an overview of the ED assessment of the substance. The DS explained that the hypothyroidism observed in humans, as well as the histopathological changes in the thyroid and changes in the circulating levels of thyroid hormone observed in experimental studies are consistent with the thyroid MoA (mode of action) via TPO (thyroperoxidase) inhibition. In addition, the DS further explained that the OECD has recently validated an AOP (adverse outcome pathway) describing the relationship between inhibition of TPO, decreased T4 (thyroxine) and neurodevelopmental alteration due to maternal low T4 concentration as having a high level of evidence for humans (AOP n°42[1]). The DS concluded that resorcinol fulfils the ED definition by the WHO (World Health Organization)/IPCS (International Programme on Chemical Safety) (2002).

In presenting the overview of the ELoC assessment, the DS explained that some of the effects that resorcinol may induce in relation to its thyroid-disrupting potential are serious and irreversible, and occur after a longer latency period. They can impact the quality of life and raise societal concern of a high and increasing burden. The difficulty to establish a

[1] https://aopwiki.org/aops/42

safe level with sufficient certainty raises concern on the capacity to manage safe use of the substance, in particular for sensitive populations, also considering that small changes in maternal T4 can affect brain development of the offspring. The DS concluded that altogether, this gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 REACH**.**

The DS outlined the main comments received in the public consultation (PC) on the Annex XV report and the DS' responses to them. The public consultation had yielded both supporting and diverging views. The DS submitter invited MSC to consider some of the issues raised as being resolved, and MSC decided the ones it wished to further reflect upon.

The adviser to the Cefic observer brought some further clarification on industry comments submitted in the public consultation, in particular concerning the arguments related to the exposure conditions in the human medical case reports and the rationale of the design of a two-generation study referred to in the Annex XV report.

MSC unanimously acknowledged that there is scientific evidence that resorcinol is an endocrine disruptor as defined by the WHO/IPCS (2002). Some members abstained from sharing their views on this, and one of them described this as a borderline case.

There were views expressed that the available scientific evidence does not show that resorcinol is a substance of very high concern because of its thyroid disrupting properties, causing probable serious effects to human health, which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57.

Several MSC observers expressed support for the DS's proposal. The EEB observer requested for a reflection from those members expressing reservations on the ELoC assessment on which elements addressed in the draft support document they considered were not met by resorcinol.

The main arguments voiced against the proposal for ELoC were similar to those expressed also in the public consultation. These included the exceptional exposure conditions encountered in relatively old and poorly reported human medical case reports (i.e. ulcerated skin and potentially changed toxicokinetics due to lipophilic vehicle) and the available experimental animal data especially the two-generation reproductive toxicity study (OECD TG 416) which they considered as the key study, which did not provide consistent evidence on thyroid adversity. Views were expressed that there is only data to demonstrate that resorcinol fits the first key events in AOP n°42 and no data for key events closer to the Adverse Outcome (decreased cognitive function).

MSC went through the text of the Support Document with amendments introduced at the meeting.

When the MSC agreement document and support document were brought to a vote, a majority of the members agreed that the available information for resorcinol is sufficient to conclude that there is scientific evidence of probable serious effects giving rise to an equivalent level of concern in relation to human health (i.e. to substances listed in points (a) to (e) in Article 57 of the REACH Regulation). However, eight MSC members abstained (including AT, CZ, DE, IE, NL, SK) and two of them requested to attach a justification of their vote to the minutes (see Section V). Additionally, three members (FI, IT, PL) did not agree on the identification of resorcinol under Article 57(f) as giving rise to an equivalent level of concern in relation to human health. SECR introduced the editorial changes required to convert the MSC agreement document into an MSC opinion, and the minority view was orally presented. The latter, to be submitted in writing after the meeting, is to be annexed to the MSC opinion.

The MSC Chairman noted that as MSC was unable to reach unanimity, the European Commission's REACH Committee will take the final decision on the SVHC proposal. After

referral of the documents associated with the MSC's opinion, the European Commission will have to prepare a draft proposal on the identification of resorcinol as an SVHC and will then make a final decision in its committee procedure.

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

Item 9 – ECHA's recommendations of priority substances to be included in Annex XIV and opinion of MSC and

Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2021-2023)

Invitation for volunteers for rapporteurship

The Chairman reminded members of the need for volunteers for rapporteurship related to the MSC opinion forming processes for both the annual draft CoRAP update and 10th Annex XIV draft recommendation. He indicated that a written invitation to be sent by email will outline the more detailed timing plans for both processes. Members were encouraged to consider volunteering until mid-September, when the actual appointment would be on the MSC agenda in October.

As regards the ECHA's 10th recommendation of priority substances to be included in Annex XIV the Chairman mentioned that the commenting on the 10th draft recommendation on the website has closed in early June and the comments should be available on the ECHA website early next week. Any confidential comment-tables are accessible to members from the S-CIRCABC platform.

Item 11 – Any other business

1. Update on appeals and court cases of relevance to MSC

SECR gave an overview of a new decision of the Board of Appeal (BoA) of ECHA in Case A-011-2018 dismissing an appeal against an ECHA dossier evaluation decision. MSC took note of the information received and in particular the BoA's decision on long term toxicity test on fish. SECR also gave a brief update on a new appeal case A-001-2020 on Evaluation. SECR further gave an overview on a new court case T-127/20 submitted to the European Court of Justice challenging BoA decision on Substance Evaluation. SECR also gave a short summary on pending court cases on Authorisation and pending appeals and court cases on Evaluation.

2. Suggestions from members

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

Item 12 – ECHA's Executive Director address to MSC

ECHA's Executive Director, Mr. Hansen, spoke to MSC on the occasion of its 70th plenary meeting, congratulating MSC for its continuous good work and achievements. He also outlined some of the future challenges ahead.

Item 13 - Adoption of main conclusions and action points

MSC adopted the main conclusions and action points at the MSC-70 meeting (see Section IV).

II. List of attendees

Members/Alternate members	**ECHA staff**
ALMEIDA, Inês (PT)	AJAO, Charmaine
ATTIAS, Leonello (IT)	ANASTASI, Audrey Anne
BARTHELEMY-BERNERON, Johanna (FR)	ANDERSSON, Niklas
CONWAY, Louise (IE)	BECKER, Falk
DE KNECHT, Joop (NL)	BELL, David
DIMITROVA, Rada (BG)	BERCARU, Ofelia
DUDRA, Agnieszka (PL)	BROECKAERT, Fabrice
FERNÁNDEZ SÁNCHEZ, Raquel (ES)	BROERE, William
FINDENEGG, Helene (DE)	CALEY, Jane
GRIZELJ, Romana (HR)	CATHERINE, Arnaud
HERMES, Joe (LU)	CLENAGHAN, Conor
HJORTH, Rune (DK)	CONSOLI, Elisa
HORSKÁ, Alexandra (SK)	DE COEN, Wim
HUMAR-JURIČ, Tatjana (SI)	DE WOLF, Watze
JANTONE, Anta (LV)	FURUNO, Shoko
KOUTSODIMOU, Aglaia (EL)	HAUTAMÄKI, Anne
KULHÁNKOVÁ, Pavlína (CZ)	HERBATSCHEK, Nicolas
MALKIEWICZ, Katarzyna (SE)	JOHANSSON, Matti
MIHALCEA UDREA, Mariana (RO)	JUTILA, Arimatti
NUGIN, Merike (EE)	KAPANEN, Anu
PALEOMILITOU, Maria (CY)	KARJALAINEN, Anne-Mari
REIERSON, Linda (NO)	KARKOLA, Sampo
RISSANEN, Eeva (FI)	LE CURIEUX, Frank
ŠPŪRIENĖ, Otilija (LT)	LEPPÄRANTA, Outi
STESSEL, Helmut (AT)	LISBOA, Duarte
TARNÓCZAI, Tímea (HU)	LUOMA, Leena
VANDERSTEEN, Kelly (BE)	NAUR, Liina
Representatives of the Commission:	O'FARREL, Norah
KOBE, Andrej (DG ENV)	PELLIZZATO, Francesca
PIRSELOVA, Katarina (DG ENV)	RÖNTY, Kaisu
WODLI, Jordane (DG ENV)	SCHULTZ, Bernadette
Observers	SOBANSKA, Marta
ASHFORD, Paul (Cefic) expert during agenda point 8	SOSNOWSKI, Piotr
BERNARD, Alice (ClientEarth)	VAHTERISTO, Liisa
CINGOTTI, Natacha (HEAL)	WOLLENBERGER, Leah
DREVE, Simina (FECC)	
DROHMANN, Dieter (ORO)	
FERNANDES DE BARROS, Mariana (Cefic)	
GRANGE, Emma (CFE)	
LEINALA, Eeva (OECD)	
LENNQUIST, Anna (ChemSec)	
LOONEN, Helene (EEB)	
PROCHAZKA, Erik (PISC)	
WAETERSCHOOT, Hugo (Eurometaux)	

Proxies
Helmut, STESSEL (AT) also acting as proxy of HERMES, Joe (LU) on 12 June

Experts and advisers to MSC members
ALIVERNINI, Silvia (IT) (Advisor to ATTIAS, Leonello)
BALČIŪNIENĖ, Jurgita (LT) (Expert to ŠPŪRIENĖ, Otilija)
BOLWIG, Asger (DK) (Expert to HJORTH, Rune)
CATONE, Tiziana (IT) (Expert to ATTIAS, Leonello)
CIESLA, Jacek (PL) (Expert to DUDRA, Agnieszka)
COPOIU, Oana (RO) (Expert to MIHALCEA UDREA, Mariana)
DOBRAK VAN BERLO, Agnieszka (BE) (Expert to VANDERSTEEN, Kelly)
EINOLA, Juha (FI) (Advisor to RISSANEN, Eeva)
FABRE, Julien (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
FANGUET, Céline (FR) (Expert to BARTHELEMY-BERNERON, Johanna)
FILIPOVA, Hristina (BG) (Expert to DIMITROVA, Rada)
GARCIA HERNANDEZ, Patricia (ES) (Expert to FERNÁNDEZ SÁNCHEZ, Raquel)
GUETZKOW, Kristine Bjerve (NO) (Expert to REIERSON, Linda)
GUHE, Christine (DE) (Expert to FINDENEGG, Helene)
HASSOLD, Enken (DE) (Expert to FINDENEGG, Helene)
HEGGELUND, Audun (NO) (Expert to REIERSON, Linda)
HÖLZL, Christine (AT) (Expert to STESSEL, Helmut)
JÖHNCKE, Ulrich (DE) (Advisor to FINDENEGG, Helene)
KAARTINEN, Tomi (FI) (Advisor to RISSANEN, Eeva)
KOKAVCOVA, Martina (SK) (Advisor to HORSKÁ, Alexandra)
KOZMÍKOVÁ, Jana (CZ) (Expert to KULHÁNKOVÁ, Pavlína)
KRUSE ANTON, Julie Marie (DK) (Expert to HJORTH, Rune)
KUROVA, Martina (SK) (Expert to HORSKÁ, Alexandra)
LANDVIK, Nina (NO) (Expert to REIERSON, Linda)
LANGE, Vivien (DE) (Expert to FINDENEGG, Helene)
LEJONKLOU HALIN, Margareta (SE) (Expert to MALKIEWICZ, Katarzyna)
LORENZETTI, Stefano (IT) (Expert to ATTIAS, Leonello)
LUNDBERGH, Ivar (SE) (Expert to MALKIEWICZ, Katarzyna)
MARTÍN, Esther (ES) (Expert to FERNÁNDEZ SÁNCHEZ, Raquel)
MARTIN, Nellie (DK) (Expert to HJORTH, Rune)
MENDONÇA, Elsa (PT) (Expert to ALMEIDA, Inês)
REDMOND, Aisling (IE) (Expert to CONWAY, Louise)
ROSENTHAL, Esther (DE) (Advisor to FINDENEGG, Helene)
STOCKER, Eva (AT) (Expert to STESSEL Helmut)
TRUBIROHA, Achim (DE) (Expert to FINDENEGG, Helene)
UNKELBACH, Christian (DE) (Expert to FINDENEGG, Helene
WIJMENGA Jan (NL) (Expert to DE KNECHT, Joop)

MSCA experts for SVHC cases
JOMINI, Stéphane (FR) (also for SEv)
MICHEL, Cécile (FR)
PASQUIER, Elodie (FR)
VIGUIE, Catherine (FR)

MSCA experts for SEv cases
BALLIAUW; Sharissa (BE)
BURGA, Karen (FR)
KINZL, Maximilian (AT)
MÜHLEGGER, Simone (AT)
STRACZEK, Anne (FR)
UOTILA, Elina (ES)
VEGA, Milagros (ES)

Apologies
WAGENER, Alex (LU)

III. Final Agenda

MSC/A/070/2020

Draft Agenda
70th meeting of the Member State Committee

10-12 June 2020
(ECHA Conference Centre)
Web conference

10 June: starts at 10:00 am
12 June: ends at 16:30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

MSC/A/070/2020
For adoption

Item 3 – Declaration of specific interests to items on the Agenda

Item 4 – Administrative issues

- Outlook for MSC-70bis and MSC-71
- Presentation on modules and use of Interact tool

For information

Item 5 – Minutes of the MSC-69

- Draft minutes of MSC-69

MSC/M/69/2020
For adoption

Item 6 – Substance evaluation
Closed session for 6.1.1

1. Written procedure plans on seeking agreement on draft decisions on substance evaluation

1.1 Introduction to the on substance evaluation when amendments were proposed by MS-CA's/ECHA and preliminary discussion *(Closed session)*:

Case	Substance	EC/List No/ Documents[2]
SEV-2-FR-013/2013	Tris(4-nonylphenyl, branched) phosphite	701-028-2

[2] Most are room documents

ECHA/MSC-70/2020/006-7

SEV-BE-008/2018	Amphoteric Fluorinated Surfactant	

ECHA/MSC-70/2020/008-9

SEV-ES-010/2018	3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)hexane	435-790-1

ECHA/MSC-70/2020/010-11

SEV-2-AT-002/2012	Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate	222-020-0

ECHA/MSC-70/2020/012

For information and discussion

1.2 Written procedure timing plans

For information

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

No cases

[For agreement]

3. General topics

None

[For information]

Item 7 – Dossier evaluation

Closed session for 7.1.1 and partly for 7.3

1. Written procedure plans on seeking agreement on draft decisions on dossier evaluation

1.1. Introduction to the PfAs and Registrants' comments on draft decisions on compliance checks and testing proposals when amendments were proposed by MS-CA's and preliminary discussion *(Closed session)*

Compliance checks[3]

MSC code	Substance name	EC/List No.
CCH-038/2020	Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate	222-020-0
CCH-051/2020	2,2'-azobis[2-methylbutyronitrile]	236-740-8

For information and discussion

1.2. Introduction of the written procedure timing plans

For information

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

No cases

[For agreement]

3. General topics

1) Dossier evaluation *in vivo* comet assay requests in case of concerns for both chromosomal aberrations and gene mutation *(Partly closed session)*

ECHA/MSC-70/2020/001 & 002

[3] Case specific documents are available in MSC S-Circabc folder 05. Dossier evaluation 1. Compliance check draft decisions

For discussion and agreement

2) Invitation to discuss a decision tree for terrestrial endpoints under dossier evaluation

For information

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

Start time: Day 1 morning

1. Written procedure report on seeking agreement on identification of SVHC[4]

ECHA/MSC-70/2020/003

For information

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

Substance name	EC/List No.	Documents
Resorcinol	203-585-2	ECHA/MSC-70/2020/004-005, ECHA/MSC-70/2020/013

For discussion and agreement

Item 9 – ECHA's recommendations of priority substances to be included in Annex XIV and opinion of MSC

Invitation for volunteers for rapporteurship

For information

Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2021-2023)

Invitation for volunteers for rapporteurship

For information

Item 11 – Any other business

3. Update on appeals and court cases of relevance to MSC

(Partly closed session)
For information

4. Suggestions from members

For information

Item 12 – ECHA's Executive Director address to MSC

For information

Item 13 – Adoption of main conclusions and action points

- Table with conclusions and action points from MSC-70

For adoption

[4] List of SVHC proposals agreed by MSC in written procedure in advance of MSC-70 meeting is available at the end of the agenda as an appendix.

INFORMATION DOCUMENTS

Information documents are not allocated a specific agenda time but the documents are available on MSC S-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 substance evaluation work (presentation slides)
- Status report on on-going dossier evaluation work (presentation slides)

APPENDIX ***to the MSC-70 agenda***

List of SVHC proposals agreed by MSC in written procedure in advance of the MSC-70 meeting:

Substance name	**EC/List No.**	**CAS No.**
Butyl 4-hydroxybenzoate	202-318-7	94-26-8
Dibutylbis(pentane-2,4-dionato-O,O')tin	245-152-0	22673-19-4

SECTION IV

Main conclusions and action points
MSC-70, 10-12 June 2020
(adopted at MSC-70)

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
Item 4 – Administrative issues	
• Presentation on modules and use of Interact tool	
MSC took note of the presentation.	**MSC members** with no INTERACT access to request physical token from MSC-S by 30th June. **MSC members** to request physical token from MSC-S by 30th June for any of their regular experts/advisors without INTERACT access. **MSC members, experts and regular Stakeholder observers** to join Interact training on 23 September 2020.
Item 5 – Minutes of the MSC-69	
MSC adopted the draft minutes as submitted to the meeting.	**MSC-S** to upload the final version of the minutes on MSC S-CIRCABC by 15 June 2020 and on ECHA website without undue delay.
Item 6 – Substance evaluation **1.1. Introduction to the PfAs and Registrants' comments on draft decisions when amendments were proposed by MS-CA's/ECHA and preliminary discussion (Closed session)**	
MSC took note of the presentations on the following ECHA draft decisions: - SEV-2-FR-013/2013 Tris(4-nonylphenyl, branched) phosphite (EC. No.701-028-2) - SEV-BE-008/2018 Amphoteric Fluorinated Surfactant - SEV-ES-010/2018 3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)hexane (EC No. 435-790-1) - SEV-2-AT-002/2012 Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate (EC No. 222-020-0)	**eMSCAs** to prepare the draft decisions or agreement document for written procedure agreement seeking by 23 June 2020.
Item 6 – Substance evaluation **1.2. Written procedure timing plans**	
MSC took note of the written procedure timing plans for the following ECHA draft decisions: - SEV-2-FR-013/2013 Tris(4-nonylphenyl, branched) phosphite (EC. No.701-028-2) - SEV-BE-008/2018 Amphoteric Fluorinated Surfactant - SEV-ES-010/2018 3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl)hexane (EC No. 435-790-1) - SEV-2-AT-002/2012 Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate (EC No. 222-020-0)	**MSC-S** to initiate the start of the written procedure for agreement seeking on 29th June. **MSC members** to cast their votes until 8th July.
Item 7 – Dossier Evaluation **1.1. Introduction to the PfAs and Registrants' comments on draft decisions when amendments were proposed by MS-CA's/ECHA and preliminary discussions**	
MSC took note of the introductory presentations on the following ECHA draft decisions: **<u>Compliance checks</u>**	**SECR** to prepare the draft decisions for written procedure agreement seeking.

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
- CCH-038/2020 Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate (EC No. 222-020-0) - CCH-051/2020 2,2'-azobis[2-methylbutyronitrile] (EC No. 236-740-8)	
Item 7 – Dossier Evaluation **1.2. Introduction of the written procedure timing plans**	
MSC took note of the written procedure timing plans for following ECHA draft decisions: **<u>Compliance checks</u>** - CCH-038/2020 Tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate (EC No.222-020-0) - CCH-051/2020 2,2'-azobis[2-methylbutyronitrile] (EC No.236-740-8)	**MSC-S** to initiate the start of the written procedure for agreement seeking on 29th June. **MSC members** to cast their votes until 8th July.
Item 7.3 - Dossier Evaluation – General topics 1. Dossier evaluation *in vivo* comet assay requests in case of concerns for both chromosomal aberrations and gene mutation *(Partly closed session)*	
MSC took note of the presentation and clarifications for the suggested approach for substances with concerns for chromosomal aberrations (CA) and gene mutation (GM). MSC agreed that a combined study of the comet assay and the micronucleus (MN) test would be most suitable when concerns for both CA and GM exist and no *in vivo* genotoxicity data are available in the dossier. MSC also agreed that this would apply, by default, to all dossier evaluation (DEv) cases (compliance checks and testing proposal examinations) at REACH Annexes VIII, IX and X. MSC noted that in the situation where only the concern for CA exists, the choice can continue to be given between the comet assay, the MN test and the CA test. MSC additionally agreed (in line with the agreement at MSC-56 for substances known to induce crosslink) to recommend to add the modified protocol for the comet assay for substances known to induce oxidative DNA damage.	**SECR** to implement the agreed approach for the standard text on DEv cases and apply it for new draft decisions to be sent to the Registrants and for ongoing cases [which have been sent to the Registrants and are to be notified to MSCAs]. **SECR** to externally communicate the new approach through appropriate channels.
Item 7.3 - Dossier Evaluation – General topics 2. Invitation to discuss a decision tree for terrestrial endpoints under dossier evaluation	
MSC took note of the information.	**MSC** to nominate Member State environmental experts, if interested and resources allow, by 3 July 2020 to the MSC FMB; supporting material can be found in EVAL IG S-CIRCABC folder *06. General Communications / 05 CCH terrestrial decision tree 2020*. **SECR** to prepare a presentation on requesting terrestrial studies under DEv at MSC-71.
Item 8. – SVHC identification **1. Written procedure report on seeking agreement on identification of SVHC**	
MSC took note of the report	**MSC-S** to upload the MSC agreement documentation on the written procedure cases on MSC S-CIRCABC (done) and to publish it on ECHA website. **SECR** to add the newly identified SVHC to the

CONCLUSIONS / DECISIONS / MINORITY OPINIONS	ACTIONS REQUESTED
	Candidate List (update foreseen by end of June 2020).
Item 8. – SVHC identification **2. Seeking agreement on Annex XV proposals for identification of SVHC**	
While members unanimously acknowledged that resorcinol fulfils the ED definition by WHO, MSC **did not reach** unanimous agreement on the Annex XV proposal to identify Resorcinol as an endocrine disruptor for **human health** giving rise to an equivalent level of concern as PBT/vPvB and CMR substances under Article 57(f). The majority of MSC supported the proposed SVHC identification for resorcinol, while a minority of three members held a different view and eight members abstained from voting.	**MSC members who voted against** the SVHC identification of resorcinol to provide their minority view(s) in writing to the MSC-S in **draft by 15th June** and its final version **by 17th June 2020**. **MSC-S** to finalise the MSC opinion documentation on resorcinol by end of **June 2020**. **MSC-S** to refer the MSC opinion on resorcinol, the minority position and the other supporting documentation to the Commission for further decision making without undue delay. **MSC-S** to upload MSC's opinion on resorcinol, the minority position and the other supporting documentation on MSC S-CIRCABC and on the ECHA website by 3rd July 2020. **MSC member who made a statement to the minutes** to provide this statement in writing to MSC-S **by 19th June 2020**.
Item 9 – ECHA's recommendations of priority substances to be included in Annex XIV and opinion of MSC **Item 10 – Opinion of MSC on ECHA's draft update of the Community Rolling Action Plan (CoRAP 2021-2023)** - Invitation for volunteers for rapporteurship	
MSC took note of the calls for volunteers.	**MSC Chairman** to send out the email invitations by 30 June 2020. **MSC members (and MSC alternate members)** to express interest to the rapporteurships by 15 September 2020.
Item 13 – Adoption of main conclusions and action points	
MSC adopted the main conclusions and action points of MSC-70 at the meeting.	**MSC-S** to upload the main conclusions and action points on MSC S-CIRCABC by 15 June 2020.

SECTION V. Statement from DE and SK members related to agenda item 8.2 with regard to the SVHC identification of Resorcinol (EC No. 203-585-2)

MSC 70: Resorcinol - Statement to the minutes by Slovak Republic and Germany

We thank France for the preparation of the dossier.

We note that -although the suggestions for a more detailed presentation of some correlations were included in the revised dossier- new data, e.g. new studies or references, have not been included into the dossier. As a result, the data and its evaluation remain unchanged. Therefore, we still have doubts regarding whether the ELoC criteria are met for the identification of resorcinol according to Art. 57(f) as an endocrine disruptor for human health.

There are two main arguments why we still have concerns on the SVHC identification:

a) There is no doubt that there are thyroid effects after the application of resorcinol. The mode of action is the inhibition of thyroid peroxidase. This has been demonstrated in various studies. However, effects on the thyroid were observed in some animal studies, while other studies did not show these effects. Thus, the administration of resorcinol does not consistently lead to adverse effects, and in the two-generation study there is no clear dose-response relationship in the effects on hormone levels.

b) Although the human case studies demonstrate the potential of resorcinol to induce hypothyroidism in humans, the specific exposure conditions impede a clear conclusion on whether resorcinol fulfils the ELoC criteria.

In conclusion, in our opinion due to inconsistency and poor quality of the existing data there is not sufficient scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e), and to conclude that resorcinol can be identified as an SVHC according to Article 57(f). Therefore, we abstained from voting.